Study for the preparation of an Implementation Report of the General Product Safety Directive

Final report

Part 2: Country reports

Prepared by Civic Consulting
July 2020

Justice and Consumers

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Directorate-General for Justice and Consumers
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I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Product Safety Act (PSA) 2004.[1]

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability

Art 5(1) GPSD was implemented in § 7(2) PSA 2004. It was criticised by stakeholders for being as vague as Art 5(1) GPSD (and hence too vague). It was said that in practice, problems concerning traceability arise with regard to no-name products which are typically sold at street markets. It was suggested to require barcodes to make identification easier and that the requirements should depend on the product in question and the potential risk associated with the product.

Despite this criticism, it is important to note that only one decision of the Austrian Supreme Court dealt with § 7(2) PSA 2004 between 2015 and 2020. Moreover, the focus of this decision was not the violation of the traceability principle itself, but rather the question as to whether the violation provides a basis for a claim for damages under the Austrian Civil Code (*Allgemeines Bürgerliches Gesetzbuch*).

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used in the area of new technologies. It is generally – for every area – stated that there should be a more clear differentiation between security and safety and also the intended use versus the foreseeable misuse.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

According to § 3 PSA 2004, "product" means "all moveables including energy". According to the explanatory remarks of the legislator, software is part of a product. Hence, the PSA 2004 covers emerging threats related to new technologies. But it seems that so far new technologies have not played a major role in practice.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

For assessing the safety of a product, the following benchmarks are used: Other European standards (not referenced in the EU Official Journal); National standards (not based on European standards); International standards and/or standards from non-EU/EEA countries; Commission recommendations setting guidelines on product safety assessment; Codes of good practice in force in the sector concerned; State of the art and technology; Reasonable consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Austria in case there are consumer product(s) on the market which are found unsafe under the GPSD

According to § 11(1) PSA 2004, measures include, but are not limited to:

"1. Requirement to add or improve instructions for use or to attach identification elements on the package or

[1] *Produktsicherheitsgesetz* (PSG) 2004

product;

2. Requirement to attach to the product a warning against dangers and directions for behaviour to avert them as are appropriate to reflect the urgency of averting such dangers;

3. Requirement to publish warnings or other urgent information in a manner and by media suitable for the market categories concerned;

4. Orders and prohibitions with regard to promotional measures for products;

5. Specification of certain quality requirements (e.g. safety precautions), in particular by declaring national or international standards to be fully or partially binding;

6. Requirement to furnish proof of compliance with specified testing requirements;

7. Prohibitions or limitations on the marketing (e.g. with regard to specified categories of persons or the type of distribution);

8. Prohibitions or limitations on export (e.g. with regard to a destination);

9. Requirement to promptly withdraw from the distribution chain any product or batch of products already placed on the market and, if necessary, its destruction under suitable conditions;

10. Obligation to carry out a prompt and efficient recall of a product or product batch already marketed from consumers, if necessary the publication of such a recall scheme in media suitable for the market categories concerned and, if necessary, the destruction of such a product or product batch under suitable conditions."

In addition, § 11(2) states that to "the extent that reasonable measures for danger aversion can be obtained on a voluntary basis, such procedure shall be given preference". In practice, most recalls are made on a "voluntary" basis. Furthermore, penalties up to 25 000 Euros may apply (§§ 25 et sequ. PSA 2004). Also, authorities in the "Bundesländer" (states) of Austria may use similar measures under § 16 PSA 2004.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Stakeholders expressed the view that said penalties are very rarely applied and that confiscation as well as "public shaming" of companies violating the PSA 2004 is more effective. In addition, it was noted that most recalls are carried out voluntarily, even before the authority gets active. The authority may also get in contact with the company before starting any formal procedure, asking for a "voluntary" recall without formal notice.

Recent case law in Austria with respect to or relevant for the GPSD/the national implementation legislation.

There was one decision by the Austrian Supreme Court (OGH)[2] between 2013 and 2020 dealing with the PSA 2004: January 22 2015, 1Ob103/14z. In this decision, the OGH ruled that § 5 PSG is not a basis to claim damages under the Austrian Civil Code (ABGB)[3] for damaged goods. The OHG differentiated in this decision between product liability and product safety.

There was also one decision by the Austrian Administrative Court (VwGH):[4] June 24 2013, 2011/11/0015. In this decision, the VwGH confirmed a ruling by the Governor of Styria which (under § 11 PSA 2004) had ordered the recall of grit (*Streusand*) which was considered to violate the PSA 2004.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Austria concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Regarding traceability, stakeholders mentioned as a practical problem no-name products which are sold on street markets. With regard to the definition of safety, it was noted that a clearer differentiation is needed between security and non-conformity as well as safety. For example, it was noted that the doll "Cayla" was a case of (data)

[2] *Oberster Gerichtshof*
[3] *Allgemeines Bürgerliches Gesetzbuch*
[4] *Verwaltungsgerichtshof*

security and not safety.

Possible improvements to make the implementation of the GPSD in Austria more effective

It would be an improvement if Austria would not apply the principle of *"mittelbare Bundesverwaltung"* (i.e., using authorities in the "Bundesländer" to apply federal law) for the PSA 2004. The result of this regulatory technique is that the enforcement lies with authorities on the state level. These authorities, however, might not have the necessary budget to be well equipped for this task. Also, it would be an improvement if harmonised and non-harmonised product safety would be the responsibility of the same authority and if the enforcement would be done by one common market surveillance authority. With regard to material law, a more concrete definition should be considered in § 5 PSA 2004.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Austria.

For non-harmonised consumer goods:

"A unit in the Ministry of Social Security, Generations, and Consumer Protection coordinates market surveillance in Austria and acts as RAPEX contact point. However, market surveillance mainly takes place through the Provincial Governors.[5] The latter are able to employ bodies with special training as supervisory bodies. Moreover, the Provincial Governor is able to make use of the customs authorities when conducting the market surveillance. The bodies appointed must in all cases report to the Federal Minister of Social Security, Generations, and Consumer Protection. The provincial governors are subject to directions of the federal minister."[6] The ministry is now called the Federal Ministry of Social Affairs, Health, Care and Consumer Protection.

Plans/programmes in place which define priorities for market surveillance of consumer products

Market surveillance authorities set their priorities according to available resources. For example, some products are more expensive to examine (e.g. because laboratory testing is required) and hence less often tested. Often, priorities are also influenced by the number of consumer complaints as well as the emotional outcry in media with regard to some products. Finally, RAPEX data may also influence the national priority setting.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Austria with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

There are so far no market surveillance activities to be reported with regard to Internet of Things (IoT). Also, there is no activity with regard to C2C activities as the PSA 2004 only applies to B2C transactions.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The market authority only carries out fact-finding activities with regard to online markets. Such activities are carried out about once a week. As there is no legal basis for mystery shopping in the view of authorities and they also lack the technical equipment (e.g. credit card provided by the authority), market surveillance authorities usually do not engage in mystery shopping. However, they might contact the platform (e.g. Amazon) to gather more information. Stakeholders noted that this works only with regard to businesses based in Europe.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Austria (except customs) with respect to product safety

Within Austria, the cooperation works on the basis of informal meetings, RAPEX and ICSMS, regular exchange of

[5] *Landeshauptleute*
[6] General Product Safety Directive (GPSD) – Comparative Inventory, p. 39, 2006 (by Baker & McKenzie).

information, joint training sessions and the inclusion in the drafting process of the market surveillance programme.

Cooperation with customs authorities in Austria with respect to product safety

The cooperation with customs works well. That being said, customs serve only as an agent. Hence, it was stated that expectations with regard to this cooperation should not be too high. A European regulation on how customs might serve as surveillance authorities would be needed. It was also noted that customs play a significant role with regard to lighters and laser pointers.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

It has been noted that there is no cooperation with non-EU/EEA countries. Within the EU/EEA, it seems that there is some cooperation with Germany and Slovenia. The cooperation with other Member States is hindered by language barriers. Hence it is not surprising that the cooperation with Germany is the most important one. However, also with regard to Germany it was noted that the cooperation works best if the contact person is personally known (e.g. from former conferences etc.) and that it is sometimes hard to compare the situation in Germany and Austria given to the specific administrative approach in Austria. One stakeholder specifically noted that her unit learned a lot from colleagues in Bavaria.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The RAPEX coordination point in Austria is based at the Federal Ministry of Social Affairs, Health, Care and Consumer Protection, Department III/2. The time between notification and reaction depends on the case and is usually can be one day only (if direct contact with the economic operator can be established) or two or three months if inspections in remote stores are required. However, national authorities are informed e.g. about incoming RAPEX notifications without any delay.

In case of non-safety related risks, other market surveillance authorities as well as other agencies (e.g. the environmental protection agency) are informed.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Both the Austrian Consumer Information Association (VKI)[7] as well as the Austrian Chamber of Commerce (WKO)[8] are members of the product safety council, and the VKI is also a member of the consumer council (with regard to standardisation). In addition, informal cooperation as well as informal meetings take place. The latter is also true for engagement with businesses.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Awareness is raised via RAPEX notifications as well as via information provided on the website of the market authorities.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Austria (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

One has to differentiate between voluntary and mandatory recalls. However, in both cases the market surveillance authority seeks to cooperate with businesses and offers advice and agree with the businesses on the information channels through which consumers shall be informed about recalls. If no responsible business operator can be found, the market surveillance authority organises the recall. The market surveillance authority examines the information given to consumers about the recall and requires information regarding other businesses in the supply chain as well as the timeline of the recall. Consumers are given information regarding the recall via the website of

[7] *Verein für Konsumenteninformation*
[8] *Wirtschaftskammer*

the authority as well as AGES (the Austrian Agency for Health and Food Security) which is then often re-published by www.help.orf.at.

Monitoring of effectiveness of product recalls by market surveillance authorities

Spot checks are carried out in order to monitor the effectiveness of the recall.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Austria that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Stakeholders noted that the only statistics available are those provided by customs.

In addition, statistics are provided by the Injury Database, collected through interviews conducted in ambulatory departments at Austrian hospitals.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Austria (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

With regard to market surveillance in general, a lack of resources was noted. Due to this lack of resources, e.g. there is no cooperation in the E-academy. The lack of testing laboratories can also be explained this way. Interestingly, stakeholders also noted a lack in cooperation with consumer agencies, even though others suggested that there is a strong cooperation with the VKI as well as the WKO.

With regard to the surveillance of the online market, many shortcomings were noted, including the lack of a legal basis for "mystery shopping" as well as the lack of technical equipment (e.g. credit cards) for such activity. Sometimes stakeholders seem to overcome such problems by using their own credit cards to buy products, which are considered to be at risk for further investigation. It was also noted that there might be a lack of expertise with regard to online markets.

Finally, with regard to recalls, as an example for a sector in which recalls work very well, stakeholders mentioned the automobile industry. This is due to the fact that the names of buyers are known to car dealers and § 40b(9) KFG (*Kraftfahrgesetz* 1967) puts insurers in charge of recalls. Another reason why recalls work very well in this sector might be that cars are consumer goods with a significant value and hence consumers are more likely to respond to a recall than for example in the food sector (where they might notice a recall but not bring the product back to the supermarket and instead just discard it). Compared to other international experiences, stakeholders consider the recall practice in Austria to be moderately successful.

Areas to make market surveillance of consumer products in Austria/the EU more effective

It was stated by stakeholders that a central (single) national market surveillance authority would be a significant improvement compared to the status quo. In particular, the *"mittelbare Bundesverwaltung"* approach (using state authorities as agents in federal law matters) should be abandoned. In addition, more resources would be needed, *inter alia* to fund a national testing laboratory. Also, improved legal instruments e.g. for online surveillance would be an advantage.

In addition, a regulatory framework for test reports (duration, form, language) is considered to be needed: at the moment there is no data available in Austria as there is no agreement on how to count cases (e.g. if all authorities in the states of Austria find baby jackets – a real case – with dangerous cords: has this to be regarded as one case or 9 (as there are 9 states)*?* Or 9 multiplied by all the stores where such jackets were located*?*)

Another improvement would be the establishment of a European market surveillance agency and a European laboratory. With regard to RAPEX, the lack of English as a standard (and only) language is seen as problematic. Hence there would also be room for improvement. This is true also with regard to establishing a rule that there should be only one RAPEX notification for each danger and better risk assessment.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Austria since 2013

It can be noted that no major changes or trends were seen to be emerging since 2013.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Austria whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Market surveillance authorities in Austria noted that they would need some new legal tools (e.g. mystery shopping). Given the fact that the GPSD does not cover C2C sales, a legislative change would be needed to become active in this area. With regard to technical tools, the need for a web crawler was mentioned.

Views of market surveillance authorities whether approaches in Austria can be considered best practice implementation of the GPSD, which could be of interest to other countries

It can be noted that market surveillance authorities in Austria are quite effective in carrying out campaigns (e.g. a campaign to detect children's jackets which contained cords).

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*4*	*n.a.*
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*15*	*n.a.*
Total (country)	***n.a.***	***19***	***n.a.***
Notes:	*No exact data available due to federal organisation of Austria*		

B. Number of inspections of consumer products (last available year)

n.a.

C. Number of recalls of consumer goods (last available year)

n.a.

D. Key sources

Legislation	Product Safety Act 2004 ("Produktsicherheitsgesetz 2004" – "PSG 2004")
Studies/reports/articles	Oberländer, Marcel / Wendt, Janine: Product Compliance: Neue Anforderungen an sichere Produkte, ZTR, 2016, 62. Brenn, Christoph / Grau, Alexander: Produktsicherheit schützt nur die körperliche Unversehrtheit, Anmerkung zu OGH 22.1.2015, 1 Ob 103/14z, EvBl 2015, 105. Bzgl § 24 – Verbraucherrat: Lachmayer, Konrad: Verfassungsrechtliche Probleme der Normung, ZTR 2015, 87. Staudinger-Leitl, Barbara: Hat das Wirtschaftsordnungsrecht Zukunft?, ÖZW 2015, 9.

	Hecht, Judith: Komm zurück!, Die Presse 2014/16/11. Rohrer, Ronald / Spitzer, Martin: Warnhinweis auf Mineralwasserflaschen, Anmerkung zu OGH 13.9.2012, 6 Ob 215/11b, EvBl 2013/16. Karollus, Martin: Produkthaftung für explodierende Mineralwasserflasche - Produktbeobachtungspflicht - Instruktionsfehler – Konstruktionsfehler, Anmerkung zu OGH 13.9.2012, 6 Ob 215/11b, ZTR 2013, 56.
Websites	https://www.ages.at/startseite/ https://www.kfv.at www.ris.bka.gv.at
Interviews	Federal Ministry Interviews with Bundesministerium für Finanzen III – Wirtschaftspolitik, Finanzmärkte und Zölle

2. Belgium

COUNTRY REPORT BELGIUM

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The General Product Safety Directive (GPSD) was implemented by the law of 18 December 2002, which modified the existing safety law of 1994 into the law concerning the safety of products and services.[9] Since 2013, the new Code of Economic Law (CEL) in Belgium has gradually codified existing economic legislation into several 'Books', and the implementation law of 2002 was inserted into Book IX CEL by the law of April 25th, 2013. The Belgian implementation shows some differences compared to the GPSD as it, for instance, protects the 'user' of the product ('*gebruiker*') instead of only the consumer. This category of protected persons is larger, since users are defined in Article I.10, 12° CEL as 'depending on the case, the consumer, the employer or the employee'. Furthermore, the Belgian implementation legislation applies to all products used in services, including those used by service providers. This follows from the Belgian definition of a 'service' in Article I.10, 5° CEL, which goes beyond the scope of the provisions of the GPSD (see Article 2(a) GPSD and Recital 9 GPSD).[10]

The enforcement provisions of the CEL are listed in Book XV CEL and these apply to all of the inserted legislation in the CEL (with the exception of competition law), including Book IX. The Belgian legislator has introduced new investigative competences in Book XV since the enactment of the CEL and that way the envisaged codification of economic law in the CEL also brought legal innovation.

According to Article XV.2 CEL, in conjunction with Article I.3° CEL, the civil servants appointed by the Minister of Economy are competent to detect and establish infringements of the Code of Economic Law, such as infringements of Book IX CEL. A Ministerial Decree of April 25th, 2014 appoints the civil servants of the Directorate General (DG) Economic Inspection within the Federal Public Service Economy (FPS Economy) with a general enforcement competence for all of the provisions of the CEL, while the civil servants within DG Quality and Safety received specific competences for the enforcement of the provisions of Book IX, but also with regard to consumer protection provisions (Book VI) and counterfeit goods (Book XI). In this respect, the civil servants of the DG Energy also have enforcement competences relating to Book IX and the Royal Decrees relating to the mixture and composition of certain goods (see Articles VI.9 and VI.10 CEL). Lastly, the customs authority was granted explicit competence to detect and establish infringements regarding counterfeit goods and product safety.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Belgium

The traceability requirement is implemented in Article IX.8 CEL and repeats the provisions of Article 5(1) GPSD. It therefore contains a general requirement to indicate the name and contact details of the producer on the product or its packaging as well as a general requirement to indicate the product reference or, where applicable, the batch of products to which it belongs on the product or its packaging. However, some minor differences with the GPSD exist. The traceability measures mentioned in Article 5(1), fourth paragraph GPSD are formulated as examples, while in Article IX.8, §2 CEL of the Belgian implementation legislation, these traceability measures are mandatory.[11]

Article 5(2) GPSD is implemented in Article IX.8, §3 CEL and replicates the requirements set out in the directive. However, in practice this legal provision is further implemented through the guidelines of the FPS Economy, as explained below.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

[9] *Wet betreffende de veiligheid van producten en diensten.*
[10] Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 28.
[11] Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 541.

The national implementation legislation copies in Article I.10, 2° CEL the definition of a 'safe product' from the GPSD. It therefore contains no express provision dealing with new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The national implementation in the CEL does not specifically cover emerging threats related to new technologies, such as cyber security or software-related threats. It confines itself to replicating the definitions of the GPSD. The DG Economic Inspection is uncertain whether any of these threats fall within the scope of the definition of a 'safe product', whereas the Safety Department of the DG Quality and Safety is of the opinion that neither cover these emerging threats. While the Department acknowledges that cyber security and software-related threats may sometimes cause personal injury to consumers (e.g. a hacked e-scooter with malfunctioning breaks), it adopts the viewpoint that these threats are not covered, since they rather bring about 'security' threats, such as threats linked with theft and illegally obtaining personal data, which fall within the competence of police services and the data protection agency.

It is possible that the very broad safety concept of Article 2 (b) GPSD can be interpreted with a certain flexibility so that it covers some of the emerging threats related to new technologies, such as connected devices.[12] Following this interpretation of the GPSD, the Belgian national implementation legislation would then also apply to those threats, as the safety definition is an almost identical implementation of the GPSD. However, even in that case, the problem remains that the GPSD does not explicitly address the new technologies and their specific characteristics.[13] This lacuna creates uncertainties in the national context.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

The national legislation replicates the benchmarks of Article 3(3) GPSD in Article IX.3 CEL.[14] Furthermore, this national provision adds in accordance with Recital 16 of the GPSD 'international standards' as an explicit seventh benchmark. The seven benchmarks mentioned in the Belgian implementation legislation are to be regarded as exhaustive,[15] whereas the list of benchmarks in Article 3(3) GPSD is indicative.

Notwithstanding this full implementation of Article 3(3) GPSD into Book IX CEL, the Safety Department of the DG Quality and Safety indicated that it does not use all of these standards in practice. While it often applies specific benchmarks, such as other European standards (not referenced in the EU Official Journal) or national standards (e.g. a French standard), it does not use the so-called 'state of the art and technology' and 'reasonable consumer expectations concerning safety' benchmarks in practice. The Department submitted in this respect that recourse to those general benchmarks is often not necessary in the presence of more specific benchmarks. This observation is in line with the idea that the specific benchmarks used for that purpose contain more explicit standards and guidelines for the required safety assessment, and hence can be seen as a more concrete expression of the rather vague concepts of 'state of the art of technology' and 'reasonable consumer expectations'.[16] Nonetheless, it is generally recommended that the presence of these open concepts in legislation should be maintained, especially to avoid the case where some products might escape a safety assessment in their absence.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Belgium in case there are consumer product(s) on the market which are found unsafe under the GPSD

The departments within the FPS Economy reported that they may require businesses to provide relevant

[12] See European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, P. 10. Article 2(b)(ii) GPSD states that the safety assessment of a product will take into account 'the effect on other products, where it is reasonably foreseeable that it will be used with other products'. It follows that software problems of connected devices can be interpreted as a safety issue.
[13] See on existing gaps in safety regulations, European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, P. 16.
[14] By contrast, the Belgian implementation does not contain an explicit reference to Article 3(2) GPSD. See on this point: Van Camp, S. (2010), Productveiligheid en product recall (Revue de Droit Commercial - Tijdschrift voor Belgisch Handelsrecht, vol. [2010]:6), P. 458.
[15] See Thierry, Y. (2003), Productveiligheid wordt belangrijke algemene kaderwet en inhoud wordt aangepast aan Europese richtlijn (Tijdschrift voor wetgeving, vol. 5), P. 161.
[16] Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 200 – 201.

information on the product and relevant information on the supply chain and the distribution of the product. Moreover, they may carry out unannounced on-site inspections and physical checks of products as well as acquire product samples for free (see Article XV.3 CEL and its Royal Decree on product sampling[17]) and seize products (Article XV.5 CEL). Producers can also be required to submit their products or services to laboratory testing (Article IX.7, 2° CEL). Furthermore, in accordance with the Articles IX.8 CEL, economic operators are legally required to organise recalls of products and other corrective measures. Pursuant to Articles IX.4 and IX.5 CEL, these measures can become mandatory. The corrective measures specified in Article IX.4 CEL are of a general nature as these apply to categories of products and services without a specific time limit, whereas the corrective measures of Article IX.5 CEL have a specific duration as these apply to serious risks concerning a specific product for a maximum period of one year, which can be extended once.[18] The general measures are taken by Royal Decree and the specific measures by Ministerial Decree. The specific, temporary measures can be converted into general, permanent measures in accordance with the procedure of Article IX.4 CEL. Thus, while the GPSD does not contain any express reference concerning temporary measures, the Belgian legislator provides for such measures that allow a quick response to serious safety risks by Ministerial Decrees, minimising the procedures to adopt such a Decree.

The costs related to corrective measures specified in the Articles IX.4 and IX.5 CEL can be reclaimed from the producers, but only if the product or service does not comply with the general safety requirement or with the requirements set out in a Royal or Ministerial Decree. It follows that when corrective measures are taken but the concerned product turns out to be compliant, the costs will remain with the government authorities.[19]

A legal distinction must be made between the measures specified in Book IX and those in Book XV CEL. While the first type of measures constitutes so-called administrative measures and decisions, the second type of measures finds its origin in criminal procedural law with no 'administrative' legal nature. Article XV.1 CEL states that the competences specified in Book XV have to be regarded as a particular application of Belgian criminal procedural law. Therefore, on-site inspections, physical checks and product sampling mentioned in Book XV are in principle subject to the procedural safeguards and checks of criminal procedural law, while the corrective measures taken pursuant to Book IX follow the administrative procedure. It follows that they can be contested through an administrative appeal before the Belgian Council of State.[20]

Infringements of the product safety requirements and provisions of Book IX CEL can also be notified to the economic operator through a formal warning. Article IX.7, 1° CEL contains an administrative warning procedure for producers to bring their goods or services into compliance and Article XV.31 CEL provides a warning of criminal procedural law whereby economic operators can be required to even stop certain activities.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Penalties are set forth in Book XV CEL and are of a criminal nature according to Article XV.69 CEL. Article XV.70 CEL defines six levels of sanctions which can be applied to infringements of the economic law provisions of the Code of Economic Law, which can be a criminal law fine, or in the case of sanctions of level 5 or 6, also imprisonment.

In contrast, the sanctions taken pursuant to Book IX CEL on product safety are in accordance with Article XV.102 CEL limited to monetary fines:

- Sanctions of level 2 are possible in the event of an infringement of Article IX.9 CEL.[21] The sanction of level 2 ranges from 26 to 10 000 Euros.
- Sanctions of level 3 are possible when an economic operator violated a warning from the authorities based on Article XV.31 CEL (see below) or when the other obligations of Book IX are violated. These other obligations pertain to the requirement to only bring products on the market which comply with Article XV.2 CEL and the requirements set out in Articles IX.4, IX.5, IX.6, IX.7, IX.8 and IX.9 CEL. The violation of

[17] Koninklijk Besluit 25 maart 2016 betreffende het nemen van monsters, zoals voorzien in artikel XV.3, 7° van het Wetboek van economisch recht, *Belgisch Staatsblad 2016011153, 12/4/2016*, P. 23577.
[18] Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 464 – 468.
[19] Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 468.
[20] *Raad van State*; This possibility for an appeal implements the requirement of Article 18(2) GPSD: 'Member States shall ensure that any measure taken by the competent authorities involving restrictions on the placing of a product on the market or requiring its withdrawal or recall can be challenged before the competent courts'.
[21] This provision contains the requirement to adapt the labels and provide other information obligations of Book IX, manuals and warranty certificates in a comprehensible language, taking into account the language area where the products or services were brought on the market.

Ministerial and Royal Decrees taken in execution of Articles IX.4, §1 to §3 and IX.5, §1 and §2 CEL are also subject to this sanction as well as Royal Decrees implementing specific EU Regulations mentioned in Book IX. The sanction of level 3 ranges from 26 to 25 000 Euros.

The monetary sanctions are always multiplied by an indexation mechanism evolving over time (the so-called '*opdeciemen*'), and in the event of a repeated infringement by the convicted defendant within 5 years, these maximum fines can be doubled (see Article XV.71 CEL).

In view of imposing these sanctions, the FPS Economy has to transfer the case to the public prosecutor ('*Openbaar ministerie*') who then has competence to start the criminal proceedings against the economic operator, but may still dismiss the case or propose a settlement. Further, the sanctions have to be pronounced by the criminal court judge. This judgement may impose additional sanctions, namely:

- The confiscation of the products as well as the goods required for the production, processing, distribution or transport of these products, and the confiscation of profits (Article XV.130 CEL);
- The publication of the judgement (Article XV.131 CEL).

However, before transferring the case to the public prosecutor, the departments within the FPS Economy are competent to direct a warning to the economic operator according to Article XV.31 or propose a settlement called a 'transaction' ('*transactie*'), according to Article XV.61 CEL. Research has shown that the application of criminal proceedings and sanctions is very rare due to a long-standing overburdening of the Belgian criminal prosecutor's offices.[22] Thus, this criminal sanctioning system mentioned above is seldom applied in practice, but the market surveillance authorities extensively propose transactions to economic operators.[23] The transactions imposed by the market surveillance authorities within the FPS Economy fulfil a similar function to an administrative fine.[24] The Royal Decree executing Article XV.61 CEL links the height of the transaction to the six sanctioning levels of the criminal fines in Article XV.70 CEL.[25]

In this respect, it also has been made clear by the DG Economic Inspection that in the context of a product recall and other corrective measures (e.g. withdrawal from shops and warehouses), the necessity to impose criminal sanctions or transactions is seldom required to dissuade economic operators from violating their responsibilities. Producers will in practice often initiate voluntary product recalls or corrective measures or comply with demanded measures as they also fear damage to their commercial reputation. Reputational damage may occur because they have put products on the market which are unsafe, and the reluctance of professional customers of these producers in the trade chain, which are the economic operators performing direct delivery to the users, to continue contracting if unsafe products were sold to them. The latter may also risk a sanction based on Article IX.8 CEL as they are legally required to contribute to the compliance with the applicable safety requirements through notifications and cooperation with corrective measures. Thus, while these economic operators do not necessarily have an impact on the safety properties of products according to Article 2 (f) GPSD, their legal requirements formulated in Article 5(2) GPSD and Article IX.8 CEL generate, according to the circumstances, commercial pressure upon other economic operators up in the supply chain and may have an important effect on how and when sanctions are applied in practice.[26]

Apart from these specific sanctions implementing Article 7 GPSD, enforcement sanctions based on general criminal law and tort law (e.g. Product Liability legislation[27]) also contribute to the effective, proportionate and dissuasive enforcement of the safety concept.

[22] See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 348 – 349.

[23] For example, in 2018 the Economic Inspection proposed 227 transactions concerning the safety of consumers on a total of 888 inspections and only forwarded 2 cases to the public prosecutors' offices. See Algemene Directie Economische Inspectie (2019), Jaarverslag 2018, P. 46.

[24] *See* Steennot, R. (2015), Public and Private Enforcement in the Field of Unfair Contract Terms (European Review of Private Law, vol 23), P. 617-618.

[25] Koninklijk Besluit van 10 april 2014 betreffende de transactie bij inbreuken op de bepalingen van het Wetboek van economisch recht en zijn uitvoeringsbesluiten, *Belgisch Staatsblad 29/4/2014*, P. 35213.

[26] Notwithstanding this effect of commercial pressure stimulating voluntary measures as reported by this Belgian authority, studies have indicated that other factors might also be at play as a business does not necessarily suffer reputation damage from executing a product recall or other corrective measures. Businesses may use such measures to their advantage by creating the perception with retail customers that a policy of thorough quality control of its products is applied or by gaining brand awareness. See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 508.

[27] Consumers can also enjoy protection against unsafe products through the Belgian law on liability for defective products (which implements the Product Liability Directive). See Wet van 25 februari 1991 betreffende de aanprakelijkheid voor produkten met gebreken, *Belgisch Staatsblad 22/03/1991*, P. 5884.

Recent case law in Belgium with respect to or relevant for the GPSD/the national implementation legislation.

To our knowledge there is only one recent case relating to product safety brought before the Belgian Council of State, and even that case concerns legislation pre-dating the insertion of the provisions into the CEL.[28] In this case of 2010, an economic operator contested a formal warning imposed on it. The Council regarded the appeal by the economic operator as inadmissible since a warning does not generate any legal effects for the concerned party. According to the Council of State, a warning must be viewed as a simple notification that reflects the opinion of the administration. It follows that the facts upon which the formal warning is based can only be contested during the criminal proceedings that may follow. Moreover, according to the Council of State, the criminalisation of the warning (now provided for in Article XV.102 CEL) has no impact on this assessment.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Belgium concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Some difficulties regarding traceability and the definition of a 'safe product' are reported. As regards traceability, the Safety Department of the DG Quality and Safety reports that the address of the producer is not always mentioned on the product or its packaging because of the ambiguity of the requirement of 'contact details' in Article IX.8 CEL (implementation of Article 5(1) GPSD).[29] According to the DG Economic Inspection, the definition of safety ('safe product') is in some cases too narrow. For instance, second-hand shops acting as an intermediary platform for consumers to bring in used products so that these can be sold again to other consumers are considered to fall outside the scope of the definition of a 'safe product'.[30] Moreover, the definition is considered as being too vague by that same authority because its reference to 'the normal or reasonably foreseeable conditions of use' is seen as a subjective element open for interpretation depending on the opinion of the person making the assessment. Some academic scholars are indeed of the opinion that this benchmark leaves too much room for interpretation,[31] whereas others point to the necessity of such vagueness in view of the case-by-case assessment.[32] However, it could also be argued that the general 'vague' nature of this definition should be maintained as the safety concept requires an assessment of all circumstances[33] and thus should allow for a certain flexibility to adequately respond to changes of circumstances, such as societal or scientific progress in the state of the art.[34]

The Safety Department of the DG Quality and Safety reports some emerging safety issues in the product areas of toys (loombands, hand spinners, toy drones and slimes) and machines (drones and new personal transporter devices).

Beside the reported problems mentioned above, a particular category of products where safety issues may emerge is that of products with embedded software, including autonomous learning systems based on Artificial Intelligence. Products with embedded software can cause problems when they are altered through such autonomous learning systems or updates and physical injury occurs as a result of such an alteration.[35] Furthermore, safety risks may emerge during the whole lifecycle of the product, e.g. a considerable period after its release on the

[28] Raad van State (3 December 2010), No 209.498, *NV Cardiff v. Belgian State*.
[29] The Safety Department mentions the requirement of a 'postal address' as an alternative, while the DG Economic Inspection suggests introducing the requirement of using a QR code.
[30] 'Consumer to consumer (C2C) sales are generally not considered commercial activities and therefore are not governed by the General Product Safety Directive'. See European Commission (2017), Commission notice on the market surveillance of products sold online (2017/C 250/01), P. 4.
[31] This stance was taken when the European Product Liability Directive was introduced, which uses the same benchmark to assess the safety of a product: 'the use to which it could reasonably be expected that the product would be put'. See Article 6(1)(b) Directive 85/374/EEC, *Official Journal L 210*, 7/8/1985, P. 29 – 33. See e.g. Faure, M. and Van Buggenhout, W. (1987-1988), Produktaansprakelijkheid. De Europese Richtlijn: harmonisatie en consumentenbescherming (deel 1)? (Rechtskundig Weekblad, Vol 51: 1), P. 11. See also on this vagueness Whittaker, S. (1985), The EEC Directive on product liability (Yearbook of European Law, Vol 5:1), P. 242.
[32] See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 157. See also on this issue Claeys, I. and Kinnaer, K. (2015), Sectorgerelateerde veiligheidsregelgeving: een bos doorheen de bomen? (in Claeys, I and Steennot, R. (eds), Aansprakelijkheid, veiligheid en kwaliteit. XLste postuniversitaire cyclus Willy Delva 2014-2015, Mechelen, Kluwer), P. 88.
[33] 'The concept of 'safe' products is appropriate and includes various aspects that enable products' safety to be assessed in terms of circumstances of which the consumer ought to be aware, such as product life, nature and composition'. See European Economic and Social Committee (2013), Opinion on the 'Proposal for a regulation of the European Parliament and of the Council on Consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC', COM(2013) 78 final – 2013/0049(COD), recital 4.4.2.
[34] See also Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 98.
[35] For example, an autonomous car can wrongly identify an object on the road and cause an accident involving injuries. See European Commission (2020), White Paper on Artificial Intelligence, P. 12.

market. These aspects are currently not addressed in the existing safety legislation.

Possible improvements to make the implementation of the GPSD in Belgium more effective

While the departments of the FPS Economy stated unanimously that no potential improvements can make the implementation of the GPSD in Belgium more effective, academic literature and other scientific research point out that there might exist some room for improvement of the current legislative framework.

For instance, as regards emerging safety issues, the GPSD does not explicitly take into account digital technologies which have gained an increasing prominence on the market since its entering into force. Hence, the GPSD shows some regulatory gaps in view of the increasingly digitalising market.[36] While the GPSD may already cover some of these risks due to its broad scope of application, alterations to the legislative framework (in the GPSD or elsewhere) dealing with digital technologies and its specific properties could lead to a more effective implementation to combat these emerging safety risks and foster increased legal certainty for the market surveillance authorities.

As regards the scope of application of the GPSD, it has been argued that this should be aligned with the Product Liability Directive.[37] For instance, the GPSD and Book IX CEL exclude some second-hand products from the safety concept and do not explicitly exclude immovable goods from the scope of application due to the definition of a product (see Article I.10, 1° CEL). The exclusion of these second-hand products from the GPSD should be removed and the Product Liability Directive should also include immovable products, which improves legal certainty and avoids the situation where some products are regarded as being safe under one set of safety regulation but unsafe under the other.

Moreover, products which do not fulfil the requirements of a safe product under the GPSD are defined as a 'dangerous product'. To avoid confusion with products which are dangerous by nature (e.g. knifes), this aspect of the safety concept should be amended by defining these products as 'unsafe'.[38]

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Belgium.

At the national level:

Belgium has a federal state structure where competences are divided between a national, federal government and separate communities and regions. Market surveillance of product safety legislation falls under the remit of the federal level where several Federal Public Services (FPS) and other federal entities are separately competent.[39]

The National Market Surveillance Programme[40] indicates that the FPS Economy[41] is competent for market supervision and enforcement of the legislation containing most of the harmonised products and the non-harmonised 'GPSD' products. Within this FPS, market supervision in the area of product safety is executed by three separately functioning Directorate Generals:[42] the DG Quality and Safety, the DG Economic Inspection and the DG Energy. A formal cooperation agreement secures the efficient supervision of the entirety of regulations in the area of product safety and the coordination between these separate DGs. The DG Energy is competent for the harmonised electric and electronic products and the DG Quality and Safety holds competence for all of the other products that fall within the competences of the FPS Economy. The DG Economic Inspection is simultaneously competent for all of these products, as it supervises the compliance of economic operators with corrective

[36] European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, P. 16.
[37] See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 89 – 90. See also on this point Straetmans G. and Verhoeven D. (2016), Other EU laws concerning similar issues (in Machnikowski, P. (ed), European Product Liability (An analysis of the state of the art in the era of new technologies), Antwerp – Cambridge, Intersentia), P. 97 – 103.
[38] See European Economic and Social Committee (2013), Opinion on the 'Proposal for a regulation of the European Parliament and of the Council on Consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC', COM(2013) 78 final – 2013/0049(COD), recital 4.4.4.
[39] Although there are no market supervision authorities at sub-national level (communities or regions), it is possible for these sub-national levels to provide input into the market supervision activities at federal level.
[40] See more extensively, FOD Economie (2020), Nationaal Programma voor Markttoezicht – België, P. 7.
[41] *Federale Overheidsdienst Economie, Middenstand, KMO en Energie*.
[42] *Algemene Directies*.

measures such as product recalls and performs on-site inspections of products at the economic operators' location, while the DG Quality and Safety focuses on services.[43] However, in practice, this division of labour between 'products' and 'services' is fading as the DG Quality and Safety increasingly assists the DG Economic Inspection in performing all of the necessary inspections, such as those in the context of European campaigns, and vice versa the DG Economic Inspection also monitors some services, such as services provided by tanning salons.

Other FPS active in the area of product safety are the FPS Health, Food Chain Safety and Environment, which supervises the safety requirements of some harmonised products, such as cosmetics and chemical products, and the FPS Mobility and Transport, which enforces the safety regulations related to, for instance, recreational crafts and motor vehicles. The FPS Employment, Labour and Social Dialogue supervises the use of certain products in a working environment, such as machines, lifts and protective gear. Lastly, the Federal Agency for Medicine and Health Products (FAMHP), the Federal Agency for the Safety of the Food Chain (FAFSC), the Federal Agency for Nuclear Control (FANC) and the Belgian Institute for Postal Services and Telecommunications (BIPT) also take part in the market supervision activities of harmonised products, which can be consulted in the National Market Surveillance Programme.[44]

Within this network of supervisory authorities, there exists no formal national organ responsible for coordination between the respective activities. However, a coordinative function was assigned to the Interministerial Economic Commission (IEC)[45] and its Internal Market committee, which is responsible for the exchange of information regarding market supervision. In practice, the Safety Regulation section[46] within the Safety Department of the DG Quality and Safety, which is competent for the GPSD, ensures coordination and the preparation of the National Market Surveillance Programme through a central notification point (hereafter: '*Centraal Meldpunt*'),[47] which was established to coordinate the flow of information regarding the safety of products and services.[48] In short, the *Centraal Meldpunt* collects the complaints regarding safety regulations of users (e.g. consumers), economic operators (e.g. producers and distributors), employers and other governments and governmental bodies (see Article IX.12, §1, 1° CEL). Producers and distributors are legally required to inform the *Centraal Meldpunt* immediately when they find out that they have brought a product on the market that lacks conformity with the safety regulations (see Article IX.8, §4 CEL) and/or when a product has caused a serious physical injury (see Article IX.12, §1, 3° CEL). The *Centraal Meldpunt* also functions as the Belgian RAPEX contact point and coordinates information campaigns regarding the safety of products and services (see Article IX.12, §1, 5° CEL). Lastly, the *Centraal Meldpunt* provides information upon request concerning the identification of products, the nature of the risks and the measures taken.

There is a monthly coordination meeting between the supervisory authorities mentioned above, joined by the RAPEX contact point and the national customs authority. Decisions are taken by consensus. Moreover, there are occasional contacts between the authorities in the framework of specific cases and campaigns. Bilateral cooperation agreements between these authorities exist, such as between the FPS Economy and the FPS Employment and between the FAMHP and the FANC.

The customs authority organises its own meetings with market surveillance authorities four times a year, and the aforementioned authorities then function as stakeholders that can give valuable input into the management plan of customs operations. This plan is furthermore constructed on the basis of RAPEX notifications and previous controls. As regards product safety, the participants in the meetings organised by the customs authority exchange information, draft or update national checklists in support of the customs officers in the field or collect relevant data. A cooperation protocol is currently under development between these authorities and the national customs authority and will provide a cooperation framework between customs and the other relevant authorities.

Plans/programmes in place which define priorities for market surveillance of consumer products

The DG Quality and Safety drafts a national surveillance programme covering all product sectors, which includes both consumer and professional products. There are also sectoral surveillance programmes.

[43] For example, routine checks of playgrounds and fairground rides. See Algemene Directie Kwaliteit en Veiligheid (2019), Activiteitenverslag 2018, P. 46.
[44] See https://economie.fgov.be/nl/publicaties/belgisch-nationaal.
[45] *Interministeriële Economische Commissie*.
[46] *Dienst Reglementering Veiligheid.*
[47] Officially: *Centraal Meldpunt voor Producten/Guichet central pour les produits*
[48] *See* https://economie.fgov.be/nl/themas/kwaliteit-veiligheid/veiligheid-van-goederen-en/centraal-meldpunt-voor

The Safety Department of the DG Quality and Safety within the FPS Economy provided for an instruction procedure for the drafting of the market surveillance programme. Stakeholders have the opportunity once per year to propose specific control actions. All the proposals are inserted in a table and are weighted against a number of criteria, such as the risk for the safety, the size of the concerned sector, the number of complaints, the political priority, etc. All criteria are reflected in points and some criteria count for more points, such as political priority.

In order to construct the national programme, the different authorities have meetings where information is exchanged and where the participants take decisions on the national priorities by consensus. The Safety Department only plays a coordinating role and has as such no decision-making influence on the market surveillance activities of other administrations or the other DGs within the FPS Economy.

A similar exercise occurs at customs, where a matrix is constructed based on the information of both internal and external sources (such as the DGs of the FPS Economy). This results in a priority classification. However, the policy of the Belgian customs authority is decided by the management plan of the Administrator General and the aforementioned classification through points is only one element in this decision-making process.[49]

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Belgium with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

New technologies, such as the Internet of Things (IoT) and connected devices, fall under the supervisory competence of the Belgian Institute for Postal Services and Telecommunications (BIPT). However, the DG Economic Inspection reports that it has analysed the problem of 'connected toys' and currently participates in a European action concerning IoT and the protection of consumers with respect to devices connected to the internet.

As regards market surveillance in an online context, the Safety Department of the DG Quality and Safety reports that online surveillance activities only take place indirectly. It selects products through the webshops of sellers located in Belgium in view of taking samples of the product from that economic operator. It is the Department's view that ordering products online would be discriminatory in respect of economic operators located in Belgium because economic operators located across borders will receive payment when products are bought online, whereas physical samples are not remunerated (see above, Article XV.3, 7° CEL).[50]

The DG Economic Inspection states that it conducts online market surveillance, but that these activities do not focus on product safety alone as the Economic Inspection also acts to combat counterfeit products and unfair commercial practices. In practice, online surveillance activities of this authority mainly focus on sanctioning businesses for infringing other rules of economic law rather than product safety legislation infringements.[51] Notwithstanding the fact that trade in some products is restricted on the basis of other legislation, for example a breach of intellectual property provisions, those products might simultaneously exhibit safety risks so that there exists a certain overlap in practice.[52]

Both DGs monitor the online market to perform market studies regarding product safety.

Lastly, it must be submitted that the definition of a 'safe product' in the GPSD, like the implementation in the CEL, refers to commercial activities. As a result, the European Commission stated in its 'Notice on the market surveillance of products sold online' that, in principle, 'C2C products' fall outside the scope of the GPSD.[53] In the same vein, the DG Economic Inspection and the Safety Department of the DG Quality and Safety do not conduct market surveillance of C2C products, the latter referring to the absence of a commercial activity. It can be submitted that this should not necessarily be the case, since the European Commission emphasised in its notice

[49] The classification primarily functions as a guidance instrument but may gain weight if decisions must be taken in times of shortage.
[50] However, there are some exceptions, such as the European coordinated activity of PROSAFE called 'JA2016 PPE Climbing Equipment', during which samples were bought online by the participating authorities and reimbursed by PROSAFE. The participating Belgian authority bought 7 samples through online sales channels. See FOD Economie, Europese Controlecampagne - JA2016 bergbeklimmingsuitrusting Belgische resultaten 2018-2019, P. 5.
[51] Apart from rules regarding counterfeit products, most of the infringements detected by the DG Economic Inspection pertained to unfair commercial practices (Articles VI.93 to VI.103 CEL), violations of information obligations of distance contracts (Articles VI.45 to VI.63 CEL) and identification obligations (Article XII.6 CEL). See Algemene Directie Economische Inspectie (2019), Jaarverslag 2018, P. 61 – 63.
[52] This was the case in a Europol action called 'In Our Sites' (IOS) where the DG Economic Inspection closed 975 webshops for selling counterfeit products in 2019. See '30 506 internet domain names shut down for intellectual property infringement'. https://www.europol.europa.eu/newsroom/news/30-506-internet-domain-names-shut-down-for-intellectual-property-infringement.
[53] See European Commission (2017), Commission notice on the market surveillance of products sold online (2017/C 250/01), P. 4.

that whether a C2C product is being supplied as part of a commercial activity must be assessed on a case-by-case basis, taking into account all the relevant criteria such as regularity of supplies and the intention of the supplier etc.[54]

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

As regards the online activities of the DG Economic Inspection, these are frequent, but it is not possible to single out monitoring activities specifically focused on product safety legislation. As is pointed out above, the DG Economic Inspection simultaneously monitors several regulations of economic law during these online inspections, as it is competent for enforcing all the provisions of the CEL (except those provided in Book IV CEL). Moreover, when a product is found that violates more than one legal ground, as is often the case, the enforcement measure will not necessarily be based on product safety legislation.

The Safety Department of the DG Quality and Safety reports a very limited frequency of online market surveillance activities of less than once a year. The existing activities focus on retailers' websites and social networks, but not online marketplaces, as there currently is no Belgian online platform or marketplace active. The department further points out that to date most of the Belgian sellers are not active on these online platforms or marketplaces. Only when it is known that sellers are located in Belgium, a visit on site can be conducted to e.g. sample products. There is no use of mystery shopping in Belgium for the purpose of enforcing the product safety requirements in Book IX CEL as the legislation does not allow this (see below).

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Belgium (except customs) with respect to product safety

The relevant authorities responsible for market surveillance of non-harmonised 'GPSD' products and harmonised products have a regular meeting once a month. These authorities participate in the preparation of the national market surveillance programme of Belgium, which is *de facto* established under coordination of the Safety Department of the DG Quality and Safety.[55] Furthermore, there are joint processes in place for dealing with dangerous products and a regular exchange of information, but also informal cooperation. The authorities all have access to the RAPEX contact point and also insert their cases into ICSMS[56].

Cooperation with customs authorities in Belgium with respect to product safety

The customs authority has regular contact with the other market surveillance authorities. Representatives of customs are present at the monthly coordination meetings regarding product safety and, *vice versa*, the market surveillance authorities join the four-monthly meetings organised by the customs authority. Moreover, the customs officers receive training regarding product safety checking. Lastly, as was mentioned above, a formal cooperation protocol with all of the market surveillance authorities is currently under development.

The DG Economic Inspection has no day-to-day contact with the customs authority, but the Safety Department of the DG Quality and Safety collaborates frequently with the customs authority. Each day, customs officers request the opinion of market surveillance authorities, such as the Safety Department, regarding products stopped and controlled at the border. The customs officers can use a national checklist for this which has been established by both the DG Quality and Safety and the customs authority. These checklists facilitate inspections at the border,

[54] In this respect, see the criteria set forth by the Court of Justice of the European Union (CJEU) in case C-105/17, 4 October 2018, *Komisia za zashtita na potrebitelite v Evelina Kamenova*). Although the Court concluded in that case that the activities of a consumer on an online platform did not constitute a commercial activity (within the meaning of the Unfair Commercial Practices Directive), it could in other circumstances be otherwise. There seems no reason to deviate from this fundamental concept of 'commercial activities' in the case of the GPSD.

[55] FOD Economie (2020), Nationaal Programma voor Markttoezicht – België, P. 8.

[56] The Information and Communication System on Market Surveillance. https://ec.europa.eu/growth/single-market/goods/building-blocks/icsms_en.

although these were elaborated in view of existing needs and are consequently not available for all products.

The Belgian customs authority is responsible for monitoring a large number of products entering the market from outside the EU/EEA as Belgium has several important ports and airports.[57] The legal conformity of imported products with product safety legislation, such as the GPSD, is checked on a daily basis. As soon as a non-conformity with product safety regulations is noted at those points of import, thereby using the available checklists, the competent market surveillance authority for this type of product will be contacted through the following cooperation procedure. Upon discovering a potential risk, the release of the product is suspended for three working days and the customs officers send pictures of the products per email to the market surveillance authority competent for the type of product concerned. The contacted authority verifies the pictures with the aim of providing an expert opinion as regards the legal conformity of the products with the applicable product safety legislation.[58] In any case, the contacted market surveillance authority takes a decision and an extension of the suspension of the release is possible when the market surveillance authority concerned decides that additional investigations are required to establish the safety and legal conformity of the concerned product, which can be technical controls (e.g. laboratory research or technical measurements) or administrative controls (e.g. by requesting and checking administrative documentation). Based on the photos or additional investigations, the competent authority can then decide that the imported product is cleared for release on the market. By contrast, it can also be decide that the concerned product(s) cannot be released on the market and may then require that the products be brought into conformity with the legal requirements prior to clearance for release (e.g. adaptation of the product or its packaging), the re-export of the product, or its straightforward destruction.

The nature of the cooperation between the customs authority and the market surveillance authority is different when there are control campaigns. Whereas the daily controls do not include the taking and sending of samples to the market surveillance authorities, the Safety Department of the DG Quality and Safety may for the purposes of control campaigns request the customs authority to send some samples for further control.

Finally, the national RAPEX contact point, which is situated within the *Centraal Meldpunt* as mentioned above, has regular contact with several Belgian authorities and sends the RAPEX notifications per e-mail to the competent authorities.[59] This includes sending RAPEX notifications to the Belgian customs authority to alert it and encourage it to take effective measures at the border.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

When a dangerous product is identified in Belgium and the economic operator is located in another country, the market surveillance authorities within the FPS Economy (Safety Department of the DG Quality and Safety and DG Economic Inspection) in the first place contact the economic operator before addressing the foreign authorities, even when they are located outside of the EU/EEA.

Subsequently, when this fails or is not possible, contact with other authorities in the EU/EEA is made through ICSMS but also through RAPEX and the Wiki confluence platform. Furthermore, contacts with other authorities take place in the context of coordinated actions on the safety of products (e.g. PROSAFE), European meetings (Administrative Cooperation groups (AdCos)) and the Consumer Safety Network (CSN).[60] These contacts can also be based on mutual assistance requests made/received outside of RAPEX. Lastly, in the Benelux, there exists formal cooperation between authorities as regards fireworks.

With authorities located in non-EU/EEA countries, cooperation takes place through the participation of the DG Quality and Safety in the OECD WP CPS (Working Party on Consumer Product Safety) meetings and the ICPHSO Symposiums (International Consumer Product Health and Safety Organization).

In the event that a market surveillance authority decides that a non-compliant product cannot be cleared for the market and has to be re-exported (see above), the Belgian customs authority issues a warning so that other

[57] When an importer wants to import products in Belgium, it always has to fill in an electronic statement or declaration ('*e-aangifte*'). The Belgian customs authority received around 9 million declarations of importers in Belgium in 2018. Between 1 and 2% of these declared imports are submitted to further inspection, which can be a documentary control or a physical control of the imported product. See https://financien.belgium.be/nl/Statistieken_en_analysen/jaarverslag/cijfers-2018/beheer-en-dienstverlening/aa-douane-en-accijnzen-1.

[58] For example, the DG Quality and Safety opened 331 cases in 2018 as the result of a request by the customs authority. See Algemene Directie Kwaliteit en Veiligheid (2019), Activiteitenverslag 2018, P. 13.

[59] FOD Economie (2020), Nationaal Programma voor Markttoezicht – België, P. 9.

[60] See also Algemene Directie Kwaliteit en Veiligheid (2019), Activiteitenverslag 2018, P. 38.

authorities in the EU are also informed.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

While all of the relevant Belgian authorities have access to RAPEX,[61] the Safety Department of the DG Quality and Safety stated that there is no formal pre-notification stage before entering the information into RAPEX.

Nonetheless, the RAPEX contact point (i.e. the *Centraal Meldpunt*, as mentioned above) stated that some measures are taken to ensure that all of the market surveillance authorities participate fully in the system, for instance by answering their questions, promoting the use of RAPEX through its regular contacts[62] or giving particular training. However, the RAPEX contact point also reported that there remains uncertainty about whether all of the cases pertaining to serious risks are transferred to RAPEX. It submitted that in its view, not all of the appropriate cases are transferred by the market surveillance authorities.

The Safety Department of the DG Quality and Safety and the RAPEX contact point both underlined that it is difficult to assess the exact duration between the detection of a dangerous risk and its notification into RAPEX as the duration is dependent on the case. Several factors may impact this timeframe. First of all, evidence is required and has to be gathered to verify and confirm that the risk is serious. The (voluntary or ordered) corrective actions taken by the concerned economic operator also have to be entered into RAPEX and, on top of gathering this information and entering it into the data fields of the notification, the economic operator has to be given the opportunity to contest the risk assessment of the market surveillance authority and the proposed measure. Moreover, if the economic operator requests a counter-analysis, this requires even more time.

As regards non-safety risks (e.g. environmental and security risks), relevant market authorities are informed and take action, where needed.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The Safety Department of the DG Quality and Safety and the DG Economic Inspection both reported that they provide answers to questions of businesses concerning the interpretation of legislation. Businesses may also send notifications concerning product safety through the *Centraal Meldpunt* as mentioned above.

Both consumer organisations and business organisations are valuable stakeholders which are consulted in the drafting of the national market surveillance plan on a yearly basis. The Safety Department of the DG Quality and Safety furthermore confirmed that it has contacts with the main federations of businesses as concerns the products under this department's competences. This cooperation is for instance aimed at raising awareness about product safety legislation, but is limited to cooperative contacts with business associations only, and not individual businesses. This takes place through regular meetings where information is exchanged (e.g. with Agoria on machinery, which is the business federation for the technology and industry sector) and informal cooperation.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The website of the FPS Economy contains several awareness measures. There is an online portal[63] related to the safety of products and services as well as a 'news' section with communication campaigns, such as on inflatable structures, and a 'newsroom'. The portal further provides access to specific regulations and contains information on these specific products with publications of reports. Lastly, the website also provides a link to EU RAPEX.

The FPS Economy also has a Communications Department. The DG Quality and Safety can propose communication items, for instance information about a control campaign, but the decision on communication is taken by this department together with the office of the Minister of Economy. This can result in a publication on the website or a press release. Lastly, social media messages are sometimes used by the Communications Department to inform the

[61] FOD Economie (2020), Nationaal Programma voor Markttoezicht – België, P. 9.
[62] *Idem.*
[63] See https://economie.fgov.be/nl/themas/kwaliteit-veiligheid/veiligheid-van-goederen-en

broader audience about safety issues (for example, small "Did you know?"-messages).

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Belgium (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and other corrective measures are requested (voluntary) or ordered (mandatory) by the market surveillance authorities. If the economic operator does not cooperate, the market surveillance authorities can prepare the adoption of a Ministerial Decree in order to enforce measures, as mentioned above. The relevant economic operators always bear the responsibility for the organisation of the recall. The DG Economic Inspection is competent for monitoring the process of product recalls and the other corrective measures.

When a product manifests a high or serious risk and this has been notified to the relevant Belgian authorities, the DG Economic Inspection traces the highest-ranking economic operator in the supply chain located in Belgium, for instance a producer or an importer, and verifies the measures already taken by this economic operator in view of recalling the products or avoiding their sale (e.g. voluntary measures). If it turns out that the measures taken are insufficient to minimise or avoid the risk, the market surveillance authority will require additional measures. A Belgian instruction procedure for recalls and other corrective measures to deal with high and serious risks has been elaborated in two guideline documents, which can be regarded as an implementation of Article 5(1), last paragraph GPSD. Those guidelines are transferred immediately to the relevant economic operators as soon as they have been traced.[64] The first guideline is targeted at the economic operators that do not conduct direct deliveries to consumers and/or users (e.g. producers).[65] The second guideline document is aimed at any other economic operator that supplies directly to consumers and/or other users (most commonly referred to as retail sellers, but can also be a producer delivering products directly through a webshop).[66,67] The measures specified in the document reflect the legal requirements of Book IX CEL regarding corrective measures and product recalls (see Articles IX.8, §2 and §3 CEL) and the more extensive European guidelines.[68] The documents transpose the legal requirements into accessible language and provide easy-to-use practical guidance for economic operators.

In short, products showing a high risk are subjected to an immediate stop of sale and must be withdrawn from the trade chain (e.g. from warehouses). The economic operators that do not perform direct deliveries to consumers/users must duly inform (about the risk, providing a description and pictures of the product) and instruct the economic operators that are in direct contact with consumers and users (i.e. about the necessary corrective measures). The latter are required to follow the communicated instructions and keep documentation available for the FPS Economy for a period of one year.

In the event of a serious risk, the product supplied to the consumer/user must be the object of a product recall, i.e. leading to the return of the product from the end-user, and economic operators are required to take additional measures for this purpose. For economic operators that do not conduct direct delivery to the consumer/user, these measures entail immediately sending the FPS Economy a description of the planned measures, drawing up a poster containing specific information (a photo and description of the products, the risks of use, return channels and the compensation for return), publication on a website and/or social media (only if available) and instruction messages to economic operators directly selling to users/consumers. These instructions encompass all the planned measures, the requirement to contact the final retail customers (users/consumers) to the extent that they are known and, if

[64] Retrieved on 31 January 2020, from: https://economie.fgov.be/nl/themas/kwaliteit-veiligheid/veiligheid-van-goederen-en/terugroeping-van-een-product.

[65] FOD Economie, Procedure corrigerende maatregel - Stopzetten van de verkoop van een product of recall - Marktdeelnemers die niet rechtstreeks leveren aan consumenten/gebruikers. Retrieved on: 31 January 2020, from: https://economie.fgov.be/sites/default/files/Files/Publications/files/Procedure-recall-tot-bij-de-consument-fabrikant-tcm325-276980.pdf.

[66] It has to be noted that the guideline documents refer to the economic operators supplying directly to consumers as 'distributors'. This is not in line with the legal terminology of the GPSD and the CEL, wherein distributors are defined as 'any professional in the supply chain whose activity does not affect the safety properties of a product'. While these descriptions may sometimes overlap for some economic operators, e.g. most retail sellers, this is not always the case. For instance, the guideline document also considers producers that directly deliver their products to consumers as distributors, whereas distributors in the GPSD can also refer to economic operators in the supply chain that only buy and sell products between professionals (but not consumers/users). For the purpose of clarity, the term 'distributors' of the guideline document is not taken over in this report. More information on the legal definition of distributors in the GPSD can be found in: Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 34 – 35.

[67] FOD Economie, Procedure corrigerende maatregel - Stopzetten van de verkoop van een product of recall - Marktdeelnemers die rechtstreeks leveren aan consumenten/gebruikers. Retrieved on: 31 January 2020, from: https://economie.fgov.be/sites/default/files/Files/Publications/files/Procedure-recall-tot-bij-de-consument-invoerder-tcm325-276979.pdf.

[68] See https://economie.fgov.be/sites/default/files/Files/Publications/files/01-Gids-notificatie-gevaarlijke-producten.pdf

direct contact with all of these customers is not possible, the requirement to display the poster in the point of sale and publish the same poster information on the website and/or through social media channels (if available) as well as in advertisement flyers. The second guidance document targeted at the economic operators that conduct direct selling repeats these instructions and furthermore contains a requirement to keep information on the recall process at the disposal of the FPS Economy for a period of one year. This information includes the customer list if consumers/users are known, the correspondence of this direct-selling operator with other economic operators in the supply chain regarding the recall (e.g. producer) and, if applicable, the number of products returned by consumers as well as the number of products sent back (e.g. to the manufacturer), repaired or destroyed. Businesses are also required to be able to provide evidence of these numbers.

Based on a random sampling method, the DG Economic Inspection checks whether the economic operators performing direct selling were duly informed by their supplier of the required measures to, for instance, recall or withdraw the product from the trade chain, and also whether the economic operator effectively complied with these required measures. As mentioned above, importers and producers often comply with the required measures to avoid reputation damage among their professional clients in the trade chain.

The market surveillance authorities within the FPS Economy further monitor this procedure. They immediately attempt to reach an agreement on the whole recall process and the measures to be adopted with the businesses concerned. Those measures include the use of the necessary information channels to alert the consumers. In this respect, the guideline documents reveal that businesses concerned are required to use all their available customer information for recalls and other corrective measures, such as customer databases. Furthermore, businesses are required to provide the authorities with several information particulars, such as the specific information activities targeted at consumers and those targeted at the other businesses in the supply chain or cooperation activities. This includes a precise timeline of the recall process and the distribution list (e.g. the retail sellers to whom a producer has delivered the products). However, it is reported that in practice, the list of distributors is not always provided to the Belgian authorities, which is problematic for tracing the product. The guideline documents further show that information regarding recall effectiveness and the destruction or withdrawal of the products is also requested.

The market surveillance authorities carefully monitor the communication to consumers and the recall strategy by, for instance, giving comments and clear advice to the economic operators concerned. In all cases, it is required that the messages sent to consumers include a picture of the product, a detailed reference and the reason for the recall, which includes a precise description of the risk.

The relevant Belgian authorities reported that they do not communicate any information themselves to consumers regarding the recall process.[69]

Monitoring of effectiveness of product recalls by market surveillance authorities

The DG Economic Inspection monitors the effectiveness of all product recalls in Belgium, including voluntary recalls, by performing spot checks in shops regarding the withdrawal of the product. The fact that economic operators are required to collect information about the number of products subject to the recall and to keep this information at the disposal of the authorities for one year secures the availability of reliable recall results.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Belgium that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The DG Quality and Safety has a database with information about all the controlled products, not only the dangerous ones. Also statistics on dangerous products intercepted at the border are well kept. Moreover, consumers, producers, distributors, employers and authorities may send a complaint to the *Centraal Meldpunt* for products and services that do not meet the legal safety requirements and/or that may harm the safety and/or health of users (also see above). For each complaint from a consumer, a file is opened and investigated.

The *Centraal Meldpunt* keeps track of the voluntary measures and the complaints regarding dangerous products in a database.[70] Upon receiving a complaint, it transfers the complaint to the competent national authority.

[69] Consumers can only subscribe to a governmental newsletter called Econews wherein references to the weekly RAPEX reports can be found and thus in a rather indirect manner information about a dangerous product and its recall. See https://economie.fgov.be/nl/over-de-fod/strategische-publicaties/econews-de-externe-nieuwsbrief.

The authorities under examination reported that there are no statistics on personal injury data available.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Belgium (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The authorities in Belgium, including the customs authority, submitted that they are faced with a lack of staff and financial resources to conduct effective surveillance. Some market surveillance authorities indicated a lack of statistics and data, namely the absence of personal injury data concerning dangerous products and a lack of useful data for the customs authority to create more efficient and detailed risk profiles. Indeed, on the basis of these risk profiles, imported products at the ports and airports are selected and stopped at the border. Subsequently, these products are submitted for compliance checks with the legislation, including the product safety requirements. An important area where the lack of data has consequences for the customs authority concerns the data fields of RAPEX notifications. To construct proper, more refined risk profiles, the customs authority would need more data such as a commodity code and an EORI-number from the operator. The lack of useful data is caused by the fact that the market surveillance authorities use different data particulars than the customs authorities. Moreover, the complex distribution of competences in Belgium generates some difficulties. While cooperation between the different competent authorities in general functions well, some of the relevant authorities confirm that it is sometimes difficult to assess which authority is competent for a specific product, for instance for customs officers in the context of the aforementioned daily cooperation activities with market surveillance authorities to request an expert opinion.[71] Also with regard to this procedure of providing expertise, the market surveillance authorities are required to respond within 3 working days to the requests of the customs authority (see Article 28 Regulation 2019/1020). However, due to this legal limitation period, it can happen that the customs authority is sometimes forced to release a previously stopped product on the market if they do not receive a timely response.

It is submitted that economic operators, such as producers, are not always aware of the product safety requirements and often only discover their roles and obligations after the market surveillance authority has contacted them (e.g. importers when their products are stopped at the border). As concerns economic operators located outside the EU/EEA, albeit rare, it is reported there are then difficulties problems to take effective action. Lastly, while consumers are increasingly purchasing products from outside the EU/EEA, the market surveillance authorities stressed that this falls outside their competence in absence of a responsible economic operator within the EU. It is correct that even in that situation the customs authority can still stop products at the border, but the increasingly growing cross-border B2C traffic makes it very difficult to inspect all those products before they reach their destination. In the same vein, goods in transit that arrive at the Belgian border cannot be checked by the customs authority as they are not formally released on the market at this point. As a result, the customs authority has no competence to stop the product and conduct inspections. Nonetheless, when the customs authority is forced to clear a product suspected of non-conformity at the border, for example when the time limit of three working days is exceeded or when the product is in transit, the customs authority will take the necessary measures to ensure that the appropriate foreign authorities of the Member State of destination are duly informed.

The surveillance of product safety in an online context also proves to be difficult due to the many reported problems. Civil servants acting as inspectors are legally required to identify themselves as being the market surveillance authority, which constitutes a legal impediment for online market surveillance as there is no mystery shopping competence applicable to the product safety requirements of Book IX CEL. The Safety Department of the DG Quality and Safety, when ordering a product online, must reveal its identity as a market surveillance authority. As a result, it might be questioned whether economic operators will always be prepared to send a sample of products. Even in the event that delivery eventually takes place, it might be questioned whether the delivered product is not rather a 'golden sample' instead of an ordinary product. Moreover, in case they need several units of one product, there is no reliable test to make sure that the received products have the same product references (article number, batch number or same colour). A last problem pertains to the payment obligation for online sampling. While there is a sampling competence for the DG Quality and Safety provided in Article XV.3, 7° CEL which is free of charge, the Royal Decree executing this competence requires that this occurs at the location of the investigated economic operator. It follows that free sampling cannot occur in an online context when the seller is

[70] In 2018 the *Centraal Meldpunt* processed 2675 notifications, see Algemene Directie Kwaliteit en Veiligheid (2019), Activiteitenverslag 2018, P. 14.
[71] An example concerns electronic products, such as e-cigarettes.

not located on the Belgian territory. The DG Quality and Safety characterises the payment for online order and delivery of a sampled product as discriminatory towards sellers who provide a free sample in a physical setting.

Mystery shopping has been introduced in the new Market Surveillance Regulation 2019/1020 and the Consumer Protection and Cooperation Regulation 2017/2394, yet neither of them apply to the GPSD. The Belgian legislation also contains a general mystery shopping competence in Article XV.3/1 CEL and extends this competence to all provisions of the CEL, including those in Book IX CEL, but the Royal Decree executing this investigative competence severely limited its scope of application. This resulted in a very limited application in practice, excluding Book IX CEL. It must be submitted that rather than legal impediments, the strong political sensitivity of this competence has short circuited its application.[72] Nonetheless, while a mystery shopping competence may resolve some of the problems related to online surveillance, the Safety Department has pointed out that several additional practical questions may surface, such as the use of credit cards, which need to be registered in name of the FPS Economy or a staff member and thus also reveal the identity inappropriately. Either the economic operator refuses the sale when the credit card is in name of the FPS Economy, as it may suspect an investigation purpose, or the identity of the staff member is disclosed as an inspector (as a result of which the inspector may be blacklisted). Credit cards would then have to be replaced regularly to avoid detection, which is an impractical administrative burden.

RAPEX has been reported to function well by the respondents in Belgium. Nonetheless, the respondents have underlined an important problem concerning multiple entries of the same information into different databases. Each national authority has its own internal system of administration, none of which are connected to RAPEX, ICSMS or each other. Moreover, since each of the administrations has developed its own internal system, the data fields that have to be completed are also different. This already results in a double entry into the internal system and ICSMS and it has even been reported that sometimes, a notified risk has to be re-entered three or four different times (for example, also into RAPEX in the event of a serious risk, and when the control occurred in the context of a European campaign, a fourth time into a separate European database). Each entry is time consuming and therefore impedes the effective use of RAPEX.

Furthermore, the effective use of RAPEX reportedly faces a lack of information, such as relevant information from other national authorities and businesses e.g. to trace notified products. Even when information is furnished, this is sometimes insufficient. For instance, when a notification states that a dangerous product is sold in another country, there is no list of distributors made available to effectively follow up on this risk. Moreover, several notifications do not always pertain to a 'serious' risk, which undermines the purpose of the RAPEX notification system. Some countries notify all of the risks that occur, which is considered problematic by the receiving authorities in Belgium.

The competent authorities regard the product recalls in Belgium with an estimated return rate of 10% as ineffective. While the economic operators often comply with the required product recall measures and other corrective measures, the number of products returned by consumers is sometimes very low as there might be a problem to reach the consumer, but also and more importantly, problems exist in making consumers more responsive to recalls. Even when consumers are contacted directly, they do not always react appropriately.[73]

Areas to make market surveillance of consumer products in Belgium/the EU more effective

The lack of data needs to be remedied by improving both the quantity and quality of data to establish more refined risk profiles for the efficient functioning of the customs authority. The introduction of a data system on personal injuries, preferably at the initiative of the EU level, has also been suggested in this respect.

As concerns RAPEX, there are many possible improvements, such as the data entry process. The different administrative systems need to be integrated by aligning the definitions of the data fields and by establishing connectivity links between them. Such a link already exists between ICSMS and RAPEX. Although it must be recognised that the surveillance authorities have elaborated their own encryption processes with the best intentions, a uniform database shared between the several Belgian authorities, including the custom authority, based upon a uniform encryption system, would arguably be capable of reducing some of the problems detected in

[72] See Vereecken, J. (2018), Het potentieel van mystery shopping om consumenten te beschermen: een kritische evaluatie (Droit de la consommation – Consumentenrecht, vol. 120-121), P. 66.

[73] However, taken from an international perspective, the low effectiveness of product recalls is a very common problem and therefore arguably not specific to the Belgian context. See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 593 – 594.

practice. Yet, it goes without saying that each authority is committed to its own system.

According to the DG Economic Inspection, the economic operator, in cases where a notified dangerous product turns out to be compliant, is faced with a very cumbersome procedure to get their product off the RAPEX list.[74] Therefore this authority recommended a simplification. Furthermore, along with the Safety Department of the DG Quality and Safety, both authorities reported problems related to the notification of non-serious risks by foreign authorities into RAPEX and advocated solving these problems by streamlining the usage of RAPEX across the EU.

The main problems of product recalls relate to reaching the consumers of the recalled product and raising their awareness. Notwithstanding the common nature of this problem, several measures are possible that might improve recall effectiveness. While registration and recalls are easier and/or well organised for some types of products, such as automobiles, this is not the case for other products, such as those of low value. Insofar as this is feasible, the Belgian authorities pointed to encouraging the registration of purchased products by consumers as a possible solution. That would mean that in the event of a recall, the responsible economic operators can directly contact these consumers as required in the guidelines. However, recall effectiveness can also be enhanced through additional communication efforts of the government. The FPS Economy already takes many communication and awareness measures through its website, but these efforts are seemingly not as visible as communications in social media. Therefore a more intensive use of social media could be advisable. Raising public awareness among consumers about the importance of product safety could generate a positive consecutive effect on recall effectiveness. Moreover, it is submitted that the Belgian authorities take on no role in the direct communication about specific product recalls. Arguably, government authorities could also play a role in ensuring communication about a product recall, notably in cases where economic operators fail to comply with the required measures. In this regard, improved recall communication could also be achieved in close cooperation with business associations and consumer organisations.

Some recalls occur in the context of a cross-border situation and it has been pointed out by the respondents that a better cooperation with the authorities from other Member States is needed. While European guides already exist, a uniform template of the recall process designed and introduced at the EU level could also contribute to the improvement of the existing situation. It could foster the cross-border streamlining between Member States of supervision and enforcement practices in the context of a product recall.

As regards cross-border cooperation in general, the EU has recently committed to enhancing the protection of consumers in the EU through the introduction of legislation dealing with the enforcement of infringements of a cross-border nature. This legislation strongly emphasises the cooperation between national government agencies through strict cooperation procedures and far-reaching minimum, and thus harmonised, competences. This follows from the revised CPC Regulation 2017/2394 in the field of general consumer protection legislation, which recently entered into force, and the promulgation of the Regulation on market surveillance and compliance of products 2019/1020. Yet, as was pointed out, the GPSD is not included in the scope of these regulations and cross-border enforcement of non-harmonised products remains, to a large extent, subject to the more informal cooperation between national authorities as it exists currently. The absence of the GPSD in these regulations extends also to the absence of a mystery shopping competence in an online context, which was reported to be a legal impediment and could be problematic for the performance of several market surveillance activities.

Thus, whereas the EU market surveillance regulations mentioned above require the Member States to arm the market surveillance authorities with a mystery shopping competence, this requirement does not apply to GPSD products. The attempt to introduce fully-fledged mystery shopping in Belgium was also embedded in strong political controversy and consequently resulted in a very limited scope of application (see above). It follows that it cannot be assumed that the implementation of the two newly-introduced EU Regulations would spur a voluntary legal extension of the Belgian mystery shopping competence to include GPSD products. From this perspective, legal intervention from the EU legislator to include GPSD products is advisable.

The remaining practical problems, such as the payment obligation in an online context and/or anonymous use of credit cards, could be remedied as follows. Alongside the mystery shopping competence, the requirement or option could be introduced that goods which were ordered online, must be refunded by the economic operator concerned, whether or not this is also limited to cases where the ordered product turns out to be dangerous. The

[74] See European Commission (2010), Commission Decision laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive), P. 30.

mystery shopping competence can then occur without costs for the national market authority and therefore also the national taxpayer. Additionally, inspiration can be drawn from certain existing mystery shopping competences and practices in Belgium to ensure that mystery shopping occurs anonymously in the online context. For instance, the Financial Services Market Authority, the Belgian market supervision authority responsible for the protection of financial consumers (e.g. retail investors), engaged professional external firms that work with third-party mystery shoppers.[75] This guarantees anonymous mystery shopping, whereas the use of credit cards may reveal the identity of civil servants of the FPS Economy after a period of time. It also would remedy the reported problems with credit cards in name of the market surveillance authority.

Finally, it has been indicated repeatedly that Belgium is confronted with a lack of staff and financial resources. In order to make market surveillance in general more effective, the Belgian authorities would require an increase of both staff members and financial capacity. If a mystery shopping competence would be introduced, the legislator should also address the problems referred to in the preceding paragraphs, so that the availability of staff and financial resources is not further reduced.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Belgium since 2013

While it is very difficult to precisely assess how the 'level of safety of consumer products' has developed since 2013, as consumers often do not report or simply dispose of defective products, some indications show that the general trend is positive. In sectors and branches where there are regular controls or where product safety campaigns have been organised, a decrease in the number of infringements is reported by the DG Economic Inspection and there is an increased level of compliance with the product safety requirements.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Belgium whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

The market surveillance authorities reported that they do not have appropriate tools at their disposal to address the new challenges. They also reported that the required expertise to adequately respond to these challenges is not present.

Views of market surveillance authorities whether approaches in Belgium can be considered best practice implementation of the GPSD, which could be of interest to other countries

The FPS Economy elaborated two 'Guidelines', which differentiate between the situation where an economic operator directly delivers to a consumer or not. The two Guidelines provide an easy-to-use Belgian instruction for product recalls and other corrective measures, and furthermore stimulate voluntary initiatives by economic operators, in line with the requirement of Article 8(2), second paragraph GPSD. In addition, legal research has emphasised that public information campaigns from relevant economic operators regarding a recall should take place through websites or social media[76] and should also be combined with individual attempts of economic operators to reach their own consumers.[77] The Belgian guidelines comply with these viewpoints and can therefore be regarded as best practices.

The Safety Department reports the development of a method which it considers as a best practice to tailor the enforcement measure (e.g. a recall or a withdrawal) to the level of risk (low – high - serious). In a fine-tuning effort, it added a fourth category to the existing levels of risk: medium risk. The Safety Department selects the level of

[75] The civil servants of the FPS Economy are required to perform the mystery shopping activities themselves. See Vereecken, J. (2018), Het potentieel van mystery shopping om consumenten te beschermen: een kritische evaluatie (Droit de la consommation – Consumentenrecht, vol. 120-121), P. 66.

[76] See U.S. Consumer Product Safety Commission (2013), The Regulated Products Handbook, P. 30. The use of websites and social media by responsible businesses is also recommended in the United States.

[77] See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 594.

measures expected from the producer in relation to the classification of the risk and the department always strives to take proportionate measures (which is in accordance with Article 8(2), first paragraph GPSD). In short, the methodology thus functions by connecting low risks to warnings and medium risk to the stop of sale at the producer level, whereas high risks result in market withdrawal and serious risks lead to product recall.[78]

Lastly, the DG Economic Inspection emphasises that the monthly meetings between the several Belgian authorities contributes to a fruitful cooperation and should be considered as a best practice.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*21,35*	*9,25*	*30,6*
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*n.a.*	*n.a.*
Total (country)	***21,35***	***9,25***	***30,6***
Notes:	*The FTEs are given for the year 2019 based on the National Market Surveillance Programme: https://economie.fgov.be/fr/publications/programme-national-de* *The figures mentioned above also include the FTE from the Economic Inspection.* *There is no staff at the sub-national level for market surveillance of products.* *The FPS Economy, DG Economic Inspection and DG Quality and Safety have no staff allocated for online market surveillance with the exclusive purpose of monitoring product safety requirements.* *These figures only concern the products under the surveillance of the DG Economic Inspection and the DG Quality and Safety of the FPS Economy, which includes all of the GPSD products and some harmonised products and can be consulted in the National Market Surveillance Programme.*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**552**	**158**	**710**
Total number of consumer products inspected	552	158	710
Total number of consumer products tested in laboratories	87	13	100
Total number of consumer products inspected in cooperation with the customs	244	87	331
Total number of dangerous consumer products found	228	55	283

[78] The Safety Department uses the Risk Assessment Guidelines (RAG) tool to assess the risk level. They select the product hazard and the type of consumer (vulnerability) and devise on that basis a typical injury scenario which consequently is used to assess the risk level. There is also a 'Template library' with several examples of risk assessments, mainly coming from the previous European campaigns. However, it is sometimes difficult to choose the right scenario and even more difficult to assess the probability of each step to injury.

Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	32	6	38
Notes:	*The data provided are for the year 2018. These answers only concern the GPSD products and following harmonised products: Aerosol, Cableways, Explosives for civil use, Lifts, Machinery, PED, SPVD, PPE, Pyrotechnical Articles, Toys.* *The data are extracted from the activity report of the Directorate General Quality and Safety: https://economie.fgov.be/fr/publications/rapport-dactivites-2018-de-la* *These numbers do not include all of the inspections by the Economic Inspection.*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	62	54	116
Total number of mandatory recalls	0	0	0
Notes:	*The data relates to the year 2018.*		

D. Key sources

Legislation	Regulation 764/2008, *Official Journal L 218, 13/8/2008, P. 21 – 29.* Regulation 765/2008, *Official Journal L 218, 13/8/2008, P. 30 – 47.* Regulation 2019/1020, *Official Journal L 169, 25/06/2019, P. 1 – 44.* Regulation 2017/2394, *Official Journal L 345, 27/12/2017, P. 1 – 26.* Directive 2001/95/EC, *Official Journal L 11, 15/01/2001, P. 4 – 17.* Wet betreffende de veiligheid van producten en diensten, *Belgisch Staatsblad 01/04/1994*. Wet van 18 december 2002 tot wijziging van sommige bepalingen betreffende de veiligheid en gezondheid van de gebruikers, *Belgisch Staatsblad 06/02/2003*. Wet van 25 april 2013 houdende invoeging van boek IX " Veiligheid van producten en diensten "in het Wetboek van economisch recht en houdende invoeging van de definities eigen aan boek IX in boek I van het Wetboek van economisch recht, *Belgisch Staatsblad 27/05/2013*. Wet van 20 november 2013 houdende invoeging van Boek XV, " Rechtshandhaving " in het WetBoek van economisch recht, *Belgisch Staatsblad 29/11/2013.* Koninklijk Besluit 25 maart 2016 betreffende het nemen van monsters, zoals voorzien in artikel XV.3, 7° van het Wetboek van economisch recht, *Belgisch Staatsblad, 12/4/2016*, P. 23577. Koninklijk Besluit 10 april 2014 betreffende de transactie bij inbreuken op de bepalingen van het Wetboek van economisch recht en zijn uitvoeringsbesluiten, *Belgisch Staatsblad 29/4/2014*, P. 35213.
Studies/reports/articles	Algemene Directie Economische Inspectie (2019), Jaarverslag 2018, 85 pages. Retrieved on 10 March 2020, from: https://economie.fgov.be/fr/publications/rapport-annuel-2018-direction Algemene Directie Kwaliteit en Veiligheid (2019), Activiteitenverslag 2018, 118 pages. Retrieved on 10 March 2020, from: https://economie.fgov.be/fr/publications/rapport-dactivites-2018-de-la Claeys, I. and Kinnaer, K. (2015), Sectorgerelateerde veiligheidsregelgeving: een bos doorheen de bomen? (in Claeys, I and Steennot, R. (eds), Aansprakelijkheid, veiligheid en kwaliteit. XLste postuniversitaire cyclus Willy Delva 2014-2015, Mechelen, Kluwer, European Commission (2017), Commission notice on the market surveillance of products sold online (2017/C 250/01). Retrieved on: March 10, 2020, from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0801(01). European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, Brussels.

	European Commission (2020), White Paper on Artificial Intelligence. European Economic and Social Committee (2013), Opinion on the 'Proposal for a regulation of the European Parliament and of the Council on Consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC', COM(2013) 78 final – 2013/0049(COD). FOD Economie (2020), Nationaal Programma voor Markttoezicht - België, 48 pages. Retrieved on 16 March 2020, from: https://economie.fgov.be/nl/publicaties/belgisch-nationaal. Pauwels, F. (2016), Huidig en toekomstig pakket productveiligheid en markttoezicht, Droit de la consommation – consumentenrecht, vol. 110, pages 3-14. Steennot, R. (2015), Public and Private Enforcement in the Field of Unfair Contract Terms (European Review of Private Law, vol 23), P. Straetmans, G. and Verhoeven, D. (2016), Other EU laws concerning similar issues (in: P. Machnikowski (ed.) European Product Liability: An analysis of the state of the art in the era of new technologie s, Antwerp – Cambridge, Intersentia). Thierry, Y. (2003), Productveiligheid wordt belangrijke algemene kaderwet en inhoud wordt aangepast aan Europese richtlijn (Tijdschrift voor wetgeving 2003, vol. 5), pages 159-164. U.S. Consumer Product Safety Commission (2013), The Regulated Products Handbook, 51 pages. Retrieved on 12 March 2020, from: https://cpsc.gov/s3fs-public/RegulatedProductsHandbook.pdf Van Camp, S. (2010), Productveiligheid en product recall (Revue de Droit Commercial - Tijdschrift voor Belgisch Handelsrecht, vol. [2010]:6), pages - . Vereecken, J. (2018), Het potentieel van mystery shopping om consumenten te beschermen: een kritische evaluatie (Droit de la consommation – Consumentenrecht, vol. 120-121), pages 45-68. Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, 730 pages.
Websites	https://economie.fgov.be/fr/themes/qualite-securite/securite-des-produits-et/guichet-central-pour-les https://economie.fgov.be/nl/themas/kwaliteit-veiligheid/veiligheid-van-goederen-en https://www.europol.europa.eu/newsroom/news/30-506-internet-domain-names-shut-down-for-intellectual-property-infringement https://financien.belgium.be/nl/Statistieken_en_analysen/jaarverslag/cijfers-2018/beheer-en-dienstverlening/aa-douane-en-accijnzen-1 https://ec.europa.eu/growth/single-market/goods/building-blocks/icsms_en https://economie.fgov.be/nl/themas/kwaliteit-veiligheid/veiligheid-van-goederen-en/terugroeping-van-een-product https://economie.fgov.be/nl/over-de-fod/strategische-publicaties/econews-de-externe-nieuwsbrief
Interviews	Federal Public Service Economy, DG Quality and Safety (3 interviewees) Federal Public Service Economy, DG Economic Inspection Federal Public Service Finance, General Administration of Customs and Excise

3. Bulgaria

COUNTRY REPORT BULGARIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The Bulgarian legislator transposed Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ("GPSD") in Chapter V, Section I (Art. 69-103) "Safety and Quality of Goods and Services" of the Bulgarian Consumer Protection Act ("CPA") enacted in 2005[79]. Prior to the CPA, the national legislation had had special provisions on the safety of consumer products since 1999, when the preceding Consumer Protection and Trade Rules Act ("CPTRA") was enacted[80].

The implementation of the CPA is supported by adopting secondary legislation relevant for safety of consumer products, namely:

- Ordinance on the conditions and procedure for withdrawal from the market, seizure from consumers and destruction of dangerous goods and the procedure for compensation of consumers in the case of seizure of dangerous goods[81].
- Ordinance on essential requirements and conformity assessment of toys[82].
- Ordinance on goods imitating food[83].
- Ordinance No. 1 of January 12, 2009 on the terms and conditions for the construction and safety of playgrounds[84].

In Bulgarian legal literature, the right of consumers to receive safe goods and services without any danger to their health and life is considered to be derived from and related to the constitutional rights to life (Art. 28 of the Constitution of the Republic of Bulgaria; "the Constitution") and personal inviolability (Art. 32 of the Constitution)[85]. Defective and dangerous products may entail exposure to risk and affect the life and personal inviolability of citizens[86]. Therefore, in the legal theory, the legislation on the safety of consumer products is deemed to have much broader impact than protection of consumers' interests and functioning of the internal market, as it indirectly also ensures the protection of some of the fundamental rights of citizens.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Bulgaria

The Bulgarian Consumer Protection Act imposes a number of obligations on producers as well as on distributors of goods aimed at ensuring the traceability of dangerous products on the market. In particular, the law establishes the following obligations:

1) On producers (Art. 76 CPA), who shall provide conditions for tracing the goods throughout the whole supply

[79] Promulgated in the State Gazette 99/9.12.2005, last amendment - the State Gazette 45/07.06.2019.
[80] Promulgated in the State Gazette 30/1999, repealed - the State Gazette 99/09.12.2005.
[81] [Наредба за условията и реда за изтегляне от пазара, изземване от потребителите и унищожаване на опасни стоки и за реда за обезщетяване на потребителите в случаите на изземване на опасни стоки]. In force since 10.06.2006, adopted with Decree of Council of Ministers № 130/ 02.06.2006, promulgated in the State Gazette 48/13.06.2006, last amendment – the State Gazette 40/02.06.2015.
[82] [Наредба за съществените изисквания и оценяване съответствието на играчките]. Promulgated in the State Gazette 99/17.12.2010, in force since 20.07.2011.
[83] [Наредба за стоките, имитиращи храни]. In force since 10.06.2006, adopted with Decree of Council of Ministers № 6/ 13.01.2006, promulgated in the State Gazette 7/24.01.2006, last amendment – the State Gazette 11/03.02.2006.
[84] [Наредба № 1 от 12 януари 2009 г. За условията и реда за устройството и безопасността на площадките за игра]. In force since 07.05.2009, adopted by the Minister of Regional Development and Public Works, the Minister of Interior and the Director of the State Agency of Child Protection. Promulgated in the State Gazette 10/06.02.2009, last amendment – the State Gazette 84/25.10.2019.
[85] Колева, Рая [Koleva, Raya] „Основните права на потребителите – теоретични и практически въпроси", сп. „Търговско право", 2009/2 с. 76 ["Rights of consumers – theoretical and practical aspects", in "Commercial Law", 2009/2 p.76];
[86] Златка Сукарева [Sukareva, Zlatka] Гражданскоправна защита на потребителя, Фенеа, с.54 [Consumer Protection 2001, Fenea, p.54]

chain, for which purpose they shall:

a) Mark the goods in such a way as to enable them to be identified by affixing the marking to the goods or to the packaging, which contains the name of the manufacturer, other information about manufacturer or the batch of goods to which the goods belong;

b) Include the goods' identification data, referred to in the previous item, in the documents issued for the distributors participating in the distribution chain of the goods;

c) Store and make available upon request from the control authorities all documentation necessary for tracing the origin of the goods.

2) Additional obligations are also imposed on distributors (Art. 77 (3) CPA), who shall participate in monitoring the safety of the goods placed on the market by:

a) Providing information on the risks associated with the use of the goods;

b) Keeping and providing documents necessary for tracing the origin of the goods;

c) Cooperating with producers and market surveillance authorities in their risk prevention measures;

Taking other appropriate measures: The traceability is a binding requirement in Bulgarian consumer protection legislation. Producers and distributors have obligations with regards to ensuring traceability of goods and services on the market. For offences of traceability requirements, the legislator foresees fines between 500 and 2000 BGN (for natural persons; approx. 255 to 1022 EUR) or penalty payments (for legal entities and traders), whose amount may range from 1000 to 3000 BGN (approx. 511 to 1533 EUR) – Art. 214 in connection with Art 76 and Art. 216 in connection with Art. 77 of CPA.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

Bulgarian legislation does not introduce any specific definition of "safety". The legal definitions of "safe products" (goods or services) and "dangerous products" (Art. 70 CPA) are almost identical to the definitions under Art 2(b) and (c) GPSD.

The same holds for the benchmarks for assessing safety from Art 3 (3) GPSD, which in Bulgarian legislation are transposed to Art. 71 (3) CPA. Their content is identical to the benchmarks in the relevant provision of the GPSD. However, the Bulgarian legislator has introduced something like an "order of precedence" of the benchmarks; for instance, Bulgarian national standards shall be taken into consideration only in the absence of national standards transposing relevant European standards; European Commission recommendations setting guidelines on product safety assessment shall be taken into consideration only in the absence of Bulgarian national standards; product safety codes of good practice in force in the sector concerned shall be taken into consideration only in the absence of European Commission recommendations, etc.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The available information does not suggest that this is the case.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

According to Art. 71 (3) CPA, in the absence of regulatory requirements and European standards referenced in the EU Official Journal, the conformity of the goods or services with the general safety requirements shall be assessed taking into account:

1) The Bulgarian standards introducing European standards other than standards referenced in the EU Official Journal;

2) The Bulgarian standards that have been developed at the national level, in the absence of standards under item 1 above;

3) The recommendations of the European Commission containing guidelines for the assessment of the safety

of goods, in the absence of standards under item 2 above;

4) The rules of good practice regarding the safety of goods or services applied in the respective sector, in the absence of recommendations under item 3 above;

5) The current state of science and technology, in the absence of good practice rules under item 4 above;

6) The normal and reasonably foreseeable expectations of users regarding safety, when it is not possible to take into account the current state of science and technology.

There is opinion in Bulgarian legal literature that if a product does not meet the above listed requirements, it is defective to the extent of being dangerous and therefore is unsuitable to be placed on the market[87].

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Bulgaria in case there are consumer product(s) on the market which are found unsafe under the GPSD

The Bulgarian legislation in force provides the market surveillance authorities with a number of administrative measures in cases where unsafe consumer products are found on the market. For instance, the authorities are entitled to:

1) Require businesses to provide relevant information on the product(s) - Art. 80 CPA, Art. 84 i.3 CPA (mark the product with clear wording and easily understandable warning texts in Bulgarian for the possible risks associated with its use), Art. 85 (to a particular category of users, for which goods or service may represent higher risk);

2) Require businesses to provide relevant information on the supply chain and the distribution of the product(s) – Art. 80 CPA;

3) Carry out unannounced on-site inspections and physical checks of products - Art. 83 i.1 CPA;

4) Acquire product samples, including under a cover identity (mystery shopping) - Art. 83 i.2 CPA;

5) May temporarily prohibit placing a good or service that may be dangerous on the market, for the period necessary to carry out safety monitoring, checking and evaluation (Art. 86 CPA); when it is established that a good, service or batch of goods is dangerous to consumers, the authorities shall prohibit its placing on the market and take accompanying measures to ensure compliance with the prohibition (Art. 87);

6) Require from economic operators to conduct recalls of products and other corrective measures (such as restrictions for placing products on the market or bringing products into compliance, stopping products from being placed on the market, withdrawal of products etc.) - Art. 82 (4) i.2 (f) (g) and Art. 88 (1) CPA;

7) Reclaim from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s) (e.g. for carrying out testing, storage etc.) – Art. 88 (4) CPA.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

For offences related to the product safety provisions, the legislator foresees fines (for natural persons) or penalty payments (for legal entities and traders), whose amount, depending on type of offence and the person who has committed it, may range from 500 BGN to 25 000 BGN (approx. EUR 255 to EUR 12 782).

In court practice, the penalty payments are often applied with a usual amount around 5 000 BGN (approx. EUR 2556)[88], which is the minimum amount for an offence of the obligation to put or provide only safe goods and services on the market (Art. 211 in connection with Art. 69 (1) CPA).

[87] Давидкова, Десислава [Davidkova, Desislava] Сборник коментари по прилагане на потребителското законодателство в България [Comments on application of Consumer Protection Law in Bulgaria], 2006, quoted by Колева, Рая [Koleva, Raya] „Основните права на потребителите – теоретични и практически въпроси“, сп. „Търговско право“, 2009/2 с. 79 [“Rights of consumers – theoretical and practical aspects”, in “Commercial Law”, 2009/2 p.79]]

[88] Decision № 2594/07.12.2018, Admin-Offensive Case № 3222/2018 the Administrative Court-Plovdiv; Decision № 935/03.05.2017, Admin-Offensive, Case № 916/2017 the Regional Court-Varna; Decision № 347/19.05.2015, Admin-Offensive Case № 627/2015 the Regional Court-Stara Zagora;

Recent case law in Bulgaria with respect to or relevant for the GPSD/the national implementation legislation.

For the last few years, the consumer products safety provisions from the CPA have been applied in a few hundred proceedings before various courts in Bulgaria – regional, provincial, administrative as well as in the Supreme Administrative Court. These proceedings are mainly in two categories – administrative cases and administrative offence cases.

The administrative cases deal with appeals against orders of market surveillance authorities – for instance, orders for temporary suspension or withdrawal of a product from the market[89].

The administrative offence cases are hearings related to fines and penalty payments for violation of consumer product safety provisions[90].

Analysis of the relevant Bulgarian case law reveals that the majority of court proceedings dealt with certain categories of goods or services, namely:

1) Toys and other goods or services for children:

   a) Playgrounds – an appeal against an order of the Commission for Consumer Protection ("the CCP") for (i) temporary suspension of service (use of a playground located on the territory of a café in the city of Plovdiv) due to non-compliance with the general requirements for the construction of playgrounds[91] and (ii) bringing the playground in accordance with the safety requirements. The court found that it was irrelevant for the case that the use of playground was for free and that there were no accidents on it. The order of CCP was held to be lawful and the appeal was rejected[92] (Decision № 14415/29.12.2016, Adm. Case № 3747/2016 the Supreme Administrative Court, VII Division).

   b) Skateboards - the existence of a previous order for withdrawal from the market of the dangerous goods meant holding them and placing them on the market was not allowed, regardless of the subsequent (after the order) change of ownership of the business, legal and organizational changes of the company, as well as re-labelling of the goods with the indication that it is intended for persons of a lower age and lower weight. The court found these circumstances irrelevant for the safety of the goods – they were dangerous due to non-compliance with technical standards, and a change of ownership or re-labelling could not rectify their non-conformity[93] (Decision № 837/26.01.2015, Adm. Case № 5738/2014 the Supreme Administrative Court, VII Division).

   c) Baby carriages – the Court found that a test report for testing a baby carriage for conformity with standards outside EU (i.e. Australia) did not invalidate the findings of the administrative authority about the product's lack of safety, as the product did not comply with European safety standards[94] (Decision № 841/26.01.2015, Adm. Case № 6125/2014 the Supreme Administrative Court, VII Division)[95].

   d) Products incorrectly classified as "toys" - the order of the CCP is illegal as it lacks a statement of facts on the basis of which the authority classified the product as a "toy" and carried out the appropriate safety check to the standards applicable to toys, which deprives the court of the ability to review the legality of the order (Decision № 10592/08.07.2019, Adm. Case № 3405/2018 the Supreme Administrative Court, VII Division).

   e) Jacuzzi bath accident - based on a publication in the media about an accident with a child in a spa centre, the CCP conducted inspection of the Jacuzzi bath (Decision № 1838/30.10.2018, Admin-Offensive Case № 2837/2018 the Regional Court-Plovdiv).

[89] See Art. 95 CPA in connection with Bulgarian Administrative Procedure Code
[90] See Art. 233 of CPA in connection with the Administrative Offences and Sanctions Act ("AOSA")
[91] Ordinance No. 1 of January 12, 2009 On the Terms and Conditions for the Construction and Safety of Playgrounds
[92] See another case for safety of playground - Decision № 5413/17.04.2014, Adm. Case № 1926/2014 the Supreme Administrative Court, VII Division;
[93] See also Decision № 1052/29.01.2015, Adm. Case № 7254/2014 the Supreme Administrative Court, VII Division; Decision № 1667/16.02.2015, Adm. Case № 8065/2014 the Supreme Administrative Court, VII Division
[94] Similar - Decision № 14620/04.12.2014, Adm. Case № 5218/2014 the Supreme Administrative Court, VII Division; Decision № 9448/07.07.2014, Adm. Case № 1648/2014 the Supreme Administrative Court, VII Division
[95] Regarding the applicability of the national standard of another Member State (i.e. the UK), which is not approved as the Bulgarian national standard, see Decision № 1944/22.02.2016, Adm. Case № 14007/2015 the Supreme Administrative Court

f) Baby pacifiers – the product was offered for sale without assessment and verification of its conformity with the statutory safety requirements (only chemical tests were performed, but no tests on mechanical characteristics of the product as required by the applicable standard) (Decision № 2594/07.12. 2018, Admin-Offense Case № 3222/2018 the Administrative Court-Plovdiv).

g) Cribs and beds for children – they were withdrawn from the market as they did not pass the tests for conformity with the applicable standards (Decision № 150/23.01.2018, Admin. Case № 1282/2017 the Administrative Court-Plovdiv).

2) Imitations of foodstuffs, which do not meet the requirements of the Ordinance on goods imitating food:

a) Candle in a glass (Decision № 153/24.03.2014, Admin-Offensive Case № 127/2014 the Administrative Court-Pleven)

b) Large lollipop product with easily detachable small coloured styrofoam balls and a plastic rod (Decision № 8187/16.06.2014, Adm. Case № 3172/2014 the Supreme Administrative Court, VII Division)

c) Product in the form of an ice cream cone with styrofoam ice cream (Decision № 2483/20.02.2014, Adm. Case № 13444/2013 the Supreme Administrative Court, VII Division)

d) Muffin-shaped product made of styrofoam (Decision № 6111/08.05.2014, Adm. Case № 14726/2013 the Supreme Administrative Court, VII Division)

e) Styrofoam fruits and vegetables (Decision № 2051/04.12.2017, Adm. Case № 1094/2017 the Administrative Court - Burgas)

3) HHO Generators (Brawn's Gas Generators) – the decision on applicable provisions or requirements (either the Low Voltage Directive or Regulation (EC) No 79/2009 on hydrogen-powered motor vehicles) and competent surveillance body (either the State agency for metrological and technical surveillance or the Executive Agency "Automobile Administration") (Decision № 8318/05.07.2016, Adm. Case № 14555/2015 the Supreme Administrative Court, VII Division).

4) Lighters with an unusual appearance (i.e. in the form of pliers, sneakers in different colours; in the form of a bitten apple), which make them attractive for children, hence increasing the risk of fire (Decision № 1059/31.05.2019, Admin-Offence Case № 1156/2019 the Regional Court - Varna).

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Bulgaria concerning traceability, definition of safety etc. / Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The relevant authorities confirm that in some cases they have encountered problems with the traceability of products from non-EU/EEA-countries.

No practical problems with the definition of safety in the GPSD (Art 2(b)) have been experienced so far.

The stakeholders mention emerging safety issues related to both non-harmonised consumer products (childcare articles, button batteries, electrical appliances and equipment outside the scope of the Low Voltage Directive[96)] as well as related to harmonised consumer products (toys[97] and electrical appliances and equipment under the Low Voltage Directive).

Possible improvements to make the implementation of the GPSD in Bulgaria more effective

The available information suggests the following areas for potential legislative amendment aimed at improving the efficiency of GPSD implementation: online sales; e-platforms; cyber security of products; sales of goods from non-EU/EEA-countries (outside the EU).

II. Functioning of market surveillance of consumer products

[96] HHO-generators (Brawn's Gas Generators) – see above Decision № 8318/05.07.2016, Adm. Case № 14555/2015 the Supreme Administrative Court, VII Division.

[97] See above the listed case law related to toy safety.

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Bulgaria.

With a view to ensuring the effective functioning of the single European market and safeguarding the free movement of goods, Bulgaria applies Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

Bulgaria has implemented the legislative framework and supporting organisation relating to the free movement of goods in order to guarantee the smooth and efficient operation of the internal market. A national market surveillance programme has been drawn up based on the Regulation, and it comprises sectoral programmes that are implemented in compliance with the common goals formulated.

General and sectoral legislation in the area of the free movement of goods is implemented through various Bulgarian laws and regulations, which set out requirements for manufacturers, importers, downstream users, distributors and retailers, so as to ensure the production and marketing of products which are safe and compliant with the harmonised criteria.

A system of bodies carrying out supervisory activities across the country ensures compliance with the applicable legal requirements. These are the "market surveillance authorities" within the meaning of Regulation (EC) No 765/2008; they use various procedures and methods for supervision and control (preventive, documentary and physical checks, withdrawal from the market, etc.) in order to prevent any unsafe or non-compliant products from entering the market.

In Bulgaria, there is not a single body designated to carry out market surveillance, nor a special legislative instrument defining how market surveillance should be carried out. Different institutions have been designated, based on different legal instruments, to supervise specific product groups. Bulgaria is one of the Member States which have chosen to carry out market surveillance primarily at a sectoral level[98].

The surveillance authorities act on a national level, and even though some of the authorities have regional units, they are not independent sub-national authorities.

Market surveillance authorities are the following institutions:

1) The Consumer Protection Commission
2) The State Agency for Metrological and Technical Supervision
3) The Ministry of Health
4) The Bulgarian Food Safety Agency
5) The Executive Agency for Medicines
6) The Technical Control Inspectorate
7) The Ministry of the Environment and Water.

The market surveillance authorities function according to the distribution of competences between four ministries, namely the Ministry of the Economy, the Ministry of Health, the Ministry of Agriculture and Food and the Ministry of the Environment and Water.

Plans/programmes in place which define priorities for market surveillance of consumer products

In fulfilment of the obligations arising from Regulation (EC) No 765/2008, a national market surveillance program, including consumer products, has been established and implemented in Bulgaria[99].

The National Market Surveillance Program consists of a few sectoral implementation programs that meet the

[98] Find more details in "Review and assessment of the functioning of market surveillance activities pursuant to Article 8(6) of Regulation (EC) No 765/2008 - 2010--2013 [Bulgaria]" - http://ec.europa.eu/DocsRoom/documents/9662/attachments/1/translations [last visited on November 26, 2019]

[99] More details can be found here - https://mi.government.bg/bg/themes/nacionalna-programa-za-nadzor-na-pazara-634-405.html [retrieved on 26.11.2019];

stated general objectives. The structuring and implementation of the document ensures that effective measures can be taken with respect to each of the product categories subject to EU harmonisation legislation, such as toys, textiles, goods imitating foodstuff, pressure equipment, aerosol dispensers, lifts and cableways, cosmetics, etc.

For instance, for the last couple of years as part of the implementation of the sectoral market surveillance program, the Commission for Consumer Protection conducted thematic national campaigns on the safety of toys and childcare goods, inflated products, leisure time and sporting goods, services safety, and electrical equipment[100].

In addition to the National Program, there are some other factors defining the priorities for market surveillance of consumer products in Bulgaria. For instance, most stakeholders point to the results of conducted inspections, RAPEX notifications, consumer complaints as well as information provided by customs. As additional sources of information relevant for setting priorities, some stakeholders also indicate coordinated actions on the safety of products organised at the EU level, accident reports and injury data, information provided by businesses and business associations, information provided by consumer organisations, news and media reports and even information provided by insurers.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Bulgaria with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

When it comes to market surveillance activities with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), the relevant stakeholders almost unanimously confirm that such activities are not conducted. The situation is similar regarding the surveillance of products sold by consumers to consumers ("C2C")[101].

The situation looks slightly better with respect to the market surveillance of products sold online. However, not all stakeholders conduct such control activities, and the ones that do conduct such activities only once per month and predominantly on products sold online from sellers established in Bulgaria. Only a few of the relevant authorities perform such controls on products sold online from sellers established in the EU/EEA or in non-EU/EEA countries, with the frequency on average of once per month. The surveillance activities on online sales cover mainly retailers' websites, but some of the stakeholders mention that they also check online marketplaces as well as social networks. Yet the inspection of online sales makes up an insignificant part of the general market surveillance activity of the competent authorities – as per their estimation, it varies between 6% and 10% (for some authorities even less – around 2%) of the total number of inspections conducted. So-called "mystery shopping"[102] is practised by only a couple of the stakeholders, and then only rarely – less than once per year. The main impediments for using this method more often are related to the lack of financial and staff resources, but some stakeholders also point out legal impediments, i.e. that the current legislation seems to be inadequate to deal with the new trends on the market. Expectations are that the new Regulation on market surveillance[103] should rectify this deficiency.

With respect to the initiatives and the documents aimed at improving the enforcement of EU rules for products sold online, only a couple of stakeholders assessed the usefulness of these, with their assessments as follows: "EC Notice on market surveillance of online products" (assessed as "4-Rather helpful"), "Product Safety Pledge" (assessed as "2-Rather not helpful") and "E-Enforcement Academy" (assessed as "3-Moderately helpful").

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

As explained in the previous section, the surveillance of products sold online is mainly conducted by inspections of retailers' websites of sellers established in Bulgaria. Some authorities also check sellers based in the EU/EEA, but only rarely do they check sellers based in non-EU/EEA countries.

Mystery shopping is seldom practised.

[100] The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]
[101] This finding corresponds to the Annual Reports of the CCP, which do not contain any data about inspections related to new technologies - The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]
[102] Purchasing of products under a cover identity
[103] REGULATION (EU) 2019/1020 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

For more details, please see the previous section.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Bulgaria (except customs) with respect to product safety

There is close cooperation between the surveillance authorities in Bulgaria.

Stakeholders indicate regular contacts between authorities with competences related to product safety (at least once per week, and some of them mention contacts even more often than once per week).

Some of the Bulgarian authorities are in regular contact with relevant authorities located in other EU/EEA countries, especially neighbouring Member States (approximately once per month), but not that often with relevant authorities located in non-EU/EEA countries (once every six months or for some of the stakeholders, never).

The cooperation between surveillance bodies is institutionalised with the Decree of the Council of Ministers No. 180 of 1 August 2005 on the Establishment of a Coordination Council and the Exchange of Information between Authorities Controlling Market of Goods[104]. The Coordination Council is formed by representatives of the above mentioned surveillance authorities, but also includes representatives from Customs, the Criminal Police, the Directorate for National Construction Control, the Executive Agency on Vine and Wine, the Executive Agency of Fisheries and Aquaculture and the Executive Agency of Variety Testing, Field Inspection and Seed Control.

The Coordination Council is convened at a regular meeting at least once every 3 months and has the following functions and tasks:

1) Prepares proposals and takes decisions regarding the coordination and exchange of information related to control activities and the effective implementation of the acts related to the control of the market;
2) Discusses and proposes solutions to questions raised in the contacts of the surveillance authorities with the consumer associations, the organisations of the traders and producers;
3) Plans joint inspections;
4) Sets up expert working groups;
5) Makes recommendations for the conclusion of agreements for interaction between the surveillance authorities;
6) Approves the national market surveillance program for the calendar year concerned, based on the sectoral programs by product category;
7) Adopts the reports on the implementation of the sectoral surveillance programs;
8) Approves the information made available to the European Commission and the other Member States of the European Union regarding the national competent market surveillance authorities as well as the national market surveillance program;
9) Reviews and evaluates the implementation of market surveillance activities (at least every four years), the results of which are made available to the European Commission and to the other Member States.

And finally, some of the relevant stakeholders point out the common use of RAPEX and ICSMS as a form of cooperation.

Cooperation with customs authorities in Bulgaria with respect to product safety

[104] Постановление № 180 От 1 Август 2005 Г. за създаване на Съвет за координация и обмен на информация между органите, осъществяващи контрол на пазара на стоки. Promulgated in the State Gazette 65/09.08.2005, last amendment – the State Gazette 40/02.06.2015

In Bulgaria, customs authorities are not considered to be a "market surveillance authority". In accordance with Art. 27, 28, and 29 of Regulation (EC) No 765/2008 they instead act in supportive function to the surveillance authorities in their activities for product safety control[105].

The National Customs Agency of Bulgaria has concluded a formal agreement with the surveillance authorities and exchanges information regarding product safety with them on regular basis. As mentioned above, the customs authorities are a member of the Coordination Council and their representatives participate in the Council's meetings.

Almost all relevant stakeholders confirm the close cooperation with the customs authority regarding product safety, which has also been confirmed by the rest of the information collected for this report[106].

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Stakeholders indicate the following channels for communication with the authorities functioning with respect to product safety in other countries in the EU/EEA:

1) Through RAPEX
2) Through ICSMS
3) Wiki confluence platform
4) Coordinated actions on the safety of products organised at the EU level
5) Mutual assistance requests made or received outside of RAPEX
6) Informal cooperation with neighbouring Member States.

None of the stakeholders confirm institutional cooperation with countries outside the EU.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc.)

The stakeholders indicate that in occurrences of dangerous products on the market, they strictly follow the RAPEX procedure by notifying the relevant market surveillance authorities, which take actions where needed.

There is a considerable difference between the time of the detection of a dangerous product and its notification to RAPEX. The majority of the stakeholders indicate 2 to a maximum of 5 days, but one stakeholder mentioned two weeks without indicating any particular reasons for these extended durations.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The information shows that the authorities maintain cooperation with both business associations and consumer organisations when it comes to product safety. The frequency of contacts varies (from once a week to once every three months), as do the channels for cooperation. For the majority of the relevant authorities, this is done through the regular exchange of information and informal cooperation with business organisations and consumer organisations; other forms of cooperation include providing advice to businesses where needed, cooperation with business associations and consumer organisations to create awareness for product safety among businesses and consumers, partnership agreements with business organisations, and regular meetings and inclusion of consumer organisations in preparing the national market surveillance programme.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product

[105] See the Statement of the Agency Customs from their Letter # 32-323207 dated 11.11.2019;
[106] See also The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]; Decision № 1944/22.02.2016, Adm. Case № 14007/2015 the Supreme Administrative Court, and The Annual Reports of the Agency Customs - Annual Reports Customs [retrieved on 20.10.2019]

safety

In addition to the channels of cooperation and information exchange mentioned in the previous sections, the authorities organise information campaigns both in traditional media (newspapers, TV, radio) and in social media. The campaigns aim at increasing businesses' and consumers' awareness of problems related to dangerous products.

Furthermore, the portal with RAPEX notifications translated into Bulgarian is pointed out as a tool for raising the awareness of businesses and consumers with respect to product safety.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Bulgaria (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Bulgarian legislation provides various options for market surveillance authorities when they establish that a certain good, service or a batch of goods placed on the market presents or is likely to pose a danger to the health and safety of consumers.

According to the CPA provisions, Bulgarian authorities can take the following measures:

1) Before goods and services are placed on the market:
    a) Temporarily prohibition of placing a good or service that may be dangerous on the market (for the period necessary to carry out safety monitoring, checking and evaluation) (Art. 86 CPA);
    b) If it is established that the good, service or badge of goods is dangerous - permanent prohibition of its placing on the market together with accompanying measures to ensure that the prohibition is complied with (Art.87 CPA);
2) After goods and services are placed on the market:
    a) Temporary suspension of the supply of goods or the provision of services on the market for the period necessary to carry out control, inspection and assessment of their safety; within 24 hours of proving the safety of the goods, the inspection body shall decide on the imposed measure to suspend the delivery of the goods or the provision of the service on the market (Art. 88 (1) i.1 CPA)107;
    b) Immediate and effective withdrawal of the goods from the market or suspension of the offering of the service, together with issuing warnings to the consumers about the risks that the good or service entails (Art. 88 (1) i.2 CPA);
    c) Recall of the goods from consumers and their destruction (Art. 88 (1) i.3 CPA). This is however a final resort, which is permissible when all other measures taken by manufacturers, distributors and control bodies are insufficient to prevent consumer risk (Art. 90 CPA).
3) Order the manufacturer, distributor or service provider to bring the goods or services into conformity with safety requirements. If that is impossible, the surveillance authority may order the use of the goods for other purposes, their return to their country of origin or their destruction within a specified period (Art. 89 CPA)[108].
4) Prohibit the manufacturing, import, export, free or gratuitous placing on the market of products that represent "a serious risk to the health and safety of consumers", withdraw the products and order their

[107] For instance, in 2016 the CCP issued 60 orders for the temporary suspension of 87 types of goods, 4 of which were orders for temporary prohibition of the placing on the market of 5 types of goods received by notifications from customs; in 2018 – 37 orders for 58 type of goods - The Annual Reports of the Commission for Consumer Protection for 2016 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]

[108] According to the CCP, in the majority of the cases the businesses take these actions voluntary following the orders by the Commission - The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]

destruction, when this is the only way to end the danger. The prohibition order is published in the State Gazette (Art. 92 CPA)[109].

5) Prescribe the manufacturer, distributor or person providing the service certain measures (enhancement of self-control by the manufacturer, supplier or distributor, training of staff, etc.) when, for reasons of non-compliance with the requirements of this section, the conditions of work or storage of the manufacturer, distributor or service provider are such that the goods or services produced, stored, made available or placed on the market present or may present a health or consumer safety risk (Art. 93 CPA).

In practice, businesses are asked to conduct (voluntary or mandatory) recalls and other corrective measures, if needed. If no responsible business operator can be found, the recalls and other corrective measures are organised by the surveillance authorities. The businesses and the market surveillance authority agree on the information channels to inform consumers on a recall. Market surveillance authorities cooperate with businesses by checking and influencing the recall strategy as well as the messages given to consumers.

The authorities explain that in the case of a recall of a consumer product, they require the following types of information from the business:

a) Information activities targeted at consumers;

b) Information activities targeted at and cooperation with other businesses involved in the supply chain (e.g. distributors, online marketplaces);

c) List of other businesses involved in the supply chain (e.g. distributors, online marketplaces);

d) Timeline of the recall process;

e) Recall effectiveness (i.e. percentage of recalled consumer products actually collected);

f) Destruction or disposal of products collected.

The authorities use both traditional media channels as well as social media to inform consumers with respect to recalls.

No code of good practice on product recalls or any other type of information documents such as guidelines on recalls have been established in Bulgaria.

Monitoring of effectiveness of product recalls by market surveillance authorities

Some of the authorities stated they monitor the effectiveness of all product recalls, while some stated that they monitor only the mandatory ones.

For the purposes of monitoring the effectiveness of recalls, the authorities collect information about recall results in terms of the absolute number of products collected, recall results in terms of the percentage of recalled products that are actually collected, spot-checks in shops (regarding withdrawal of product), and about the awareness of consumers with respect to the recall.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Bulgaria that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

No comprehensive statistical data concerning dangerous products and related consumer complaints and injuries is available in Bulgaria. No separate database on consumer complaints related to product safety is maintained, nor is there a systematic collection of injury data (injuries caused by the use of consumer products).

The annual reports of some of the surveillance authorities, such as the Commission for Consumer Protection,

[109] For instance, in 2016 the CCP issued 32 such orders for 45 types of goods; in 2017 – 50 orders for 69 goods; in 2018 – 35 orders for 62 goods - The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]

contain information about the number of conducted inspections and categories and the number of dangerous products found[110], however no centralised database is maintained with statistical information about all the dangerous consumer products found on the Bulgarian market, and related consumer complaints and injuries.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Bulgaria (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The following practical problems or impediments to effective market surveillance of consumer products were identified:

1) Lack of expertise in new technologies;
2) Lack of expertise in online market surveillance;
3) Lack of financial resources for testing of consumer products;
4) Problems in taking effective action when the responsible economic operator is outside the EU/EEA;
5) Problems in controlling products from non-EU/EEA-countries directly reaching consumers;
6) Lack of suitable product testing laboratories;
7) Impediments related to the lack of financial/staff resources;
8) Legal impediments to effective surveillance online.

When it comes to impediments to using RAPEX, the authorities identified the following:

1) Insufficient human or financial resources for RAPEX;
2) Difficulties with risk assessment;
3) Lack of information from other national authorities in Bulgaria for notification to RAPEX;
4) Lack of information from national authorities in other countries;
5) Lack of information from businesses;
6) Lack of sufficient information to trace notified products.

Despite the above impediments, the authorities have a positive view of the functioning of RAPEX, considering it to function 'very well' or 'rather well' with respect to the needs of Bulgaria.

Conversely, the effectiveness of product recalls in Bulgaria is assessed to be moderate and dependent on the business operator[111].

Areas to make market surveillance of consumer products in Bulgaria/the EU more effective

Not all authorities expressed an opinion on this matter. Some only briefly stated that there is a room for improvement of RAPEX, yet without specifying in what aspects; others gave some practical recommendations, for instance increasing the limit of the size of documents uploaded to RAPEX platform.

Some of the authorities made more general recommendations about the possible areas in which market surveillance of consumer products in Bulgaria as well as within the EU can be made more effective, namely with respect to the online sale of goods, through e-platforms, and sale of goods from non-EU/EEA-countries outside the EU.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

[110] For instance, The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019]

[111] For instance the annual reports of the CCP do not list many cases of recall – see The Annual Reports of the Commission for Consumer Protection for 2016, 2017 and 2018 - https://kzp.bg/godishni-dokladi [retrieved on 20.10.2019

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Bulgaria since 2013

Overall there appears to be a positive trend toward improving the safety of consumer products in Bulgaria since 2013.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Bulgaria whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc.)

The relevant authorities almost unanimously stated that there are not enough and not sufficient tools and resources to tackle the new challenges on the market related to e-commerce, the platform economy and new technologies. This is partially due to the fact that the current legislation is not sufficient or adequate to deal with these new challenges. Some authorities also raised issues related to the insufficient budget for testing tools. In their opinion, any help (including from the EU) with regard to developing technological approaches and tools in their market surveillance activities (e.g. data collection and mining of social media to identify safety issues with products, a web crawler to identify new products) would be very welcome.

Views of market surveillance authorities whether approaches in Bulgaria can be considered best practice implementation of the GPSD, which could be of interest to other countries

None of the available evidence suggests that certain market surveillance approaches of the Bulgarian authorities can be considered best practices which could be of interest to other countries. Nevertheless, for instance, the Coordination Council, as a forum of all relevant surveillance bodies for meetings, strategy discussions and decision-making, can be shown as a good example of efficient implementation of the GPSD, which could be useful for other Member States as well, especially for those with the same market surveillance model as Bulgaria (i.e. without a single body designated to carry out market surveillance).

Annex: Ministry of Economy/Commission for Consumer Protection

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*69*	*69*
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*69*	*69*
Total (country)	*n.a.*	***69***	***69***
Of which staff allocated to market surveillance activities regarding products sold online	*n.a.*	*Inspectors are not working exclusively on safety of products online*	*Inspectors are not working exclusively on safety of products online*
Notes:	*Data for 2019*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc.)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*n.a.*	**4624 inspections**	**4624**
Total number of consumer products inspected	*n.a.*	*n.a.*	*n.a.*
Total number of consumer products	*n.a.*	28	28

tested in laboratories			
Total number of consumer products inspected in cooperation with the customs	*n.a.*	27 348 243 (items)	27 348 243 (items)
Total number of dangerous consumer products found	*n.a.*	124 types of products	124 types of products
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	*n.a.*	8 products from 2 types of products - childcare articles	8 products from 2 types of products - childcare articles
Notes:	*Data for 2018*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc.)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*n.a.*	1 type of product - bicycle	1 type of product - bicycle
Total number of mandatory recalls	*n.a.*	3486 (items from 124 types of goods)	3486
Notes:	*Data for 2018.*		

Annex: State Agency for Metrological and Technical Surveillance

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*65*	*n.a.*	*n.a.*
Total (country)	***65***	*n.a.*	*n.a.*
Of which staff allocated to market surveillance activities regarding products sold online	*n.a.*	*Inspectors are not working exclusively on safety of products online*	*Inspectors are not working exclusively on safety of products online*
Notes:	*Data for 2019*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc.)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*7286*	*n.a.*	*n.a.*
Total number of consumer products inspected	*7286*	*n.a.*	*n.a.*
Total number of consumer products tested in laboratories	*76*	*n.a.*	*n.a.*

Total number of consumer products inspected in cooperation with the customs	*1121*	*n.a.*	*n.a.*
Total number of dangerous consumer products found	*8*	*n.a.*	*n.a.*
Notes:	*Data for 2018*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc.)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*(127)**	*n.a.*	*n.a.*
Total number of mandatory recalls	*(219)**	*n.a.*	*n.a.*
Notes:	*Data for 2018. *Number of withdrawal of goods*		

Annex: Ministry of Health

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*n.a.*	*28 Regional Health Inspectorate*
Notes:	*Data for 2019*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc.)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*n.a.*	*n.a.*	**19222**
Total number of consumer products tested in laboratories	*n.a.*	*n.a.*	10290
Notes:	*Data for 2018*		

C. Number of recalls of consumer goods (last available year)

n.a.

D. Key sources

Legislation	The Consumer Protection Act Promulgated in the State Gazette 99/9.12.2005, last amendment- the State Gazette 45/7.06.2019. Ordinance on the conditions and procedure for withdrawal from the market, seizure by consumers and destruction of dangerous goods and the procedure for compensation of

	consumers in the case of seizure of dangerous goods [Наредба за условията и реда за изтегляне от пазара, изземване от потребителите и унищожаване на опасни стоки и за реда за обезщетяване на потребителите в случаите на изземване на опасни стоки]. In force since 10.06.2006, Adopted with Decree of Council of Ministers № 130/ 02.06.2006, promulgated in the State Gazette 48/13.06.2006, last amendment – the State Gazette 40/2.06.2015. Ordinance on essential requirements and conformity assessment of toys [Наредба за съществените изисквания и оценяване съответствието на играчките]. Promulgated in the State Gazette 99/17.12.2010, in force since 20.07.2011. Ordinance on goods imitating food [Наредба за стоките, имитиращи храни]. In force since 10.06.2006, adopted with Decree of Council of Ministers № 6/ 13.01.2006, promulgated in the State Gazette 7/24.01.2006, last amendment – the State Gazette 11/3.02.2006. Ordinance No. 1 of January 12, 2009 On the Terms and Conditions for the Construction and Safety of Playgrounds [Наредба № 1 от 12 януари 2009 г. За условията и реда за устройството и безопасността на площадките за игра]. In force since 7.05.2009, adopted by the Minister of Regional Development and Public Works, the Minister of Interior and the Director of the State Agency of Child Protection. Promulgated in the State Gazette 10/6.02.2009, last amendment – the State Gazette 84/25.10.2019. Decree of the Council of Ministers No. 180 of 1 August 2005 on the Establishment of a Coordination Council and the Exchange of Information between Authorities Controlling Market of Goods [Постановление № 180 От 1 Август 2005 Г. за създаване на Съвет за координация и обмен на информация между органите, осъществяващи контрол на пазара на стоки]. Promulgated in the State Gazette 65/9.08.2005, last amendment – the State Gazette 40/2.06.2015.
Studies/reports/articles	Големинов, Чудомир [Goleminov, Tchudomir] Правна защита на потребителите [Consumer Protection] 2001 Колева, Рая [Koleva, Raya] „Основните права на потребителите – теоретични и практически въпроси“, сп. „Търговско право“, 2009/2 и 3 [“Rights of consumers – theoretical and practical aspects”, in “Commercial Law”, 2009/2,3] Сукарева, Златка [Sukareva, Zlatka] Гражданскоправна защита на потребителя [Consumer Protection] 2001, Fenea Давидкова, Десислава [Davidkova, Desislava] Сборник коментари по прилагане на потребителското законодателство в България [Comments on application of Consumer Prorection Law in Bulgaria], 2006 Комисия за защита на потребителите [Commission for Consumer Protection] - Годишни доклади [Annual Reports] – 2016, 2017, 2018, Retrieved on 20.10.2018 from https://kzp.bg/godishni-dokladi The Annual Reports of the Agency Customs retrieved on 20.10.2019 from https://customs.bg/wps/portal/agency/about-us/agency-in-codes-and-facts
Websites	https://kzp.bg/ https://customs.bg/wps/portal/agency/home https://mi.government.bg/bg https://www.damtn.government.bg/en/ https://www.moew.government.bg/en/ http://www.babh.government.bg/en/
Interviews	Ministry of Economy Commission for Consumer Protection State Agency for Metrological and Technical Surveillance Ministry of Health Republic of Bulgaria Ministry of Environment and Water Bulgarian Food Safety Agency (Ministry of Agriculture, Food and Forestry) National Customs Agency

4. Croatia

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Croatia, the GPSD (as well as the Directive (87/357/EEC)) is transposed through the General Product Safety Act (Official Gazette 30/09, 139/10, 14/14, 32/19) (hereinafter: GPSA). Also, the relevant implementation legislation includes:

Regulation on the system of rapid exchange of official information on products which pose a risk for the health and safety of consumers (RAPEX) (Official Gazette 5/11, 120/14, 39/19).

A list of Croatian standards in the field of general product safety (Official Gazette 101/18).

Decree on notifications on products dangerous for consumers (Official Gazette 55/10, 90/10, 109/14, 23/19).

Order on placing lighters safe for children on the market and the prohibition of placing lighters "Noviteta" on the market (Official Gazette 19/11, 54/11, 40/12, 58/13, 57/14).

Order on prohibition of placing on the market products containing biocide dimetil-fumarat (Official Gazette 19/11 i 40/12).

Order on placing cigarettes on the market (Official Gazette 13/13).

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Croatia

In Croatian legislation Art 5(1) GPSD is implemented in such a manner in Article 7 GPSA that the labelling requirement is transposed without qualifying it as an "example". In accordance with Article 7 GPSA in Croatian legal system traceability requirements are binding requirements. Hence, the GPSA imposes obligations upon the producer in excess of what was intended by the GPSD.

According to market surveillance authorities, traceability requirements for non-harmonised consumer products and for those harmonised products for which EU legislation does not provide specific traceability requirements, in Croatian legislation include a general requirement: a) to indicate the name and contact details of the producer on the product or its packaging; b) to indicate the product reference or, where applicable, the batch of products to which it belongs on the product or its packaging; c) to use a barcode or other machine readable identification on the product or its packaging.

Although some market surveillance authorities are unaware of any practical problems with respect to the application of Art 5(1) GPSD, others mention problems with traceability of products imported from the People's Republic of China.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies. In Croatia, Art 4(2) GPSA applies, which literally transposes Art 2 (b) GPSD.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The national implementation legislation of the GPSD does not cover emerging threats related to new technologies (e.g. cyber security/software related threats), but there are discussions on the necessity for the introduction of rules covering emerging threats related to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

If European standards referenced in the EU Official Journal do not exist, according to the national legislation (Art 5(4) GPSA),the safety of a product is assessed in line with:

a) the voluntary national standards transposing relevant European standards other than those referred to Art 3 (3) GPSA;

(b) other standards drawn up in Croatia;

(c) Commission recommendations setting guidelines on product safety assessment;

(d) product safety codes of good practice in force in the sector concerned;

(e) the state of the art and technology;

(f) reasonable consumer expectations concerning safety.

However, most of the market surveillance authorities consider Croatian national standards (which are not based on European standards (under b)) to be used most frequently for assessing the safety of a product in such cases.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Croatia in case there are consumer product(s) on the market which are found unsafe under the GPSD

In case there are consumer product(s) which are found unsafe, market surveillance authorities in Croatia agree that they can require businesses to provide relevant information on the product(s) and on the supply chain and the distribution of the product(s). Also, they can carry out unannounced on-site inspections and physical checks of products and require from economic operators recalls of products and other corrective measures.

Some authorities also mention the possibility to require businesses to provide relevant information to ascertain the ownership of websites, where relevant. Others indicate that they can reclaim from the relevant economic operator the costs of the administrative activities with respect to the unsafe product(s).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Penalties foreseen under Art 7 GPSD are provided under Art 14 (1)Croatian GPSA:

A monetary penalty in the amount of 50 000 – 250 000 HRK (approx. 6 714 to 33 573 EUR) for the legal person which:

- Contrary to Art 5 (1) GPSA places unsafe products in the market;

- Contrary to Art 5 (5) GPSA manufactures, imports, exports, markets and places on the market a dangerous product or a dangerous imitation;

- Contrary to Art 7 GPSA does not inform consumers or other users appropriately, does not take appropriate actions in order for them to avoid the danger, does not safeguard documents relevant for tracking the origin of the product and does not cooperate with the competent authority under Art 11 GPSA;

- Contrary to Art 11 GPSA does not act according to the enforceable decisions of the competent authority.

Market surveillance authorities have no data on the application in practice.

Recent case law in Croatia with respect to or relevant for the GPSD/the national implementation legislation.

No case law available.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Croatia concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Market surveillance authorities in Croatia only mention problems concerning traceability of products from the People's Republic of China.

Possible improvements to make the implementation of the GPSD in Croatia more effective

Overall, it seems that there is a significant legal fragmentation of Croatian legislation on consumer protection which undermines its successful implementation. In the field of product safety, such fragmentation is visible insofar as

there are several legal acts regulating the matter (General Product Safety Act, General Use Items Act etc.). At the same time, there are relevant provisions on consumer protection in the Consumer Protection Act, Obligations Act and other acts. For example, Article 1074 Obligations Act defines a "product" (in line with Directive 1999/34/EC) as any movable good/object, even if it is imbedded in another movable good/object or immovable good/object. In Article 5/p. 20 Consumer Protection Act a "product" is every good or service, including immovable properties, rights and obligations. According to Article 4 General Product Safety Act a "product" is any product, including a service, in terms of a product intended for consumer use, that is, which might be used by consumers under reasonably predictable conditions, even if it is not intended for their use, which is delivered or available, for payment or free within a commercial activity, regardless if it is new, used or processed.[112]

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Croatia.

In Croatia, market surveillance in individual product sectors is organised at the national and sub-national level.

It is undertaken by different inspection bodies established within the ministries and the central administration authorities according to the area of their competence provided under the Act on the Organisation and Competences of Ministries and Other Central State Administrative Bodies (Official Gazette 93/16, 104/16, 116/18).

Market surveillance is predominantly under the competence of the Market Inspection (part of the State Inspectorate which was recently re-established under State Inspectorate Act (Official Gazette 115/18)).

The Market Inspection section conducts inspection and other activities related to the application of legislation in the field of consumer protection, including public services which are calculated and charged to consumers; inspection of technical and security requirements for products placed on the market; the process of establishing compliance with the prescribed requirements; documents required for products placed on the market; labelling and presentation of products.

The Market Inspection section consists of the Service for the protection of economic interests of the consumer and the Service for product safety.

Other inspection authorities (sanitary inspection, veterinary inspection, agricultural inspection, hunt inspection, forest inspection, etc.)also participate in market surveillance according to their competence in specific sectors:

- Ministry of Health-Medical products, etc.;
- Croatian Regulatory Authority for Network Industries (HAKOM)-Radio and telecommunications equipment sector;
- The Ministry of the Sea, Transport and Infrastructure-Marine equipment, recreational craft and cableway safety sectors;
- The Ministry of the Interior-Pyrotechnics, explosives for civil use, equipment and protective systems intended for use in potentially explosive atmospheres;
- The State Office for Metrology-Measuring instruments, non-automatic weighing instruments, pre-packaged products and measurement units;
- The Ministry of Agriculture-Mineral fertilisers sector.

(For more information please see the National Market Surveillance Programme 2019 Republic of Croatia).

Plans/programmes in place which define priorities for market surveillance of consumer products

There is a National Market Surveillance Programme in the Republic of Croatia which defines priorities for the market surveillance of consumer products.

The National programme for consumer protection for the period 2017-2020 (Official Gazette 20/18; hereinafter:

[112] Mišćenić, Mrak, p. 149.

National programme 2017-2020) also defines the further development of product safety policy in Croatia as one of its specific goals. The development of the internet and growing popularity of online shopping requires the introduction of measures which will contribute to the safety of products sold online. One of the measures proposed in the National programme 2017-2020 is conducting market surveillance in order to introduce a trust mark for online traders, important for gaining more consumer confidence and improving the quality of services provided by traders. Also, due to a large amount of food products sold online, specialisation of a certain number of inspectors for surveillance in that field is suggested.

Priorities for market surveillance of consumer products in Croatia are set on the basis of inspection results, RAPEX notifications, consumer complaints, customs information, information provided by businesses/business associations and information provided by consumer organisations.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Croatia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products*?*

Market surveillance activities in Croatia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices) are not conducted.

Market surveillance of products sold online is conducted only in cases where economic operators are established and they keep traditional shops as well, so that in a case of sampling, a sample of the product can be taken on the premises of the economic operator concerned. The frequency of such market surveillance activities depends on the frequency of inspections in traditional shops.

Further activities regarding education and specialisation of inspectors for online trade are planned and they are expected to enhance the efficiency of surveillance. Also, regarding the extension of the scope of competence of the national inspection authorities, the possibility to block the website of the traders in cases of repeated violations of consumer rights in cross-border trade is suggested. From 1 January 2020 the State Inspectorate will have additional competences related to Inspection of products sold online.[113]

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance activities that focus on products sold online only cover retailer websites.

In cases where the Croatian authority participates in joint cross-border actions and the sampling of products sold online is required, the Market Inspection organises market surveillance of the economic operator who is selling the product both in the traditional way and online.

The Market Inspection does not conduct mystery shopping activities.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Croatia (except customs) with respect to product safety

Cooperation between the relevant Croatian authorities with respect to product safety takes place at least once a year, depending how frequently the cooperation is needed, through RAPEX, ICSMS, through formal agreements, inclusion of other authorities in preparing national market surveillance plan/programme, regular meetings, and informal cooperation. Cooperation with other relevant authorities located in EU/EEA countries takes place once a week, by means of RAPEX, ICSMS, the Wiki confluence platform and coordinated actions on the safety of products organised at the EU level. Although the market surveillance authorities are not certain of the frequency of cooperation with other relevant authorities located in non-EU/EEA countries, they mention cooperation through mutual assistance requests made/received and informal cooperation.

Cooperation with customs authorities in Croatia with respect to product safety

[113] See https://dirh.gov.hr/vijesti/trgovina-buducnosti-digitalno-doba-trgovine/83

The Market Inspection is authorised to provide continuous surveillance of the products imported to Croatia (product checks at import for the purpose of placing on the European Union market in accordance with Articles 27–29 of Regulation (EC) No 765/2008) in cooperation with the Ministry of Finance – the General Administration of Customs. If the surveillance reveals that a product poses a serious risk for the health and safety of consumers, the Market Inspection is authorised to take measures to prohibit the placement of the product on the market.

More specifically, if the Customs Administration decides to suspend the release of a product for free circulation on the EU market based on the check of the product's characteristics, it notifies the relevant market surveillance authority accordingly. The market surveillance authority performs an inspection within three working days of the suspension and, depending on its findings, takes appropriate measures which may include prohibiting the product from being placed on the market in case of a serious risk or non-conformity or, alternatively, if it finds that the product does not present a risk to human health or the environment, and that it complies with the applicable legislation, the Customs Administration releases the product for free circulation.

With regard to the control of products entering the EU market and with a view to achieving a higher level of safety of the products placed on the market, the Croatian Customs Administration and the market surveillance authorities have established cooperation in product sectors which fall within the competence of the specific inspection authorities.

Croatian market surveillance authorities cooperate with customs once a month, usually when the authority receives a notification from the customs authorities. In order to safeguard control of product safety at the borders, a common strategy for product safety enforcement is applied, joint processes for dealing with dangerous products are initiated, a regular exchange of information is conducted and means of informal cooperation are also applied.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

In cross-border cases, when the market surveillance authorities identify a dangerous product, they always communicate with the economic operator established in Croatia regarding their responsibilities. Where the economic operator responsible for placing the product on the EU market is located in another EU Member State, they use ICSMS to request assistance from the competent authority in the other Member State and the RAPEX system to inform the European Commission and other EU Member States. In cases where the authority is situated in non-EU/EEA country the cooperation functions through mutual assistance requests made/received. Also, this cooperation is enhanced through study visits or TAIEX.

The Croatian Market Inspection also participates in the implementation of projects aimed at incorporating best practices and improving the surveillance of the market. In 2015, the Market Inspection joined the PROSAFE JA2014 project (co-financed by the European Commission). Market inspectors participated in the surveillance of baby equipment (protective fences), LED and CFL lamps and electronic tools, risk assessments and e-learning.

Along with 13 Member States and Turkey, the Croatian Market Inspection participated in the PROSAFE MSTyr15 project (from 2016 to 2018), which was aimed at efficient application of regulation on labelling of automobile tires. The enhanced surveillance should contribute to the removal of incorrectly labelled automobile tires and the saving of at least 105 GWh/per year on the Market.

Some authorities also mention that they cannot take actions against an economic operator that is not based in Croatia.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

While other market surveillance authorities cannot provide an estimate, according to the RAPEX contact point, the average duration between the detection of the dangerous product and its notification to RAPEX depends on the product, the risks and the testing. The Sanitary Inspection at the Ministry of Health and the State Inspectorate estimate the duration between the detection of a dangerous product and its notification to RAPEX to be more than two weeks (14 days).

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

While the Market Inspection does not cooperate with business associations or businesses, other market

surveillance authorities (including the Safety Gate contact point –RAPEX) cooperate with business associations and businesses as appropriate. The cooperation consists of a regular exchange of information with business organisations, providing advice to businesses where needed and providing information and explanations regarding inspections of specific products (within the scope of their authority) in cases where such explanation is necessary.

Croatian Chamber of Economy (for the period 2017-2020) continuously undertook (and still undertakes) activities which raise the awareness of businesses and consumers in the field of product safety, in cooperation with the market surveillance authorities.

In order to enhance the level of consumer protection and provide safety in the market, a meeting was held on 22 July 2019 between the representatives of the State Inspectorate (under which the Market Inspection operates) and the Croatian Chamber of Economy under the working title "Businesses and the State Inspectorate - for the partnership"(Poduzetnicii Državniinspektoratzapartnerskiodnos), where the future cooperation between the re-established State Inspectorate and the business associations/businesses was discussed.[114] The importance of adequate education and regular provision of information to businesses on product safety, efficient and transparent work of the Market Inspection, and replacement of restrictive measures with preventive measures was highlighted. Overall, a foundation for an intense cooperation between businesses and State Inspectorate was laid.

The Market Inspection does not cooperate with consumer organisations. Other market surveillance authorities (including the Safety Gate contact point – RAPEX) cooperate with consumer organisations at least a few times a year, as appropriate. There is regular activity and meetings within the National Council for consumer protection, where both market surveillance authorities and consumer organisations participate.

Hence, the cooperation mostly consists of joint activities to create awareness for product safety among consumers and regular meetings.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Activities of the Market Inspection (and the State Inspectorate) related to informing and awareness raising of consumers with respect to product safety includes the posting of information on the portal with RAPEX notifications translated into national language(s) (where the consumers may also find a link to the EU RAPEX website on the official website).[115]

On the same page, there is information on the obligation of businesses (according to the Ordinance on the notifications on the product dangerous for consumers (Official Gazette 55/10, 90/10, 109/14)) to deliver notifications on dangerous products placed on the market.

There is also information that businesses have the possibility to provide notifications on dangerous products placed on the market through the Product Safety Business Alert Gateway application.[116]

The same information and links are posted at the Central Consumer Portal, which provides all relevant information to consumers in Croatia and covers consumer-related topics. It is established and maintained by the Ministry of Economy (MINGO).[117] In relation to product safety, there is also a link to the preliminary results of the PROSAFE JA2016 project.[118]

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Croatia (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

According to the Market Inspection, in Croatia, businesses are asked to conduct voluntary and mandatory recalls and other corrective measures, if needed. Businesses and the market surveillance authority, according to some authorities, agree on the information channels to inform consumers on a recall. Recalls and other measures are

[114] See https://dirh.gov.hr/vijesti/poduzetnici-i-drzavni-inspektorat-za-partnerski-odnos/82
[115] Available at http://potrosac.mingo.hr/hr/rapex/opasni-proizvodi.php
[116] Available athttps://webgate.ec.europa.eu/gpsd/
[117] Available athttps://www.szp.hr/sve-potrosacke-teme-na-jednom-mjestu/rapex-sustav-brzog-uzbunjivanja-za-opasne-neprehrambene-proizvode/175
[118] Available athttps://www.szp.hr/UserDocsImages/dokumenti/ZAJEDNIČKA%20AKCIJA%20JA2016.pdf

organised by the authorities if no responsible business operator can be found.

Businesses have a main role and are required to use all their available customer information for recalls and other corrective measures (including from customer databases, loyalty card information, etc.). If there is a specific recall of a product, the Market Inspection checks and influences the recall strategy of the business. In case of a recall, the Market Inspection requires information on the activities targeted at consumers, a list of other businesses involved in the supply chain (e.g. distributors, online marketplaces), the timeline of the recall process, recall effectiveness (i.e. percentage of the consumer products actually collected), and the destruction/disposal of products collected. The role of the Market Inspection in communicating information on a recall to consumers is to provide information to consumers through a public recall database. Other market surveillance authorities in Croatia carry out their role in providing information to consumers through authority websites where the information on dangerous products are published.

Monitoring of effectiveness of product recalls by market surveillance authorities

Market surveillance authorities monitor the effectiveness of product recalls by monitoring recall results in terms of the absolute number of products collected.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Croatia that is relevant for market surveillance (e.g. concerning dangerous products*, related consumer complaints and injuries)*

Neither relevant statistics for the period 2018-2019 nor a detailed description of the approach for the use of the collected data have been provided. The Market Inspection only confirmed that the statistics relevant for market surveillance are collected through a national market surveillance system that also registers relevant complaints by consumers.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Croatia (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Market surveillance authorities confirm that there are practical problems and impediments to effective market surveillance of consumer products in Croatia.

There are limited staff resources for market surveillance; a lack of expertise in new technologies; a lack of expertise in online market surveillance; a lack of financial resources for testing of consumer products; unclear distribution of competences for market surveillance at the national level; a lack of suitable product testing laboratories; a lack of awareness of businesses with respect to product safety requirements; a lack of cooperation of online actors; and problems in controlling products from non-EU/EEA-countries that reach consumers directly. This is also evident from the Report on the implementation of the national programme for consumer protection in the period 2013-2016. According to the Report, the market surveillance of product safety in 2014 was conducted through administrative measures (checks of the required documentation and labelling of the products) while the planned surveillance through sampling and product testing in laboratories was not conducted as the financial resources were not available.

With regards to effective surveillance online, there are legal impediments (lack of the relevant legal framework) and the already mentioned impediments related to the lack of financial and staff resources.

As a contribution to resolving these practical problems and impediments, market surveillance authorities suggest the introduction of measures for better cross-border cooperation, more education to enhance expertise in online market surveillance, and more suitable product testing laboratories.

Market surveillance authorities consider RAPEX to be well or even very well-functioning in Croatia. However, there have been some impediments which are caused by insufficient human or financial resources for RAPEX, a lack of information from other national authorities in Croatia for notification to RAPEX, a lack of information to businesses, and a lack of sufficient information to trace notified products.

While the Market Inspection and Sanitary Inspection consider product recalls to be moderately effective, according to the RAPEX contact point they are rather effective. The RAPEX contact point thereby highlights the effectiveness of the voluntary recalls.

Areas to make market surveillance of consumer products in Croatia/the EU more effective

Market surveillance of consumer products in Croatia, according to the Sanitary Inspection, could be more effective in the area of online (internet) sales.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Croatia since 2013

Market surveillance authorities confirm that the general trend is positive and that safety has improved. The trend depends on the product type or sales channel.

The efficiency of the inspection system of the market surveillance authorities is based on the findings of past inspections, both planned and *ad hoc*. Data on the inspections performed and the measures imposed are maintained as official records. Individual market surveillance authorities manage these data through electronic applications and use it to evaluate the efficiency of past inspections and plan ahead.

According to the State Inspectorate, in their section, since 2017 when there were breaches found in 70 % of inspected cases, now this percentage is lowered to approx. 40 % breaches found in all of the inspected cases.

According to the Digital Scoreboard, in 2016, over 82.2 % Croatian online consumers had no difficulties with their online purchases. Compared to the EU Member State average of 68 %, it is evident that the Croatian score is among the highest in the EU.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Croatia whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Market surveillance authorities in Croatia did not provide an answer to this question.

Views of market surveillance authorities whether approaches in Croatia can be considered best practice implementation of the GPSD, which could be of interest to other countries

Although the following example might not be considered as best practice, it is an interesting approach to resolving a significant issue of product safety. Namely, in Croatia, on average there were approximately 3 650 injuries of children between age of 5 and 12 at playgrounds (data for 2016), including light to heavy injuries which cause serious damage to children's health (long medical treatments and rehabilitation, permanent disability) and sometimes even death. Hence, the safety of products in children's playgrounds became one of the priorities in this area. There was a comprehensive analysis of the legal framework and factual state in regards to product safety which resulted in a Guideline on safety at children's playgrounds.[119]

The Guideline includes an overview of the legal framework and relevant norms as well as answers to questions of responsibility of legal and natural persons in maintaining safety standards in the building, servicing and supervising of children's playgrounds. There are also examples from court practice and case descriptions of the most common injuries and guidance on how to avoid them (for engineers constructing the playground, manufacturers, contractors, playground owners and other persons responsible for the safety of the playground).

This Guideline is an important contribution to enhancing product safety for children.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

[119] Published at: www.mingo.hr/page/kategoriia/e-publikaciie.

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total**(all consumer products)
Responsible authority/ies at the national level	*8 authorities*	*1 authority*	*9 authorities*
Responsible authorities at the sub-national level (regional/provincial/local)	*There are regional offices for every authority:* ***Sanitary inspection** (7 regional offices)* ***Market inspection** (4 regional offices)* ***Agricultural inspection**(20 regional offices)* ***Maritime Inspection*** ***HAKOM**/*Croatian Regulatory Authority for Network Industries (No regional offices) ***HALMED**/Croatian Pharmaceuticals and Medical Devices Agency* (No regional offices) ***Metrological Inspection*** ***Inspection of Production and Trade in Explosive Substances***	*4 regional offices (Zagreb, Rijeka, Split, Osijek)*	*(25 regional offices)*
Total (country)	***8 authorities***	***1 authority (with 4 regional offices/they are not separate authorities)***	***9 authorities (25 regional offices)***
Notes:	*This is the relevant data for 2019* *There are approx. 100-110 inspectors within the Market Inspection (part of the State Inspectorate).* *There are 17 Inspections (for different areas) in the State Inspectorate and an additional 23 Inspections within different Ministries.* *Regional offices regularly operate under the competent authority (and as such are not separate authorities). All of the collected data include the data collected and processed by the regional offices as well.*		

B. Number of <u>inspections</u> of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	2254	n.a.	n.a.
Total number of consumer products inspected	2295	n.a.	4475 products*

Total number of consumer products tested in laboratories	Toys: 45 products Cosmetics: 40 products	15 products*	115[120]/ 235 products according to another body
Total number of consumer products inspected in cooperation with the customs	Toys[121]: 989 inspections Cosmetics:1225 inspections	n.a.	10 products*
Total number of dangerous consumer products found	9	n.a.	47 notifications*
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	n.a.	n.a.	350 reactions*
Notes:	** Data available for 2018-2019a*[122]		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	173	22	195
Total number of mandatory recalls	10	18	28
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	n.a.	n.a.	n.a.
Notes:	*Data available for 2018-2019a*		

D. Key sources

Legislation	Directive 2001/95/EC, Official Journal L 11/4, 15/1/2002. General Product Safety Act (Official Gazette 30/09, 139/10, 14/14, 32/19) Regulation on the system of rapid exchange of official information on products which pose a risk for the health and safety of consumers (RAPEX) (Official Gazette 5/11, 120/14, 39/19). A list of Croatian standards in the field of general product safety (Official Gazette 101/18). Decree on notification on products dangerous for consumers (Official Gazette 55/10, 90/10, 109/14, 23/19). Order on placing lighters safe for children on the market and the prohibition of placing lighters "Noviteta" on the market (Official Gazette 19/11, 54/11, 40/12, 58/13, 57/14). Order on prohibition of placing on the market products containing biocide dimetil-fumarat (Official Gazette 19/11 i 40/12). Order on placing cigarettes on the market (Official Gazette 13/13). Additional legislation (toys): Zakon o predmetimaopćeuporabe/General Use Items Act (Official Gazette 39/13, 47/14). Pravilnik o sigurnostiigračaka (Official Gazette 83/14).

[120] 115 products according to the State Inspectorate and the Ministry of Health, 235 products according to a Senior Market Inspector.
[121] Data available for 2018
The table is not complete due to the fact that the competent bodies did not deliver additional dana. There was a change of competence of bodies in charge in 2019, and the State Inspectorate gained competence while prior to the change, the Inspection was under the competence of Ministry of Economy (MINGO). Although the Market Inspectorate regularly collected dana, the Ministry of Economy considered it unnecessary to participate in the Study.
[122] 2019a (first part of 2019, till July).

Studies/reports/articles	Nacionalni program zaštitepotrošačazarazdoblje od 2017. do 2020. godine (Official Gazette 20/2018) (1.3.2018.) Nacionalni program zaštitepotrošačazarazdoblje od 2013. do 2016. (Official Gazette 90/13) National Market Surveillance Programme Croatia, Zagreb, 2019. Retrieved on 1.10.2019, from: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation_en T. Josipović, „Enforcement Activity in Consumer Protection Regulation in Croatia“, Journal of Consumer Policy, br. 36, 2013, 287. E. Mišćenić, „Croatian Consumer Protection Law: From Legal Approximation to Legal Fragmentation“, StudiaIuridicaToruniensia, vol. 21 i 22, 2018. E. Mišćenić; I. Mrak, Zaštitapotrošačaodproizvodadvojnekvalitete, Harmonius, 2018, p. 148-150.
Websites	www.enterwebsitehere.com https://dirh.gov.hr/ https://zdravlje.gov.hr/djelokrug/uprava-za-unaprjedjenje-zdravlja-710/predmeti-opce-uporabe-i-zastitu-od-buke/igracke/rapex-sustav/958 http://potrosac.mingo.hr/hr/potrosac/lista.php?id=10272 http://www.glas-slavonije.hr/406606/1/Primljeno-gotovo-dvije-i-pol-tisuce-zalbi-potrosaca-na-razne-proizvode https://www.tportal.hr/biznis/clanak/drzavni-inspektorat-nece-bit-represivno-tijelo-vec-tijelo-koje-upozorava-20190528 https://dirh.gov.hr/vijesti/poduzetnici-i-drzavni-inspektorat-za-partnerski-odnos/82 https://dirh.gov.hr/vijesti/trgovina-buducnosti-digitalno-doba-trgovine/83
Interviews	Državni inspektorat/State Inspectorate of the Republic of Croatia Tržišna inspekcija/Market Inspectorate RAPEX/ Safety Gate Contact Point Ministarstvo Zdravstva/Ministry of Health Državni inspektorat/State Inspectorate

5. Cyprus

COUNTRY REPORT CYPRUS

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The GPSD has been transposed into the Cypriot legal order through the General Product Safety Law of 2004, Law 41(I)/2004 (the basic law). Since its inception, it has been amended twice, namely in 2009 and 2010. The basic law, along with the two amending laws, are together called the General Product Safety Laws of 2004-2010.

The first amending law, namely the General Product Safety (Amending) Law of 2009, Law 85(I)/2009, was passed in order for Cyprus to comply with EU Regulation amending Regulation (EC) No 1207/2001 on procedures to facilitate the issue or the making out in the Community of proofs of origin and the issue of certain approved exporter authorisations under the provisions governing preferential trade between the European Community and certain countries.[123]

The second amending law, namely the General Product Safety (Amending) Law of 2010, Law 22(I)/2010, is a longer text, but the main amendments were as follows. First, said amending law inserted the following new provision in the basic law as Section 45A: "The Minister issues Orders which are published in the Official Gazette of the Republic, for the implementation of the Decisions which are issued under Article 13 of the Directive 2001/95/EC" (free translation from Greek text). The second main amendment is closely related to the first as it again concerns the Decisions issued under Article 13 GPSD.[124]

The national implementation law transposes the Directive by copying its substantive provisions, and therefore, it does not expand upon said provisions or add any significant detail to them. The main differences between the two legislative texts are to be noticed in the several additional provisions in the Cypriot law which respond to Articles 6(3) and 7 of the GPSD, thereby laying down the duties and powers of the competent authorities as well as the sanctions in case of a breach of the substantive obligations laid down by the law.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Cyprus

Article 5 GPSD is transposed largely verbatim by Section 7 of the Cypriot Law. The traceability requirement is applied via general requirements for businesses to indicate the identity and contact details of the producer as well as the product reference or batch on the product. These requirements are not *explicitly* provided for "by way of example", as it is the case with Article 5(1) GPSD but are not *explicitly* made mandatory or requirements either. More specifically, the corresponding Section 7(3) of the Cypriot Law states that said requirements are included in the traceability measures that must be adopted by producers but the provision seems to suggest that traceability can be achieved in alternative ways. The exact wording is the following: "The measures referred to in sub-section

[123] More specifically, it amended Section 12 of the basic law by replacing Section 12(4) with the following new provision: "In the case of products entailing a serious danger (or risk), the competent authority takes timely the suitable measures which are mentioned in paragraphs (b) – (f) of Section 11. The existence of a serious danger is determined by the competent authority, which assesses each case separately, taking into account the guidelines" (free translation from Greek text). This amendment in fact corrected a mistake in the basic law, which initially referred to the producers and distributors as the parties to take the measures mentioned in paragraphs (b) – (f) of Section 11, instead of the competent authority, as per the corresponding provision in the GPSD, namely Article 8(3). In other words, the said amending law brought the national implementation in line with the GPSD.

[124] More specifically, it has changed the title of Part V of the basic law, which up until that point read as "Information to the Commission", to "Information to the Commission and Implementation of the Decisions issued under Article 13 of the Directive 2001/95/EC". Moreover, Section 28(1) was replaced with the following: "The competent authority takes all necessary measures for the implementation of the Decisions issued under Article 13 of Directive 2001/95/EC, through Orders issued in accordance with Section 45A of the basic law", and Section 28(2) was replaced with the following: "Exports of dangerous products for which a Decision has been issued by the Commission as stated in paragraph (1) are prohibited, unless the Decision provides otherwise" (free translation from Greek text). Obviously, the 2010 amending law aimed at covering the implementation of the Decisions issued under Article 13 GPSD; all of the rest of its provisions concern linguistic amendments aiming at adjusting the provisions of the basic law to the Orders introduced by Section 45A and therefore do not concern the essence. It is worth noting that the Minister has issued one such Order (under Section 45A) to implement Commission Decision 2006/502/EC concerning the safety of lighters. No Regulations have been issued under the Cypriot transposition law so far.

(2) *include, among others*: (a) an indication, by means of the product or its packaging… ". It follows that though the CPS primarily requires and/or looks for the aforementioned requirements explicitly referred to in the Law, the CPS can accept alternative ways in which a producer may choose to comply with the traceability obligation, as long as such alternative ways achieve traceability indeed. The iCPS made no reference to any alternative ways of achieving traceability and most certainly, there are no specific requirements referring to particular approaches towards traceability, such as barcodes or electronic identification.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

No, there is no such definition of safety in the area of new technologies. Accordingly, the general definition and assessment benchmarks transposed almost literally in Sections 2 and 6 of the Cypriot Law respectively shall apply to products using new technologies as well.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The Cypriot transposition law does not, as previously indicated, essentially deviate from the provisions of the GPSD, and accordingly, it does not specifically provide for emerging threats related to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Assessment benchmarks are listed in Section 6(3), which transposes Article 3(3) GPSD verbatim. The only difference between the two provisions does not concern its essence, as it simply concerns the replacement of the words "national" or "member state" in Article 3(3) GPSD with the words "Cypriot" or "Cyprus". In practice, the benchmarks used for assessing the safety of a product are non-official European standards, international standards and Commission guidelines.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Cyprus in case there are consumer product(s) on the market which are found unsafe under the GPSD

These are the administrative measures listed in Section 11 of the Cypriot law, which transposes Article 8(1) GPSD almost literally. The only essential difference between the wording of the two provisions relates to Section 11(d) and (f) (transposing Article 8(1) (d) and (f) GPSD). More specifically, the Cypriot provision clarifies that said measures will be taken through the serving of the producer or the distributor with a notice of suspension or withdrawal in accordance with Section 19 of the Cypriot law. It arises from Section 19 that a notice of suspension requires the economic operator not to market the product without the consent of the competent authority (for a period which cannot exceed six months) while a notice of withdrawal requires the economic operator to withdraw the product from the market.

The competent authority mainly requires businesses to provide information on the product and the supply chain. It also carries out on-site inspections and physical checks and acquires product samples. Moreover, it requires recalls and withdrawals of products, though many such recalls and withdrawals are voluntarily effected by the economic operator who is in touch (and in collaboration) with the competent authority.

Section 20 of the law empowers the competent authority to apply to the court to seek an order authorising the confiscation of products, whether or not there is a pending criminal prosecution; however, this power does not seem to be exercised in practice. By virtue of Section 16 of the Law, the competent authority can also seek entry and search court orders, yet it seems that the exercise of these rather drastic powers are not common.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

These are criminal sanctions stated in Sections 29 and 30 of the Law. Section 29 criminalises the violation of the

obligations in Sections 5 and 7-9 of the law (transposing Articles 3(1), 5(1), 5(2), 5(3) and 5(4) GPSD). The sanctions are a maximum of two years imprisonment and/or a fine of a maximum of EUR 8 816[125]. Section 30 imposes the same criminal sanctions for the violation of any Regulations or Ministerial Orders issued under the law when these impose specific obligations or prohibitions regarding the circulation of a product in the market or the performance of a specific test, amongst others. As for whether they are applied in practice, the research for this study led to only one criminal prosecution, specifically for a violation of Sections 5 and 8(1) of the Law (namely *criminal case 13703/14*) in which the defendant producers and distributors were found guilty. Additional criminal sanctions are stated in Sections 31-33, which criminalise the failure to comply with a notice of suspension (Section 31), the failure to provide information or the provision of false information in the context of Section 11(a) (Section 32), and the hindrance of an authorised officer of the competent authority or of a customs officer when said officer acts in accordance with the Law (Section 33). In relation to Section 31, the sanctions are the same as those provided for in Sections 29 and 30. In relation to Sections 32 and 33, the criminal sanction is only a fine of a maximum of 3 527 euros.

Apart from criminal sanctions, administrative sanctions (in the form of administrative fines) are foreseen in Section 37 of the Law. These can be imposed regardless of any criminal liability or prosecution for a limited range of violations. More specifically, they can be imposed on the producer or distributor when they fail to provide the competent authority with the required documents or information concerning specific products, or when they hinder the said procedures or provide false or misleading information (Section 37(a)). They can also be imposed on any person who wilfully hinders an authorised officer of the competent authority or a customs officer who acts in accordance with the provisions of the Law (Section 37(b)). The administrative fine that can be imposed is a maximum of 3 400 euros. Administrative fines have so far been imposed in accordance with the aforementioned Section 37(a) only, specifically in six cases between 2015-2018 concerning laser light pointers, lighters and children's clothing. The fines imposed were 200 euros (case no. 2016/11), 500 euros (case no. 1ΓΑ/2015), 1 000 euros (case no. 2017/1), 1 000 euros (case no. 2016/09), 3 000 euros (case no. 2016/15) and 3 000 euros (case no. 2018/5). In the cases where the fine was higher (i.e., 1 000 and 3 000 euros), the economic operator had also had issues relating to product safety with the competent authority in the past.[126]

Recent case law in Cyprus with respect to or relevant for the GPSD/the national implementation legislation.

The research conducted returned three cases with respect to the GPSD and the national implementation in Cyprus. One of them is a criminal case and is the one also mentioned above, namely *Limassol Police Director v Nicolettos Textiles Industry Ltd and others, case no. 13703/14, 2/5/2017*. The defendants were found guilty for breach of Sections 5 (as producers) and 8(1) of the Law (as distributors) (transposing Articles 3(1) and 5(1) GPSD respectively) in relation to children's clothing which was found not to comply with the European Standard EN 14682:2007. In that case, the court found that the defendants were producers in relation to clothes they have imported into Cyprus from Egypt, a non-EU country, but not in relation to those imported from Greece. It also interpreted the term 'distributor' to cover the seller of a product. An interesting question arose as to whether the same party can be both a producer and a distributor in relation to the same product. This is what the court seems to have found in this case (as the court found the defendants guilty for a violation of Section 8(1) referring to distributors not only in relation to the clothing products for which they were not found to be producers, but also in relation to the clothing products from Egypt for which they were recognised as producers), despite the fact that the definitions of 'producer' and 'distributor' seem to be mutually exclusive. It is also worth noting that apart from the defendants 1 and 2 (a company and its director), who were found guilty, there was a third defendant, namely an employee of the company, who was acquitted (as not being a party which can be prosecuted under the Law).

The other two cases are administrative law cases. The first, namely *ANDREAS CHRYSOSTOMOU GENERAL TRADING LIMITED v. Ministry of Commerce and others, administrative case no. 621/2014, 24/11/2017*, is a case in which the applicant-distributor in Cyprus of mechanical pencils sought the annulment of the communication to RAPEX concerning the relevant products which had previously been withdrawn from the market for not complying with the safety requirements of EU Regulation 1907/2006 by the Department of Labour Inspection (the relevant competent authority). The Administrative court found that the inclusion of products and relevant communications

[125] This is the conversion in euros of the amount of 5 000 Cypriot Pounds, to which the law still refers despite the fact that the currency of Cyprus has been the euro since 2008.

[126] It should be noted that the above is according to the information published on the website of the Consumer Protection Service (CPS), specifically in the section on "Decisions". It may be that there have been more cases in which an administrative fine has been imposed, as during the interview, the CPS referred to 19 cases between the years 2013 and 2019.

in RAPEX do not constitute administrative acts or decisions subject to judicial review; the administrative act that could be subjected to a judicial review application was the decision of the Department of Labour Inspection regarding the withdrawal of the products from the market. The judicial review application was accordingly dismissed. This ruling seems to be correct and in line with Section 43 of the Law (transposing Article 18 GSPD) which refers to remedies at the disposal of economic operators in relation to measures taken by the competent authority entailing "restrictions on the placing of a product on the market or requiring its withdrawal or recall"; clearly, RAPEX notifications do not per se impose such restrictions. The second case, *STAEDTLER Mars GmbH & Co. KG v. Ministry of Commerce and others, administrative case no. 622/2014, 31/8/2018*, was a judicial review application against the same RAPEX notification which was brought by the German producers of the mechanical pencils referred to in the previous administrative case. Unsurprisingly, the outcome of the case was the same as the one just discussed.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Cyprus concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Interviewees have indicated that they have not encountered any practical problems regarding traceability or the definition of safety, nor has the research conducted for the purposes of this report led to any relevant discussions or debate.

Possible improvements to make the implementation of the GPSD in Cyprus more effective

The competent authority (and main market surveillance authority in Cyprus) has pinpointed the recall process as an area where improvement is warranted. As the GPSD does not describe the recall process, and there is no relevant code of practice or other guidelines in Cyprus either, authorities mostly rely on voluntary recalls by the economic operator and have serious doubts as to the effectiveness of the recalls. Many consumers do not respond to recalls at all, and while it is believed that direct contact with the consumer would be much more effective, there are concerns regarding data protection rules (particularly, those in the GDPR). As the GPSD does not spell out the process and therefore does not explicitly legitimise communication with consumers in the context of a recall, authorities are unsure as to their freedom to take steps to increase the effectiveness of recalls, such as insisting that businesses directly contact consumers.

It is not clear, however, that the recall process could or should be spelled out in the GPSD. Though it seems possible for certain general requirements regarding the recall process to be introduced in the GPSD, it may be that such matters should belong to internally-set procedures or codes of practice. The European Commission could take steps to ensure that relevant procedures, guidelines or codes of practice utilised in Member States are shared with the authorities of Member States, such as Cyprus, which do not have such codes, especially when national authorities think they would benefit from some guidance on the recalls procedure, which would also increase their effectiveness. As far as the GDPR is concerned, it is probably the case that it does not preclude direct communication with consumers who are in possession of an unsafe product. More specifically, Article 6(1)(d) GDPR which legitimises processing of personal data when such processing "is necessary in order to protect the vital interests of the data subject or of another natural person" would seem to permit processing for the purpose of direct consumer communication in the context of recalls, yet this needs to be made clear at the EU level (probably in a Commission Guidance document) so that there is no doubt or uncertainty. If the GPSD specifically stated that economic operators can or shall inform consumers in possession of unsafe products about the recall, then Article 6(1)(c) GDPR legitimising data processing necessary for compliance with a legal obligation could probably also be relied upon.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Cyprus.

The Consumer Protection Service (CPS), one of the seven departments of the Ministry of Energy, Commerce and Industry, is the national market surveillance authority. The CPS is responsible for coordinating and effectively implementing the national legislative framework ('Laws of 2002 to 2013 on the basic requirements that must be met by specific categories of products'), which encompasses 20 New Approach Directives, and Regulation (EC) No 765/2008 of the European Parliament and of the Council. In that context, it also provides information and advice to consumers and economic operators on product safety and on how to effectively implement the national legislative

framework (the New Approach Directives) and Regulation (EC) No 765/2008. Indeed, apart from specific information campaigns, the CPS website contains a section titled "information to consumers"[127] and another one titled "Information to businesses"[128] which contain leaflets, illustrative videos and specific advice. Product safety is a category addressed in both of these sections.

For specific product sectors, the safety of which is governed by specific legislation, such as a New Approach Directive, the competent market surveillance authority is not the CPS. Instead, five different Ministries, namely the Ministry of Interior, the Ministry of Health, Ministry of Labour, Welfare and Social Insurance, the Ministry of Agriculture, Rural Development and Environment and the Ministry of Transport, Communication and Works, act as the market surveillance authorities in said product sectors. For example, in relation to cosmetics, the market surveillance authority is the Ministry of Health.[129] The CPS is responsible for coordinating all of these market surveillance authorities, with which the CPS is thus frequently in touch to exchange information and hold relevant meetings.

The CPS, however, acts as the competent market surveillance authority for products not covered by specific safety legislation, and thus falls (in relation to all safety-related matters) within the scope of the GPSD as well as one product sector governed by a New Approach Directive, namely toys. In other words, apart from being the (umbrella) national surveillance authority, the CPS is also a competent authority for specific product sectors.

Pursuant to Article 27 of Regulation (EC) No 765/2008, the Customs and Excise Department is the competent authority for checks at external borders. All market surveillance authorities, the CPS as the coordinating authority, and the Customs and Excise Department thus work together and exchange information in order to effectively implement national legislation and Regulation (EC) No 765/2008. Customs indicated that it works very closely with the CPS and strictly in accordance with its instructions and guidance with regard to its duties related to product safety. In other words, the Customs Department confiscates (as dangerous) or releases a product in the market following instructions from the CPS.

The CPS is responsible for the operation and management of the RAPEX system, and it is also the European Commission's National Contact Point for Cyprus. As such, it cooperates with other market surveillance authorities. As stated in the National Market Surveillance Programme of 2019, its relevant tasks consist of collecting information via the system; classifying/sorting notifications according to the competent authority; notifying the competent authorities accordingly; issuing a weekly press release; and updating the system.

The CPS is also responsible for the operation and management of the ICSMS national contact point.

Market surveillance by the competent market surveillance authorities in Cyprus is conducted through the following means, as listed in the National Market Surveillance Programme of 2019:

- Seasonal, sectoral, proactive and/or reactive inspections;
- Product sampling and laboratory testing;
- Measures for non-compliant and/or hazardous products placed on the market;
- Responding to complaints and/or queries;
- RAPEX, Business Application, ICSMS and CPSC notifications;
- Communication with consumers and economic operators;
- Public announcements;
- Campaigns;
- Penalties for economic operators.

Plans/programmes in place which define priorities for market surveillance of consumer products

Yes. The most recent one is the National Market Surveillance Programme of 2019. National Market Surveillance

[127] See http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/8CD956F7F0890DE0C2257E84002BC573?OpenDocument
[128] See http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/4566D0E9E57E8153C2257E29002E869C?OpenDocument
[129] The market surveillance authority responsible for each product sector is shown on pages 6 and 7 of the National Market Surveillance Programme of 2019.

Programmes are prepared by the CPS.

Priorities in the context of market surveillance are based on inspection results of previous years, RAPEX notifications, consumer complaints, customs information and coordinated actions on the safety of products organised at the EU level. As indicated earlier in this country report, the CPS is the coordinator of all competent market surveillance authorities and can therefore derive information from all of them regarding inspection results. Moreover, the CPS is in close contact and cooperation with the Customs Department, as the latter always acts in accordance with its instructions and guidance; accordingly, the CPS is in possession of relevant customs information. The CPS is also the responsible authority for RAPEX, hence it possesses all information with regard to RAPEX notifications. As for consumer complaints, these are received by the CPS through the consumer telephone line 1429.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Cyprus with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

There are no market surveillance activities in Cyprus with respect to the safety of products containing new technologies. A surveillance campaign for products sold online was conducted only once in 2019 on certain electronic stores in relation to toys and other children's products such as clothes and stationary and was mainly aiming at identifying any RAPEX-listed products being sold. Such products were in fact identified on some investigated online stores and had been withdrawn as a result. The said surveillance exercise was not conducted in accordance with any standardised procedure for online products, as there is not one. It had been decided *ad hoc*.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

As indicated in the previous question, the CPS makes no use of any surveillance technique for products sold online. Such surveillance is conducted very rarely and only covers the websites of certain main online retailers in Cyprus. According to the CPS, the problem mainly has to do with the limited staff working on product safety; there are only five officers and 35 inspectors who are also responsible for the enforcement of other legislative instruments.

The online context is therefore somewhat neglected as far as market surveillance is concerned. It should be noted however that even though online sales have been on the rise in Cyprus, e-commerce remains less developed than in other Member States.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Cyprus (except customs) with respect to product safety

Communication between the market surveillance authority and public authorities occurs at least once a week (as the CPS communicates the RAPEX notifications to the other authorities weekly). Additional communication may however occur when a dangerous product is detected in the market. More generally, there is a regular exchange of information and informal cooperation including meetings and educational events. Cooperation also occurs in the form of the common use of the national market surveillance IT system and common use of RAPEX and ICSMS. Additionally, as stated in the National Market Surveillance Programme 2019, the CPS also attends the meetings of the administrative cooperation group on toy safety (TOYADCO), the expert group on toy safety and the Toy Safety Committee organised by the European Commission. It also takes part in different joint market surveillance actions organised by PROSAFE. Finally, it works closely together with the General Chemical State Laboratory, to which toy samples are sent for laboratory testing.

Cooperation with customs authorities in Cyprus with respect to product safety

There is definite communication once a week through the communication of the weekly RAPEX notifications letter to the Customs Department by the CPS. The Customs Department reviews the weekly RAPEX notifications letter so that they can update the parameters in the risk analysis that the Customs Department conducts in the context of the checks at the borders. For example, if RAPEX notifications indicate that a particular product with safety issues is on the rise in the market, the Customs Department may update system parameters so that 40% (instead of 25% for example) of the relevant products are stopped at the borders (though when there is a particular issue with a given product type, there is direct contact between the CPS and the customs for this purpose). Other than that, the RAPEX notifications newsletter offers support to customs. In particular, it helps them to compile statistics regarding

product safety which the Customs Department has to send annually to Directorate-General of Taxation and Customs Union of the European Commission.

Additional frequent communications between the CPS and customs take place in accordance with needs, i.e., when a dangerous product is detected by customs. More specifically, when the Customs Department detects a dangerous product in the context of their random checks at the border, they inform the CPS and request guidance and instructions. This is an urgent procedure with strict timeframes, as customs can only hold products suspending their release to the importer for 3 days. This is stated in Section 22 of the Law. The CPS checks relevant product documentation and offers instructions to customs as to whether a product must be withheld as dangerous or released. Cooperation (and communication with customs) additionally occurs when the CPS instructs customs to focus on specific products suffering from safety problems that flourish in the market at a given time. One recent example concerned laser pointers.

Overall, cooperation takes the form of informal cooperation and regular exchange of information, and there is definitely a common strategy of product safety enforcement. Relevant communication mainly takes the form of sending guidelines and recommendations and answering questions raised during the customs clearance of products with respect to the completeness of the technical documentation and the required markings.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

There is no established cooperation procedure or even a standard communication schedule; communication occurs should the need arise, yet this is a very rare or infrequent occurrence. In relation to EU/EEA-based authorities, however, cooperation occurs through RAPEX, the ICSMS, the Wiki confluence system and the coordinated actions on product safety organised at the EU level. The CPS finds such coordinated actions particularly useful.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

When there is suspicion regarding the safety of a product, the CPS requests information from the relevant economic operator. If the CPS is not satisfied by the documentation and information on a given product from the economic operator (or the product immediately appears to be dangerous, such as when it is evident that it does not comply with relevant provisions in safety standards or guidelines, in which case no explanation/documentation is requested from the economic operator), the product is notified to the RAPEX without delay. However, when the product does not immediately appear to be dangerous, the notification to RAPEX usually takes 20 days, as the procedure of seeking, receiving and reviewing views and documentation (by the economic operators) and reaching a final decision leading to the RAPEX notification usually lasts this long. As far as non-safety risks notified through RAPEX are concerned, the CPS communicates any such risks to the relevant market surveillance authorities, mainly the Environmental Department of the Ministry of Agriculture, Rural Development and Environment and the Department of Labour Inspection of the Ministry of Labour, Welfare and Social Insurance (which act as competent market surveillance authorities in relation to specific market sectors).

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Businesses often seek the advice of the CPS on safety before proceeding with importing a particular product, most obviously to avoid the costs inherent in importing a product only to have it withheld by Customs due to safety issues. The CPS provides such information and/or advice when requested. Other than that, there is contact between the CPS and business associations once a week through the communication by the CPS of the weekly RAPEX notification newsletters. Moreover, the CPS attends as a speaker at events organised by business associations aimed at educating their members. In general, the cooperation between the CPS and business associations takes the form of cooperation to improve awareness among businesses, informal cooperation, and providing advice to businesses. The Customs Department also cooperates with business associations, albeit in rare cases and in the context of educating businesses on the application of Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products.

As for consumer organisations, the CPS usually holds 1-2 meetings per year with consumer organisations to hear their views and explain product safety developments and requirements. There is also contact between the CPS and consumer organisations once a week through the communication by the CPS of the weekly RAPEX notification newsletter. In general, the cooperation between the CPS and business associations takes the form of regular

meetings, informal cooperation and cooperation to improve awareness among consumers. The Customs Department also cooperates with consumer organisations, specifically through an annual seminar educating them on product safety laws and regulations.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The CPS is very active when it comes to raising awareness, and all common methods of raising awareness, such as press releases, information campaigns, social media are used.

The CPS operates a rich and "active" (with regards to updates) website.[130] It displays information and advice both for businesses and consumers in a user-friendly and well-organised manner or structure. Separate and specific reference is made to product safety.[131] The CPS also distributes paper leaflets on product safety, such as the safety of toys.

Moreover, the CPS distributes the weekly RAPEX notification newsletter.[132] This newsletter is widely publicised in the mass media including online and in social media. It is also directly communicated to all market surveillance authorities such as the Department of Labour Inspection, the Pharmaceutical Services of the Ministry of Health and the Department of Electrical and Mechanical Services of the Ministry of Transport, Communications and Works, as well as to consumer and business associations.

The CPS also issues announcements which refer to safety checks and inspections relating to particular products. The CPS also engages in product safety campaigns, especially during festive periods such as before Christmas or Easter, and also announces the withdrawal from the market of specific dangerous products.[133] All of these announcements are listed on its website and are accessible to all. The Service also uses YouTube and social media in the context of product safety campaigns.[134] Weekly RAPEX notification newsletters are also communicated in the form of user-friendly videos posted on the Facebook page of the CPS.[135]

Apart from the above, as stated in the National Market Surveillance Programme of 2019, the CPS issues a weekly product safety bulletin. Bulletins are forwarded to the media, consumer organisations and other bodies. They are also posted on the Service's website. Newsletters are sent on a regular basis to importers of childcare articles, informing them of their obligations and providing them with advice and instructions. Regular visits are also paid to distributors and importers, during which they are given verbal information and subjected to inspection. Finally, where appropriate, seminars may be organised during the year for educational purposes. In relation to toys, newsletters are sent on a regular basis to toy importers, informing them of their obligations and providing them with advice and instructions. All communications from the Service are sent to the Press and Information Office to be forwarded to the media. The Service draws up a monthly summary of all hazardous toys notified in the rapid information exchange system for hazardous products (RAPEX) and sends it electronically to all economic operators in the sector, and also asks them to provide information on whether they have sold any of these products. This is done in cooperation with the Department of Labour Inspection, which is the authority responsible for implementing the REACH Regulation.

As far as the Customs Department is concerned, raising awareness is not among their duties or responsibilities. However, they do organise and/or participate in educational events for the benefit of consumers or in schools (educating pupils on aspects of product safety).

[130] See http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/index_en/index_en?OpenDocument
[131] See http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/8CD956F7F0890DE0C2257E84002BC573?OpenDocument, http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/F7D4916C8BCCD259C2257FDF002B01FB?OpenDocumet
[132] See: http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/3AD858A843E017E6C22584A80022A100/$file/%CE%94%CE%B5%CE%BB%CF%84%CE%AF%CE%BF%20RAPEX%202019-44.pdf?OpenElement
[133] An example announcement referring to a product withdrawal can be found here: http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/All/732A34F769040A83C225849B0022B990/$file/%CE%91%CE%BD%CE%B1%CE%BA%CE%BF%CE%AF%CE%BD%CF%89%CF%83%CE%B7%20%CE%B1%CF%80%CE%BF%CF%83%CF%8D%CF%81%CF%83%CE%B5%CF%89%CE%BD%20%CE%B5%CF%80%CE%B9%CE%BA%CE%AF%CE%BD%CE%B4%CF%85%CE%BD%CF%89%CE%BD%20%CF%80%CF%81%CE%BF%CF%8A%CF%8C%CE%BD%CF%84%CF%89%CE%BD%20(08-2019).pdf
[134] An example video, specifically a product recall campaign on Facebook, can be found here: https://www.facebook.com/ConsumerGovCy/videos/3115400911835323/
[135] An example can be found here: https://www.facebook.com/watch/?v=2401060463462216

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Cyprus (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls in Cyprus are conducted through a rather informal (not standardised) cooperation between the CPS and the business concerned. In some cases, the CPS will require that the business recall the product (mandatory recall or other corrective measure), however most of the recalls and other corrective measures are voluntary. The CPS agrees with the business on the information channels through which to communicate the message to consumers. The CPS also requires the business to use consumer information in customer databases or loyalty scheme databases in order to make sure that the recall message reaches consumers. However, businesses often put forward arguments against such a practice relating to GPDR compliance. The recall strategy as well as the message to be communicated to consumers is decided by the business, which submits them to the CPS for approval. In that context, the strategy and message are approved, often following some amendments. The CPS then assists in the dissemination of the recall message, mainly through its social media pages and by adding the recall into its weekly RAPEX newsletter. In the context of this communication/cooperation between business and the CPS, the latter requires that the business provide information on the information activities targeted at consumers and other businesses in the supply chain as well as on the timeline of the recall process and the destruction/disposal of any collected products. However, the effectiveness of the recall is not monitored by the CPS and there is no relevant code of practice or other guidance documents related to recalls. The CPS expressed doubt regarding the effectiveness of recalls, stating that many consumers simply do not respond to them. The Customs Department naturally has no involvement in product recalls, as its duties are confined to checks and inspection at the market entry point (borders).

Monitoring of effectiveness of product recalls by market surveillance authorities

As stated in the answer to the previous question, effectiveness is not monitored. This seems to be confirmed from the content of the National Market Surveillance Programme of 2019, which contains very limited information on recalls. However, it arises from said Programme that the role of the competent market surveillance authority in relation to recalls is quite active in the sector of motor vehicles.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Cyprus that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Yes, there are statistics concerning dangerous products found in the market complied by the CPS and statistics concerning products intercepted at border compiled by the Customs Department. Regarding consumer complaints, these are received on the call line 1429. All complaints received are entered into the system of the CPS and are assigned to an inspection officer who investigates the complaint mainly through contacting the economic operator, seeking views and documentation. The complaint is usually resolved by product replacement or repair or a withdrawal of the product from the market. The whole cycle of the process and the communications involved in complaint handling are registered in the system/sharepoint. The consumer is informed about the outcome of his/her complaint. However, no statistics are available related to consumer complaints. There are no statistics related to injuries either.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Cyprus (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

There are several impediments or problems related to market surveillance. The need for sufficient technical expertise and limited staff and financial resources are the main ones identified by the CPS and seem to be timeless problems. Indeed, the budget is approximately 5 000 euros for sampling and laboratory testing and the staff consists of 5 officers and 35 inspectors (also responsible for ensuring the implementation of other legislation). The same issues can be seen as being behind the total lack of online market surveillance in Cyprus, though in this case, a specific problem mentioned is that the CPS has very limited access to the Internet. There is no access to Facebook or online platforms, for example. There are also problems with the cooperation with businesses, mainly due to some of them lacking knowledge on safety requirements and also delaying their submission of requested information or submitting false or incomplete relevant information. An acute problem also relates to the inability of the CPS to control the safety of products which are directly purchased by consumers from other countries,

especially non-EU countries, most commonly online. Such purchases are on the rise in Cyprus. However, the Customs Department has a role in this context in collaboration with the Cyprus Post Office. Product checks are conducted at the post office depending on the nature of the product and the country of origin.

The CPS believes that RAPEX functions very well and it has already been improved. Apart from the insufficient human and financial resources, an impediment encountered with the use of RAPEX is that the information provided by economic operators (businesses) may be incomplete or inaccurate, or there may be delays with the operator obtaining all the relevant information from the manufacturer, especially if the latter is based outside Cyprus. The Customs Department noted that although RAPEX is not among the main tools of exercising their duties, RAPEX is not sufficiently known to consumers and relevant information campaigns should take place in order to raise awareness.

As far as recalls are concerned, the CPS feels that they are not fully effective; consumers do not respond to them, in most cases showing indifference.

Areas to make market surveillance of consumer products in Cyprus/the EU more effective

An area identified by both the CPS and the Customs Department as one meriting improvement seems to relate to expertise. Product safety is a highly technical domain, and therefore a lack of sufficient expertise of the competent officers can greatly lower the quality or effectiveness of market surveillance. Indeed, the CPS called for more frequent training for officers and inspectors. The Customs Department raised a related issue when it stated that due to some product safety regulations being highly complex or requiring special knowledge, it would be better if a market surveillance officer were present at the border on a permanent basis; this is not currently the case, resulting in delays at the very least. There is no academic literature on this subject in Cyprus, but one point could be made in relation to the expertise problem relating to inspectors and how often they move to another position in the government. It may be the case that precisely because product safety is a domain in which specific expertise is important, inspectors which get to acquire expertise as a result of them being in the particular position should not easily or very frequently be moved or placed in different positions in the public sector, as in this case, the inspector positions will be filled by new people without sufficient experience and hence, expertise.

RAPEX does not seem to be in need of specific improvement. In relation to recalls, where concerns have been expressed by the CPS, areas of improvement have been identified and explained in the answer to Question I.5 above. In relation to online market surveillance, it should be pointed out that this will not be possible for as long as the CPS (or other market surveillance authorities) do not have free access to online marketplaces such as platforms and social media. It may be the case that precisely because of the nature of their duties, the Internet should be considered an important tool of performing their duties and should thus perhaps be exempted from any general policy of limited Internet access to which governmental employees seem to be subject.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Cyprus since 2013

There is no statistics illustrating the development of the level of safety of consumer products. However, the CPS was positive that there has been substantial improvement. More specifically, the district offices of the Ministry are more active on product safety as the training of inspectors has been more frequent in recent years than in previous ones. Expertise has improved due to training sessions conducted at the EU level, and there are joint actions which enable testing and analysis which would not be possible to be conducted in Cyprus (due to a lack of relevant expertise and the very high costs involved). The Customs Department also said that safety has improved. This improvement is attributed to safety explanations and guidance posters placed in all entries to Cyprus such as airports and ports and in all customs offices as well as to improvement in the quality/sophistication of the checks at the border.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Cyprus whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

It is clear that market surveillance authorities in Cyprus do not have the tools necessary to address new challenges.

The limited human and financial resources combined with the limited access to the Internet make it clear that they are in a weak position vis-à-vis new (especially technological) challenges. The CPS reported that there are no relevant technological approaches currently under development.

Views of market surveillance authorities whether approaches in Cyprus can be considered best practice implementation of the GPSD, which could be of interest to other countries

The CPS considered that no market surveillance approach in Cyprus can be considered best practice implementation of the GPSD. There is no academic literature on the GPSD or the national implementation in Cyprus. It has arisen from the interviews and the research conducted for the purposes of this study that Cyprus is in need of best practices coming from other Member States rather than being a best practice originator itself. However, it should be noted that the Customs Department emphasised the great informal cooperation that exists between the authorities involved in market surveillance as a very important factor that increases the quality or effectiveness of market surveillance in Cyprus.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*96*	*40*	*96*
Total (country)	***96***	***40***	***96***
Notes:	*This is based on information in the National Market Surveillance Programme 2019 concerning the year 2018. It is important to note that the numbers concern staff who in many cases do not devote the whole of their time to product safety, or only a small percentage of their time (i.e., 10%) is devoted to product safety. Also, the 40 employees working on non-harmonised consumer products are the same as those 40 working on toys, which have also been included under the harmonised consumer products column. It is for this reason that the total is 96 and not 136. Lastly, the staff stated under the 'harmonised consumer products' are the (same) staff engaged in all of the product sectors listed in the table, which is as attached as ANNEX A to the National Market Surveillance Programme of 2019, which includes products such as measuring instruments and eco-design and the energy labelling sector.* *Please note that there is an ostensible inconsistency between the numbers provided by the interviewed CPS (which stated staff for non-harmonised products to be 21 officers and inspectors) and the information in the National Market Surveillance Programme 2019, which states that this number is 40. According to the interviewed CPS, the 21 officers and inspectors are the ones focusing exclusively on product safety whereas the total of officers and inspectors of the CPS is 40.*		

B. Number of <u>inspections</u> of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**n.a.**	**n.a.**	**7 105**
Total number of consumer products inspected	n.a.	n.a.	n.a.
Total number of consumer products tested in laboratories	94	12	106
Total number of consumer products	6	4	10

inspected in cooperation with the customs			
Total number of dangerous consumer products found	141	160	301
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	5	9	14

Notes: *The numbers in this table have been provided by the CPS and concern only toys and non-harmonised products which fall within the authority of the CPS as a competent market surveillance authority. Again, there seems to be an inconsistency between the number of inspections as provided and the corresponding number in the National Market Surveillance Programme 2019 according to which the total of on-site inspections rises to 9 690 (4 390 for toys and 5 300 for non-harmonised products). When this was brought to the attention of the CPS, the CPS noted that the numbers in the National Market Surveillance Programme are more reliable because they certainly reflect numbers about the whole of the 2018.*

Regarding all product sectors listed in Annex A of the National Market Surveillance Programme 2019, the number of checks and inspections (excluding non-harmonised products) rises to 8 100 (of which the 4 390 concern toys). Approximately 1 800 of those checks/verifications concern measuring instruments and related products (see section 2.12 of the national programme). Quality control sampling operations (with regard to fertilisers) are included in the number, as are labelling checks (such as in relation to fertilizers, tires and energy labelling).

1. *Regarding products tested in laboratories, there is some information in the national programme which is as follows: Cosmetics: 100 products*
2. *Construction materials: 450 samples*
3. *Electrical equipment and EMC: 3 tests which led to inspections – 65 inspections resulted in a finding of non-compliance*
4. *Electrical equipment/LED: 34 tests which led to inspections – 77 inspections resulted in a finding of non-compliance*

C. Number of recalls of consumer goods (last available year)

N.a.

D. Key sources

Legislation	General Product Safety Directive The General Product Safety Law of 2004, Law 41(I)/2004 (and the two amending laws specified in the answer to Question I.1 of this Report.
Studies/reports/articles	The National Market Surveillance Programme 2019
Websites	Consumer Protection Service website, http://www.consumer.gov.cy/mcit/cyco/cyconsumer.nsf/index_gr/index_gr?OpenDocument Cyprus case law database: http://www.cylaw.com
Interviews	The Consumer Protection Service, Product Safety Section, Ministry of Energy, Commerce and Industry The Customs and Excise Department, Ministry of Finance

6. Czech Republic

COUNTRY REPORT CZECH REPUBLIC

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

- Act No. 102/2002 Coll. On General Product Safety, last amendment by Act No.183/2017 Coll. (hereinafter: Czech Product Safety Act)
- Act No. 634/1992 Coll. On Consumer Protection, latest amendment by Act 179/2019 Coll. (hereinafter: Czech Consumer Protection Act)
- Government Regulation No. 396/2004 on Procedures, Content and Form of Information on the Occurrence of Dangerous Non-Food Products

(The administrative Acts concerning specific forms of market surveillance are not included here.)

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in the Czech Republic

Traceability is ensured in the Czech Republic by requirements at two levels: first through information and documentation requirements, second by commensurate measures. Art. 5 of the GPSD is mainly transposed by § 4 Czech Product Safety Act, but some requirements are to be found in § 5.

Information requirements concerning “accompanying documentation” and “product labelling” belong to the duties of producer according to § 4 of the Czech Product Safety Act. Interestingly, § 4 (3) considers “product labelling” as a measure to enable the risk of products to be assessed or for assessing any kind of information according to the safety of the product; in parallel, § 4 (4) requires the producer (and distributors) to notify in the "accompanying documentation” of potential dangers or the parts of the product that may cause danger, if they are not immediately obvious, as well. The chosen method of how producers ensure product labelling and the accompanying documentation is at their discretion; they can use EAN barcodes or QR codes, whichever they find more efficient. Regarding the method used, we couldn´t find any sectoral soft law recommendation (e.g. recommendation by a business association). However, barcodes are not obligatory in the Czech Republic, although they are a very widely used method. It was mentioned by several stakeholders that non-EU/EEA products are often produced by companies that use barcode labelling but control activities by the competent national authority reveal that the product origin is false.

The information and documentation requirements which focus on traceability are more detailed and are also included in the Act No. 634/1992 Coll. on Consumer Protection. According to § 10, the “seller” shall ensure that products are visibly and intelligibly marked, which includes also the designation of the producer, importer or supplier (…). This obligation requires the name and contact details of the producer, or a person responsible for marketing a consumer product, and places the information obligation on the seller, in a different way to Art. 5 (1) GPSD.

3. Definition of safety in Art. 2 (b) GPSD and benchmarks for assessing safety in line with Art 3 (3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

In the Czech Republic, no specific definition of safety exists. The definition of Art 2 (b) GPSD was transposed to § 3 (1) of the Czech Product Safety Act with a small supplement concerning the labelling of products, namely that all information shall be provided in the Czech language.

No definition is currently available in the Czech legislation regarding new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

National legislation transposing the GPSD does not cover explicitly any of the emerging threats related to new

technologies. In the opinion of the Czech Ministry of Industry and Trade, certain aspects could be still covered by the existing legislation; however, interpretation issues are increasing. Czech market surveillance lacks expertise in these issues, while other authorities added that, for example, regarding chemical materials, new technologies are not relevant. However, the authorities agreed that these aspects have to be discussed specifically and resolved at the EU level instead of at the national level.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

In the context of Art 3 (3) GPSD, the following benchmarks are used for assessing the safety of the product according to § 3 (5) of the Czech Product Safety Act:

(a) Czech technical standards that adopt a relevant European standard;
(b) The national technical standards of the Member State of the European Union in which the product is placed on the market;
(c) A Commission recommendation laying down guidelines for product safety assessment;
(d) The rules of good product safety practice applied in the relevant field;
(e) The state of science and technology;
(f) Reasonable consumer expectations concerning safety.

The Czech Republic fully transposed the EU norm concerned. The effect of the Czech technical standards and whether not meeting the requirements of the technical standards can lead to a dangerous product notice was challenged in case law. The confirmation of the Highest Court was necessary in 2010 to tackle whether a single reference by Government Regulation to the Czech Technical Standard can result in a binding effect for a technical standard, without the special authorisation of an Act (see: Decision of the Highest Administrative Court No. 5 As 69/2009-86 of 16.11.2010), although technical norms are not binding in general according to § 4 Act No. 22/1997 Coll. on Technical Requirements for Products. The reference made by Government regulation 198/2007 Sb. on the safety of lighters was problematic, because § 3 (2) of the national regulation in connection with § 2 f) stated: "unusual types of lighter" whereas according to European Standard specification 3.2, they should always have been considered dangerous and prohibited from being placed on the market. Later decisions also dealt with the issue of whether a product that does not fulfil the requirements of the Czech Technical Norms should be considered a dangerous product. As can be seen in the Decision of the Prague City Court No. 9 A 131/2010- 34 of 27.11.2013, the court clearly gave an affirmative answer. Later legislative amendments of 22/1997 Coll. on Technical Requirements for Products, see Act. 265/2017 Coll., solved these problems followed the noted case law.

Authorities added that the Appendix "Risk assessment guidelines for consumer products" to the Commission Implementing Decision (EU) 2019/417 of 8 November 2018 is a helpful guidance for market surveillance authorities, as well as other tools.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in the Czech Republic in case there are consumer product(s) on the market which are found unsafe under the GPSD

Czech market surveillance has quite a wide arsenal of administrative measures at its disposal if unsafe consumer products are found, but some practical problems, mainly lack of financial and human resources, can reduce the effectiveness of these measures. The competent authorities have four main administrative measures according to § 7 (2) of the Czech Product Safety Act. They can:

1. Ban the marketing or selling of a product;
2. Order a product to be recalled;
3. Require the withdrawal of a product; and
4. Inform consumers about dangerous products.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The concrete penalties and sanctions in relation to non-food product safety are established by the Czech Product Safety Act. The maximum level of penalties foreseen under Art. 7 GPSD is relatively high for the Czech Republic, it can be set at CZK 50 million (around EUR 2 million). The maximum penalty for breaching requirements on information duties as stipulated in the Czech Consumer Protection Act related to product safety is up to 3 million

CZK (circa EUR 120 000).

Regarding the concrete amount of the penalty, there is national horizontal legislation, Act No 250/2016 Coll. on liability for offences and relevant proceedings, which regulates how to impose a sanction and which factors should be taken into consideration, but as an *ultima ratio* rule, it is required that the penalty can never risk the liquidation of the business entity. This Act provides, among others, conditions for liability for offences, types of administrative penalties and sanctions and principles for their imposition. It applies to all market surveillance authorities and covers all general aspects regarding administrative proceedings. When reading published case law, a trend can be seen that the amount of penalty upon first sanctioning is between CZK 50 000 and CZK 100 000 (EUR 2 000 to 4 000), which is 0.1-0.2 % of the maximum sanction. These fines are generally higher when the authority finds continued violations at the second, follow-up control.

Recent case law in the Czech Republic with respect to or relevant for the GPSD/the national implementation legislation.

According to the relevant authorities, there are not too many decisions of the competent authorities that are challenged in court. In case of Regional Hygienic Station there are almost none; in the case of the Czech Environmental Inspectorate and Czech Trade Inspectorate only a few, which mainly focus on getting the imposed penalty reduced. From the current two cases which are connected with product safety issues, one only concerns the sanction. The Judgment of the Prague City Court[136] of 19.9.2019 rejected the plea against the decision on sanctions for a tanning salon operator. In that case, the City Court observed the criteria for sanctioning by an administrative organ and stated that a fine of only 0.11 % of the maximum possible amount does not seem disproportionate. The second decision, the Judgement of the Prague City Court No 9A 74/2016 – 68 of 31.5.2018, is much more relevant, because it challenged the safeguard measure ordered by the authority due to voluntary recall and withdrawal by the producer. Interestingly, this court decision also dealt with the indirect effect of Art. 8 (1) of the GPSD and the encouragement and promotion of voluntary actions by producers and distributors. It states that recall as a corrective measure can be ordered by the national competent authority according to § 7 (2) of the Czech Product Safety Act only if the producer or distributor fails to fulfil its legal obligations on a voluntary basis, and it is necessary to withdraw the dangerous product from the market as *ultima ratio*. According to the court, the Czech Trade Inspectorate failed to verify the statements of the producer on the voluntary recall and whether the recall was satisfactory, although § 7 (2) h of the Czech Product Safety Act delivers the right to order recall from consumers only if the producer or distributor did not recall the dangerous product voluntarily, or the recall was incomplete. The court therefore overruled the decision of the CTI and returned the case to it for a further procedure. The decision is very well argued and shows that although the producer tried to conduct a constructive dialogue with the market surveillance authority, such a dialogue is not satisfactory in every case.

No further relevant case law could be found, neither in the relevant databases of national jurisprudence, nor in the new commentary on the Czech Product Safety Act.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in the Czech Republic concerning traceability, definition of safety etc. / Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The main issues related to traceability and emerging safety issues in the Czech Republic are mainly connected with non-EU/EEA products and dangerous products sold by smaller rogue firms in markets and related to identifying the products' origins. In these cases, distributors use fake invoices and false addresses and either do not cooperate with the authorities or submit insufficient accompanying documents, according to which the products cannot be correctly identified, e.g. incomplete invoices.

These problems should be distinguished from the issue of incorrect product identification. Incorrect product identification should not necessarily mean that products are unsafe. On the other hand, according to the Regional Hygiene Stations, the definition of safety is appropriate; even this range of the definition is necessary to work effectively, hence there is no question that defining the scope of safety cannot be resolved easily. Nevertheless, according to the current definition, it is not clear whether it includes cyber- and environmental risks, which should be clarified at the European level to avoid the fragmentation of national practices.

[136] No 10A 146/2016 – 35

Possible improvements to make the implementation of the GPSD in the Czech Republic more effective

Several ideas should be noted. First, according to the experts of the Czech Ministry of Industry and Trade, it is necessary to withdraw the "Safety Package" submitted by the European Commission in 2013 from the legislative procedure. The current situation is unclear and the status of EU legislation and also the single market has gone through a lot of changes since 2013; as such, the 2013 proposals do not correspond to existing market needs. This year, the new regulation on market surveillance on harmonised products has been published, so retaining the proposal on market surveillance from 2013 no longer makes any sense.

Second, the Czech national legislation transposing the GPSD does not explicitly cover any of the emerging threats related to new technologies. Although, in the opinion of the Ministry of Industry and Trade, certain aspects of these threats can still be covered by the existing legislation, interpretation issues are increasing and the Czech market surveillance authorities lack expertise in these issues. These aspects therefore have to be discussed specifically and solved at the European - instead of at the national - level, to prevent fragmentation.

Third, due to problems with products originating from non-EU/EEA countries, it is necessary to establish new requirements to indicate the name and contact details of a reachable person who would be responsible for placing these products on the EU market. In an ideal situation, this person should be settled in a Member State of the EU, or should hold European citizenship. In general it is necessary to discuss the issue of traceability at the EU level, and the Ministry of Industry and Trade assume that such a discussion will be open during the future revision of the GPSD. A further expert opinion should be added to the issue of dangerous products from non-EU/EEA states, which might deviate from the prevailing opinion of the authorities; namely, if *ex-post* control of these products is inadequate and the related costs of removing these dangerous products and the harms they have caused are disproportionately high, *ex-ante* control mechanisms should be introduced to prevent dangerous products from being distributed within the internal market. An obligatory *ex-ante* safety control at the competent customs point, where these products are first placed on the internal market, is therefore recommended. Also more efficient consumer campaigns would be necessary to raise consumer awareness concerning dangerous products from non-EU/EEA countries.

Fourth, barcodes could also be efficient in terms of traceability, but it should also be mentioned that mandatory barcodes unfortunately do not solve the problems of non-EU/EEA products being assigned false origins. While several producers of non EU/EEA products use barcode labelling, the competent national authority found out after undertaking control activities that the product origin is false.

However, any other options for ensuring traceability should be considered as well.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in the Czech Republic.

At the national level:

At the sub-national (regional/provincial/local) level:

The general organisation of the Czech market surveillance as already described in the Czech report on the Review and Assessment of the Functioning of Market Surveillance activities pursuant to Art. 18 (6) of regulation (EC) No 765/2008 – 2010-2013 is briefly described below:

Market surveillance in the Czech Republic is carried out by numerous central government bodies and authorities which are subordinated to specific ministries. The distribution of competencies is mainly "product-based".

Concerning the GPSD, market surveillance is carried out by the following authorities in the Czech Republic:

- Czech Trade Inspectorate (main market surveillance authority) (shown as CTIA in the figure)
- Customs Authorities
- Czech Environmental Inspectorate
- Regional Hygiene Stations (shown as Regional Public Health Authorities in the figure)
- Ministry of Transport (marine equipment, vehicles and spare parts.)

The Czech Trade Inspectorate is the main, so-called “umbrella” or “last resort” market authority according to § 7 (1) of the Czech Product Safety Act. It should be stressed that market surveillance is only one of the wide range of activities these authorities perform. Therefore, several authorities mentioned the lack of human or financial resources, which can negatively impact the elimination of dangerous products from the Czech market. The market authorities usually consist of a Central Inspectorate based in Prague and several regional Inspectorates. For instance, the CTI has seven regional inspectorates and the CEI has nine. The Regional Hygiene Stations have a special status. They are subordinated to the Ministry of Health, which functions as a national market surveillance authority, but it only creates the methodology for control activities and the yearly control plans and coordinates and controls their activities. It also acts as a “court of third instance” for appeals against decisions by the Regional Hygiene Stations. The 14 Regional Hygiene Stations (which could also be called Public Health Authorities) are independent entities.

The activities and organisation of all of these authorities are regulated in different acts, but the Czech Code on Administrative Procedure and the Czech Control Code are binding for all authorities. These authorities operate on the basis of Annual Market Surveillance Programmes, where control actions are planned in advance. Joint action and formal cooperation among these authorities exists, and they react to notifications from other authorities and bodies, including customs; however, their data collection (e.g. on dangerous products or control activities) is not interlinked, since each market surveillance authority has its own IT system (presumably because of data protection issues, and it was presumed by some authorities that it will also not be connected in the near future).

Plans/programmes in place which define priorities for market surveillance of consumer products

According to § 27 of the Czech Control Code, each control authority is obliged to prepare its yearly control plan following the current priorities. This is a general obligation for all national control authorities, including market surveillance authorities performing checks on non-food products. In principle, market surveillance first follows general control activity plans, then concrete regional control plans, and third, extraordinary circumstances (e.g. if responding to consumer complaints or other internal information – for instance from customs – makes conducting control activity urgent). For controls of harmonised products, Article 16 (5) of Regulation (EC) No 765/2008 is relevant and thus specific control programmes for each specific controlled sector have to be available.

Market surveillance authorities however do not always use the same source of information, due to their scope of work. For example, information from "Coordinated actions on the safety of products organised at EU level” is only used by the Czech Trade Inspectorate Authority, which is regularly involved in joint control activities.

2. Market surveillance regarding <u>new technologies</u>, <u>online sales</u> and <u>C2C products</u>

Market surveillance activities in the Czech Republic with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

New technologies are comprehensive problem areas in need of more attention. Because of their novelty, no adequate legal tools are available, neither at the European nor at the national legislative level. For these reasons, the right to control activities is not sufficiently certain in this field. A further problem is inspection authorities’ analytical deficiencies.

The Czech Trade Inspectorate has been sometimes involved, at the European level, in joint programmes concerning new technologies, such as the ADCO RED programme, which controlled household appliances and climate technology for a long time. On the other hand, both the Czech Environmental Inspectorate and the Regional Hygiene Stations stated that they do not focus on new technologies.

Concerning C2C products, it should be noted that they are not within the direct scope of any Czech authority, and therefore no control activity can be reported.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The frequency of market surveillance of products sold online varies between the different authorities. Some, such as CTI, added that they check products sold online several times per week, and others, such as CEI and RHS, only once a month or only if the product sold is not found among the usual assortment sold by normal shops. As already mentioned, the CEI and RHS face several legal and organisational problems in conducting mystery shopping. First, neither of their IT systems is sophisticated enough to hide the identity of the Inspectorate by, for example, creating a new web address or postal address; second, the Environmental Inspectorate – unlike the Czech Trade Inspectorate – does not have a credit card with which to buy products online. For these reasons, these two

authorities buy products in normal shops or take samples of materials in the classic way.

Mystery shopping creates also a financial risk for the authorities, because reimbursement for the bought products can be problematic. However, according to Czech Control Code, the business entity is required to reimburse the price of the sample if the test shows discrepancies from the requirements (e.g. the product doesn't comply with the requirements of a safe product). In other European countries – not to mention non-EU/EEA countries – this Act is not enforceable, and the risk of not recouping the investment could be an unbearable financial risk for authorities. The Czech authorities therefore conduct mystery shopping only for products provided by business entities located in the Czech Republic. In the authorities' experience, the bigger business entities can be checked appropriately, but smaller and so-called rogue traders are often problematic or out of the scope of more intensive product control activities.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in the Czech Republic (except customs) with respect to product safety

The given frequency of cooperation with other public authorities in the Czech Republic depends on the competencies of the authority, on the types of controls performed and the controlled product, and on the extent of the need to cooperate. In general, a relationship of "greater scope of authority – more frequent cooperation" can be reported. Due to the common use of the RAPEX application, market surveillance authorities are in regular contact on a weekly basis. Authorities using ICSMS are also in regular contact with market surveillance authorities in other EU/EEA countries, but the level of ICSMS use is very low. A functioning link with RAPEX would be appreciated. While the Czech Trade Inspectorate is cooperating once a week, the CEI and RHS do so only once a month with other Czech authorities, apart from customs.

Cooperation with customs authorities in the Czech Republic with respect to product safety

Cooperation with customs in the Czech Republic is based on formal agreements and mainly on formal and informal exchanges of information. Depending on the competencies of the authority and on the planned control activities, the frequency of the cooperation could be daily if they have a common joint action, but usually it is monthly.

However, a common IT system for all national market surveillance or for authorities with customs does not exist; nevertheless, cooperation between different market authorities and customs should be considered very effective. With constant development in IT technologies, the critical data protection issues should be satisfactorily solvable, and the interlinking of IT systems should be manageable, namely by the future mandatory use of ICSMS system by all market surveillance authorities.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with the authorities of EU/EEA countries mainly involves three activities: RAPEX notification, information of ICSMS, or communication via the Interact Portal (PD-NEA) in the case of chemical products; but also by participation in EU joint control activities. Cooperation is not that frequent – on average once a month, but this depends on the actual situation. Cooperation is quick and efficient. Czech authorities usually have the most experience of market surveillance with the neighbouring countries.

The Czech Environmental Inspectorate is involved in Custom 2 Pilot Project - ECHA and a Visegrad 4 Project - Customs 2020, and the CEI has finished a jewellery control among the Visegrad 4 States.

Concerning non-EU/EEA authorities, all Czech authorities reported the lack of cooperation. The Czech Trade Inspectorate has requested information from the Chinese authorities, e.g. information on producers of products that were found to be dangerous, but in no case could the producer be discovered nor any relevant information transferred to the CTI. This situation is unsatisfactory. Despite this, the Czech Trade Inspectorate Authority mentioned only informal meetings with non-EU/EEA countries close to the Czech Republic, but only very limited cooperation exists with the authorities in these countries.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Coordination between Czech market surveillance authorities and RAPEX is clarified by the Czech Government Regulation No. 396/2004 on Procedures, Content and Form of Information on the Occurrence of Dangerous Non-

Food Products and follows the administrative procedure of the new Guideline for the National RAPEX Network, which was updated by Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System RAPEX. According to this procedure, the national authorities have to comply with the format in the RAPEX application and submit notifications to the RAPEX National Contact Point (hereinafter: NCP), which is located at the Ministry of Industry and Trade, in due time, in about two weeks, maximum one month. At the national level, the Interdepartmental Expert Group for RAPEX has been established, which discusses basic issues related to the functioning of RAPEX, both at the national and EU level. It should be added that the inspectors from each market surveillance authority are regularly trained in product safety issues and on the functioning of RAPEX. All members of the national RAPEX network have access to the wiki confluence platform and to the RAPEX application and exchange of information is possible on a daily basis via the given contact persons.

The procedure mainly consists of two steps: first the national market authority should enter the system of the National Contact Point, and then the NCP will enter the dangerous product into the RAPEX system without delay, within 48 hours. However, depending on the internal organisation of the national authority, the notification in the NCP system can require further steps. In the case of Regional Hygiene Stations, there is a four-step system: first an RHS informs the Main Hygiene Station at the Ministry of Health, which informs the RAPEX contact point at the Ministry of Health, which finally contacts the National Contact Point at the Ministry of Industry and Trade.

The duration of the notification to the RAPEX system depends on several factors, e.g. time needed for testing, type of risk and difficulties with risk assessment, e.g. in case of laboratory testing it could last even longer, just because of the duration of microbiological tests. Experts from the Czech Environmental Inspectorate and RHS added that the current legal framework sets a relatively high investigative burden on these authorities, because before entering a dangerous product in RAPEX, they should be absolutely certain of a violation of a legal requirements; the laboratory tests must therefore be positive, and these tests takes approximately a month to be confirmed. The CEI also reported that they also take the cross-border effect into account and only if a dangerous product is distributed in other Member States will they deliver the product notification to the RAPEX NCP. Experts are aware of different practices among authorities in other Member States, which might pay less attention to the identification of a real cross-border effect. These differences could lead to the result that some authorities notify very different numbers of dangerous products. According to the experts, questions of cross-border effects should be managed and harmonised better at the European level, in order to have similar practices in all Member States.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

All market surveillance authorities cooperate with economic operators and business associations, but the method of cooperation and its extent is different. Some market surveillance authorities actively participate in different workshops and discussions organised by various business organisations based on a request or invitation. They also provide information to economic operators by various means, e.g. exchange of information, regular meetings and providing advice. In certain specific cases, market surveillance authorities (mainly the Czech Trade Inspectorate) participate in awareness-raising projects in the field of product safety for businesses. The main cooperation partners are different business associations, depending on the product field, e.g. the Chemical Industry Association concerning chemical products; SYBA concerning food contact materials and packaging, or Prokos concerning cosmetics, or the Czech Association for Branded Products. The cooperation activities with consumer organisations differ significantly, but they also have several layers. At the Ministerial level, both representatives of consumer organisations and authorities are regularly invited to meetings on consumer problems, and the authorities and consumer organisations (and also business associations) are involved in the legislative procedure. Consumer organisations contact authorities with cooperation requests less frequently, but this also happens in a few cases.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Market authorities mainly use their website as the primary information channel for informing consumers and businesses on product safety issues, and market surveillance authorities deliver advice for both groups via the telephone. In certain specific cases, some market authorities participate in awareness-raising projects, for example, the RHS regularly inform consumers in cooperation with the National Institute of Public Health on health issues by publishing flyers or, in urgent cases, via regional mass media, for example on quality of sun creams.

Information on *Safety Gate/RAPEX* is available on the Ministry of Industry and Trade's web pages; however, from

the consumer point of view, the published information is more a summary of statistical reports on product safety and on some campaigns rather than a real information channel on current dangerous products.[137] A link to the Safety Gate is thus available on the Ministerial website, although only under several layers of content, thus the information can hardly be found by a typical consumer.[138]

Information on *Safety Gate/RAPEX* is more easily available on the CTI's site, and consumers are also informed of the recall resolutions made by the CTI,[139] but there is only a link to *Safety Gate/RAPEX* without any further explanation for the consumer. A national online information system on dangerous products in Czech does not exist, nor is one planned, but dTest, the main consumer organisation, provides information on dangerous products in Czech.[140] This page also includes a form for consumers to notify that they found a dangerous products and these will be forwarded to the CTI.

Social media are nowadays very rarely used to inform consumers about dangerous products or safety campaigns.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in the Czech Republic (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

According to § 7 in connection with § 5 of the Czech Product Safety Act, market surveillance authorities do not organise and carry out recall procedures themselves and do not cooperate with businesses concerning recalls, since recalls are the responsibility of economic operators. However, economic operators might consult on the procedure for recalls or their recall strategy with market surveillance authorities. Corrective measures must be proposed by economic operators themselves (on a voluntary basis) or they can be required by the competent authority.

With regard to the required information on recalls, it should be noted that market surveillance authorities are free to stipulate all the information that should be delivered to the authorities for recalls. Some authorities regularly ask for a financial statement on disposing of the dangerous products or information on how the business entity transmitted the information on the withdrawal to the consumer. Distributors set out flyers at the point of sale and provide information on their website and in urgent cases place announcements in regional newspapers. Social media are rarely used as communication channels with consumers. Market surveillance authorities also have to inform consumers on unsafe products on their websites, including advising consumers on how to proceed with unsafe products if necessary.

Market surveillance authorities regularly check how business entities implemented corrective measures. Although comprehensive information is required from businesses, the information provided is often insufficient, because middle and small businesses are either not capable or unwilling to provide statistics or detailed information. Fewer problems can be reported concerning bigger businesses, where voluntary recalls are often performed properly, e.g. automobiles fitted with inadequate safety belts, or white goods, such as refrigerators. Problematic mandatory recalls mostly relate to products sold on ad hoc open air and seasonal market places.

Concerning "Codes of good practices on product recalls", it should be added that such Codes do not exist in the Czech Republic and possible voluntary frameworks for recalls – as stated in Art. 5 (1) GPSD – are not even mentioned in the Czech Product Safety Act.

Monitoring of effectiveness of product recalls by market surveillance authorities

The market surveillance authorities monitor whether a recall procedure really took place; follow-up control activities are conducted in shops. Economic operators are obliged to send information on the results of recall procedures, although mainly in the case of mandatory recalls. However, there are no specific procedures for a systematic collection of this kind of information. Moreover, the IT systems of the market authorities are not able to deliver suitable statistics from the recall results.

For mandatory recalls, the controlled business entity (producer or distributor) is asked to provide feedback on the volume of product actually recalled and also how the recalled products were disposed of, but the quality of

[137] See: https://www.mpo.cz/cz/ochrana-spotrebitele/bezpecnost-vyrobku/
[138] See: https://www.mpo.cz/cz/ochrana-spotrebitele/eu-a-spotrebitel/aktuality-z-eu/safety-gate-_-system-rychle-vymeny-informaci-o-nebezpecnych-nepotravinarskych-vyrobcich--242173/
[139] See: https://www.coi.cz/pro-spotrebitele/rizikove-vyrobky/
[140] See: https://www.dtest.cz/nebezpecne-vyrobky

feedback is often insufficient to assess their effectiveness. Once again, it is much harder to receive sufficient information from small and medium sized business than from bigger ones.

6. Availability of statistics relevant for market surveillance

Are there statistics available in the Czech Republic that are relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

According to information submitted by market surveillance authorities, there are no specific national statistics on dangerous products. However, each market surveillance authority has its own market surveillance system, which contains information on dangerous products identified during their market surveillance activities and thus information can be extracted if needed. Information from consumers on possible injuries caused by products is usually more relevant for market surveillance purposes; however, there is no specific collection of this kind of data and also no specific register of consumer complaints on dangerous products in the Czech Republic. Only a National Register of Injuries and a database of the Poison Information Centre (TIS) are available, whose data are not used by authorities due to their very limited degree of usefulness in market surveillance and also due to the complicated way of accessing them.

The National Register of Injuries was established to register data concerning injuries treated in connection with hospitalisation, and with the health status of the patient in relation to the injury and its diagnosis and therapy, the circumstances of the injury, a detailed description of the place and time of the injury, the speed of intervention of the emergency service, data on primary transport, detailed records of the care provided on emergency admission and subsequent health service provision, and data needed for identifying the providers of in-patient health care to the hospitalised patient. The data are used to achieve a higher quality of health services in response to injuries and for better results in determining the optimum efficiency of therapeutic procedures.

The second relevant database is the database of the Poison Information Centre (TIS), which is a continuous nationwide telephone medical information service for cases of acute poisoning in humans and animals. TIS aims to reduce the number and severity of poisonings (greater public awareness through preventive programmes) and to positively influence the course of accidents already occurring (communicating knowledge of the contact to TIS and its use ensures the appropriate treatment of the patient and their optimal safety). The database contains information on poisons and injuries caused by chemical substances. Both databases were established by the Ministry of Health.

However, as mentioned above, these registers are not used for market surveillance purposes.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in the Czech Republic (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Market surveillance authorities certainly face a number of problems in their activities. One of the main problems is the increasing administrative burden concerning their control activities. The constant ratcheting up of the requirements distracts their focus from market surveillance. Among other problems mentioned, some market surveillance authorities also named the “lack of suitable product testing laboratories”, and “lack of expertise in new technologies”. It is evident that market surveillance authorities have to stay flexible in order to follow trends in the market, but this is very difficult and is always connected with additional requirements for staff, training, expertise, testing facilities and, of course, financing.

One of the most crucial issues is to ensure effective control of imported products from non-EU/EEA countries that reach consumers directly and, in this case, close cooperation with customs authorities of other Member States would also be necessary. However, the relevant aspects, e.g. how to deal with the situation when a product has been already paid for (thus, the impact on consumers), also need to be discussed. Efficient cooperation with online marketplaces would be also important in this regard. It is also necessary to strengthen cooperation among EU Member States on enforcement measures if the economic operator is settled in a Member State other than the one in which a product inspection was performed.

The RAPEX system is assessed as well functioning, critical remarks concern only the follow-up procedure of the notification, because instead of a short notification, a long e-mail with several attachments is necessary, which prolongs the procedure significantly. This, however, will be solved by a new version of RAPEX application. Experts from Regional Hygiene Stations noted that dealing with the notification is often a challenge for regional inspectors, because of the lack of language skills.

RAPEX is the only common market surveillance system used by all Czech authorities (due to the lack of a common national Czech market surveillance IT system). The second IT tool – the ICSMS system – is regularly used only by CTI, other authorities use it only rarely. A relevant problem related to RAPEX concerns the assessment of chemical risks, mainly for new compounds that have not been tested before. However, it should also be added that the Guides published by the European Commission on chemicals are very helpful documents for the authorities.

Some remarks should be added concerning recalls. As already mentioned, no specific procedures exist in the Czech Republic for a systematic collection of recall information. The existing IT systems of the market authorities are not able to deliver suitable statistics from the recall results, and the inspectors already complain about the constantly rising administrative burden surrounding control activities. Similarly, the Ministry of Industry and Trade also lacks data on the effectiveness of the return of unsafe products by consumers. It is reasonable to assume that consumers return more expensive products that were found to be dangerous, but for cheap products, such as toys or cosmetics, bought at marketplaces, no returns can be predicted.

Areas to make market surveillance of consumer products in the Czech Republic/the EU more effective

Four ideas for improvements should be noted:

First, it is necessary to better interconnect the RAPEX system and ICSMS in order to share the entered information.

Second, it is necessary to inform consumers of their rights regarding returning and getting refunds for dangerous products and where the distributor fails to fulfil its obligation.

Third, a general obligation to provide barcodes for any kind of product, or other options for identification of goods, could be a convincing idea, although bar codes cannot help in cases of fake distributors from non-EU/EEA countries and grey or rogue businesses. Block chains could also improve traceability and should be used more by market surveillance authorities.

Fourth, quick measuring instruments based on X-ray fluorescence (XRF) and RAMAN spectroscopy for quick screening to analyse product composition fundamentally increase the effectiveness of product control. Providing funds for and training on their use would be highly beneficial.

Regarding new technologies, regular training at the national and European level and also sharing practices are necessary to learn from the best practices of other authorities. It needs to be pointed out that because of the broad scope of authority competences in the Czech Republic, limited staff resources are a very significant issue, shared by all market surveillance authorities.

For recalls, legislative amendments would be necessary according to these reports but dealing with the compliance information from businesses should not overstrain the inspectors. Best practices of other Member States' authorities would be welcomed on this topic. The traceability of recalls is a similarly important issue, as the traceability of products in general and the enforcement level should be increased. As a final improvement, the legal impediments to effective mystery shopping in the Czech Republic should be eliminated and, in addition, the missing methodology for testing new materials should be developed, mainly in the field of non-harmonised products. It is hoped that the competent Ministries will tackle the existing problems over mystery shopping and the reimbursement of laboratory testing as part of the legal amendments connected. Furthermore, the European legislator could consider establishing a European institution that could refund national testing laboratories as well as establishing a methodology for new materials.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in the Czech Republic since 2013

It was noted that the safety level of consumer products depends on the product type. According to the Czech Trade Inspectorate, the level of safety has clearly improved for both harmonised and non-harmonised EU products, but products from non-EU/EEA countries are still not safe and their traceability is complicated and inefficient, not to mention those products that are distributed online or sold at open air or seasonal marketplaces, which in practice can barely be supervised. New challenges have arisen related to AI and new technologies. For the Ministry of Industry and Trade, it seems that the new problems connected with new technologies are currently difficult to manage. The indicators for this assessment are the results of market surveillance, complaints from consumers and

information from consumer organisations.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in the Czech Republic whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc.)

No new tools for solving the challenges of digital industry are available for the Czech market authority. C2C sales do not belong within the competences of any market surveillance authority. Therefore, the delimitation of real business activities from C2C activities will be a challenging question in the near future. The new platforms and the shared economy make the definition of C2C businesses even more complicated.

These aspects are discussed at regular meetings with consumer organisations and business associations, including representatives of the "digital industry" at the Ministry of Industry and Trade, but legal amendments would be necessary to tackle the problems, mainly at the European level.

Views of market surveillance authorities whether approaches in the Czech Republic can be considered best practice implementation of the GPSD, which could be of interest to other countries

As best practices of Czech Republic, the use of quick measuring instruments concerning chemical materials should be noted. The Czech Environmental Inspectorate uses two types of these instruments, the first is based on X-ray fluorescence (XRF), and the second is RAMAN spectroscopy for quick screening to analyse product composition, which fundamentally increase the effectiveness of product control. These measuring instruments can be recommended for all market surveillance, because the results of the measuring are important and quick indicators for further laboratory testing.

Concerning new technologies and digital challenges, several competency problems will arise in the future. Therefore it could be recommended that –similar to the Czech distribution of competencies – a so-called "umbrella" or "last resort" market authority should be named for new areas which are not in the scope of other market surveillance authorities. With this "last resort" solution, the Czech Trade Inspectorate shall be responsible for the market supervision according to § 7 (1) of the Czech Product Safety Act if the powers of the supervisory authority cannot be determined in the usual "product-based" way. From a consumer point of view, a one-stop - last resort authority could be a more suitable solution for product safety issues, because the information and alerts of several authorities could be collected in one platform.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*54*	*219*	*273*
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*8*	*49*
Total (country)	***54***	***227***	***281***
Of which staff allocated to market surveillance activities regarding products sold online	*4*	*4*	*4*

Notes: Data for 2018, source: Ministry of Industry and Trade

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)

Total number of inspections	**9 951**	**2 276**	**12 227**
Total number of consumer products inspected	14 032	3 046	17 088
Total number of consumer products tested in laboratories	593	327	920
Total number of consumer products inspected in cooperation with the customs	n.a.	50	50
Total number of dangerous consumer products found	151	5	156
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	91	1	92
Notes:	*Data for 2018, source: Ministry of Industry and Trade*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	130	2	132
Total number of mandatory recalls	23	4	27
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	30%	100%	30%
Notes:	*Data for 2018, source: Ministry of Industry and Trade*		

D. Key sources

Legislation	- Act No. 102/2002 Coll. on General Product Safety, last amendment by Act No.183/2017 Coll. - Act. No. 22/1997 Coll. on Technical Requirements for Products, latest amendment by Act No. 277/2019 Coll. - Act No. 634/1992 Coll. On Consumer Protection, latest amendment by Act 179/2019 Coll. - Act No. 64/1986 Coll. on Czech Trade Inspection - Act No 258/2000 Coll. on Protection of Public Health - Act No. 282/1991 Coll. on Czech Environmental Inspection - Act No. 255/2012 Coll. on Control - Act. No. 500/2004 Coll. on Administrative Proceeding - Act No. 350/2011 Coll. on Chemical Materials - Government Regulation No. 396/2004 on Procedures, Content and Form of Information on the Occurrence of Dangerous Non-Food Products
Studies/reports/articles	KOUKAL, Pavel (2010) K povinnostem vyplývajícím ze zákona o technických požadavcích na výrobky (The obligations arising from the Act on Technical Requirements for Products), In: Právní rádce, Praha, Vol. XVIII, No. 5 (2010), p. 45-48 PRŮŠOVÁ, Eva (2013) Novela zákona o technických požadavcích na výrobky (Amendment to the Act on Technical Requirements for Products), In: Stavební právo, Praha, Vol 18, No 2 (2013), p. 1-5. KLABUSAYOVÁ, Naděžda (2016) Zákon o obecné bezpečnosti výrobků – Zákon o požadavcích na výrobky (General Product Safety Act - Product Requirements Act) – Commentary, Praha: Wolters Kluwer CR, 2016 p.1-244.

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Websites	https://www.mpo.cz/cz/ochrana-spotrebitele/bezpecnost-vyrobku/ https://www.coi.cz/pro-spotrebitele/rizikove-vyrobky/ http://www.cizp.cz/Vyrobce-nebezpecnych-chemickych-smesi-dostal-od-inspektoru-CIZP-pokutu-140-tisic-korun.html https://www.khspce.cz/category/nebezpecne-vyrobky-archiv/ https://www.mzp.cz/cz/nebezpecne_latky_stavebni_vyrobky https://www.dtest.cz/nebezpecne-vyrobky
Interviews	Ministry of Industry and Trade and RAPEX National Contact Point Czech Trade Inspection Ministry of Health of Czech Republic, Regional Hygiene Stations Czech Environmental Inspectorate

7. Denmark

COUNTRY REPORT DENMARK

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The current legislation on product safety in Denmark is the Consolidation Act no. 3 of January 3, 2019 on Product Safety, which consolidates Act No. 1262 of December 16, 2009 on product safety with the amendments that follow from Sec. 53 of Act No. 1231 of December 18, 2012 and Sec. 42 of Act No. 525 of April 29, 2015. The purpose of the new consolidation act is to bring the formulations more in line with the GPSD and the requirements of regulation (EC) No. 765/2008 of July 9, 2008 on the requirements for accreditation and market surveillance for the marketing of products. However, the act does not introduce any substantial changes to how the law has been administrated so far. The new law explicitly only covers consumer goods (which is in line with the previous administration of the law). Furthermore, there has been a clarification of the powers of the surveillance authorities to reflect the seriousness of the product safety risks as well as an increased focus on market surveillance and control (e.g. a right to enter publicly accessible rooms without a court order). This is supported by a special regulation on the collaboration and coordination between authorities and economic operators, see Order no. 545 of May 29, 2017 on the Assignment of Powers to the Security Agency, and Order no. 243 of March 16, 2012 on notification, cooperation and coordination relevant to consumer products between producers, distributors and control authorities and on the application of the Community system for the rapid exchange of information. According to the act and orders, the supervisory authorities are under the obligation to collaborate and coordinate in order to conduct proactive market surveillance programs. Furthermore, there are special regulations on toys and other products that can be confused with food products or toys.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Denmark

The Consolidation Art. 9 implements GPSD Art. 5(1). In line with the GPSD the Consolidation Act has no general mandatory requirement for producers nor distributors to indicate the name and contact details of the producer or distributor on the product or its packaging, or to include electronic identification or barcodes. The Consolidation Act only requires that the producer or distributor may indicate the name and contact details or product reference or, where applicable, the batch of products to which it belongs, on the product or its packaging, if this is necessary in order to trace and recall the products or batch of products. Thus the producer or distributor may choose not to indicate name etc., if there are other adequate measures to trace and recall products. According to the Consolidation Act sec. 10, distributors must keep records that enable the traceability of products in the products lifespan, however not longer than 5 years from the ending of the accounting year the distributor acquired the product.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

No, the safety of new technologies is subject to the general rule on the definition of safety in Sec. 4 of the 2019 Consolidation Act on Product Safety.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Although the surveillance authorities express some doubts as to whether these emerging risks are adequately covered, it is most likely that the safety of new technologies is subject to the general rule on the definition of safety in the Sec. 4 in the 2019 Consolidation Act on Product Safety. In the case of a cybersecurity/software related risk, the supervisory authorities will contact the police as well.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

If no European standards in the EU Official Journal exist, other European standards, national standards, international standards outside EU, Commission recommendations and the RAPEX online risk assessment tool will be applied, all in light of the reasonable consumer expectations on product safety, cf. Sec. 4 of the 2019 Consolidation Act on Product Safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Denmark in case there are consumer product(s) on the market which are found unsafe under the GPSD

In the case of unsafe products, the surveillance authorities may require the business to provide relevant information on the product(s), information on the supply chain and the distribution of the product(s), information to ascertain the ownership of websites, carry out unannounced on-site inspections and physical checks of products, and block websites if required. Furthermore, they may require economic operators to recall products and perform other corrective measures (such as restrictions on the placing of products on the market or bringing products into compliance, stopping products from being placed on the market, withdrawal of products, etc.) The surveillance authority may also reclaim the costs of administrative activities with respect to the unsafe product(s) (e.g. for testing, storage, destruction etc.). However, in practice this is only used when mandatory measures are imposed on the economic operator. It is expected that the surveillance authorities may be allowed to use mystery shopping in an upcoming revision of Chapter 4, Sections 13-29 of the 2019 Consolidation Act on Product Safety (on market surveillance). This revision will also improve the powers to shut down websites as well as raise the levels of penalties imposed when economic actors violate the regulation.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

According to Sec. 35 of the 2019 Consolidated Product Safety Act, the sanctions for violating the Consolidated Product Safety Act are penalties (fines) unless a higher penalty is to be paid under other legislation. Reference is mainly made here to section 188 (1) of the Criminal Code. 1, no. 2, and Chapter 25 crimes against life and body.[141] The police is in charge of evaluating and issuing penalties (fines) which must be proportionate to the danger the violation of the rules has resulted in. In addition, repeated violation of the rules as well as the company's turnover could be considered when measuring the penalty. The fines also depend on whether the Product Safety Act is intentionally or negligently violated, e.g. if the product has been marketed even though the economic operator knew that it was dangerous. Anyone who, intentionally or through gross negligence, or repeatedly, fails to comply with an injunction or violates a prohibition, is fined. Fines are also applied if the operator responsible for incorrectly affixing a CE marking is instructed to remove the mark within a specified period and this is neglected. A fine can be set for a person who wilfully, or by gross negligence, does not send the inspection authority the information it requires. A fine may be imposed on producers and distributors who do not comply with the obligation to store and disseminate information that is needed to track the origin of the products. Producers and distributors may be fined for failure to report to the control authorities if they know that a product, they have made available on the market does not meet the general safety requirements. The fines can be from 2 000 to 5 000 euros or more. (The Danish Safety Technology Authority has not seen an infringement of the GPSD in the past 2 years that has led the Authority to ask the police to open a criminal court case.) The Danish Government has just announced that the penalties awarded by the police are insufficient, and that a general increase in the level of fines should be implemented by the next revision of the Consolidated Product Safety Act, raising the fines up to 10 000 euros.

Recent case law in Denmark with respect to or relevant for the GPSD/the national implementation legislation.

In the single case known in connection with the Product Safety regulation was reported in the Danish Weekly Law Journal U.2000.679S, the question concerned whether the presentation of a tea light lamp, which on the shop signs was designated as a "tea light lamp" (fyrfadslampe) for hanging, sufficiently warned the consumer that only low tea lights with a height of not more than 17 millimetres could be used (usually bags of such tea lights are sold in supermarkets, etc.). One consumer had complained that the lamp had fallen down because a solder in the lamp's suspension had melted as a result of the use of a light stub of approx. 50 mm in height. The surveillance authority issued an injunction and prohibited the sale until adequate information was given. This injunction was upheld by

[141] *Forbrydelser mod liv og legeme.*

the court as a proportionate measure in light of the need for a high level of protection, and that the risk could be easily avoided by correct information (markings on products or packaging or signs in the shops). The decision showed that since consumers could reasonably expect that the concept of a tea light lamp would encompass all other types of candles, and since the ordinary consumer does not think too deeply about the risks of lit candles and is able to put all possible candles into the lamp, which created a risk of heating the solder such that the lamp could fall down and cause a fire, the consumer had to be warned separately.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Denmark concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

It is sometimes difficult for the surveillance authorities to identify the role of the economic actor on the marking of products and the information in the technical documentation. The surveillance authority finds that the definition of safety in the GPSD seems too wide or too general and lacks clarity. The existence of harmonised standards helps define the safety levels and so does the RAPEX risk assessment tool. Emerging issues around safety are seen with childcare articles (e.g. bay nests and bed boundaries) and electrical appliances and equipment outside the Low Voltage Directive (Lithium Ion batteries).

Possible improvements to make the implementation of the GPSD in Denmark more effective

It would help if it were required to display information about the producer, CE marking and warnings together with the product on websites. It would allow for a quicker and automated initial screening (digital WebCrawler) of the products, allowing the authorities to focus on those companies that fail to provide the correct marking of products. Mystery shopping and increased levels of penalties are also areas for improvement which are currently being considered by the legislators.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Denmark.

Market surveillance in Denmark for the vast majority of consumer products is the responsibility of the Danish Safety Technology Authority. The Authority is responsible for enforcing the following directives and regulations:

- GPSD
- Toys Directive (in cooperation with the Danish Environmental Protection Agency which enforces the chemical requirements)
- Personal protective equipment directive
- Construction products directive
- Aerosol dispensers directive
- Simple pressure vessels directive
- Transportable pressure equipment directive
- Machinery directive
- Lifts directive
- Cableway installations directive
- Equipment for explosive atmospheres directive (ATEX)
- Pyrotechnic articles directive
- Explosives for civil use directive
- Gas appliances directive
- Measuring instruments, weighing instruments, etc. (several directives)
- Low voltage directive
- EMC directive
- Radio equipment directive
- Eco-design and energy labelling directive, labelling of tyres
- Recreational craft directive

- Motor vehicles and tractors directive

There are a few other national authorities, first and foremost the Danish Environmental Protection Agency (which deals with chemicals and environmental issues) and the Consumer Agency.

There is no market surveillance organised on a sub-national level (due to the small size of the country).

Plans/programmes in place which define priorities for market surveillance of consumer products

Both the Danish Safety Technology Authority and the Danish Environmental Protection Agency have annual plans or work programmes in place.

These are based on several sources including results from inspections in former campaigns or activities, RAPEX notifications, complaints from consumers, accident reports, information from customs, information from business associations or consumer organisations as well as reports from media or the political level. The plans include participation in EU coordinated actions and projects.

Customs have allowed room in their plans for following up on cases notified by the authorities and for monitoring imports of product groups identified by the authorities as being “of interest”.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Denmark with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Products containing new technologies are checked like any other kind of products if they fall in a product group that will be targeted. There is no special focus on products containing new technologies.

The Danish Safety Technology Authority sources most of their samples from online traders. Moreover, the Authority monitors platforms and other websites offering products for sale. This includes the purchase of products from online traders in non-EU/EEA countries that market their products to Danish consumers. What is important for the Authority is whether the product falls in a product group that meets the criteria laid down in a given year’s risk profile. Enforcement of goods from non-EU/EEA country sellers is handled according to the Product Safety Pledge.

Regarding C2C sales, the Danish Safety Technology Authority has taken the approach that any form of sales from one party to a consumer will make the selling party a business operator in the meaning of the law. The Danish Environmental Protection Agency has experienced a few cases where consumers sell prohibited chemicals or substances to each other using Facebook or other social media to get in contact.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The Danish Environmental Protection Agency also frequently inspects websites as part of its inspection activities. These inspections are split almost evenly across Danish, EU and non-EU/EEA websites. Danish and EU websites are inspected to enforce the legislation, whereas inspections on non-EU/EEA websites are undertaken in order to gain knowledge about "what is out there".

None of the authorities use “Mystery Shopping”. It is (currently) illegal according to Danish law.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Denmark (except customs) with respect to product safety

The authorities cooperate regularly (i.e. monthly) with each other. This is supplemented with ad hoc cooperation when necessary. Cooperation takes place using several channels, e.g. regular exchange of information, regular meetings and informal cooperation.

Cooperation with customs authorities in Denmark with respect to product safety

Both the Danish Environmental Protection Agency and the Danish Safety Technology Authority cooperate very frequently with customs - more than once a week.

Both authorities have a formal agreement with customs. In addition to this, they have developed joint processes, they regularly exchange information, they meet regularly, and they exchange information informally when necessary.

The Danish Safety Technology Authority and customs have spent time together to establish a common understanding of the risks and a common risk profile. Moreover, they have developed checklists for customs which can be used by the inspectors in their practical controls.

The Danish Environmental Protection Agency have given customs a list with "alert points" that will prompt customs to contact the Agency. Their experience is that the TARIC codes are often less useful when it comes to stopping risky goods because the categories are very broad. (If the Agency wants to look for e.g. "dolls", that category does not exist. It is part of the much broader category of "toys".) The Agency's experience is that it is far better to base the screening on customs' routine scanning of goods with e.g. x-ray.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The main vehicle for practical cooperation with authorities in other EU countries is the RAPEX system and the ICSMS system with its "pass the baton" feature. The Danish Safety Technology Authority indicated that they often try to contact the economic operator in the other country directly to discuss the case. If this is not successful, they will contact the authority in that country for help.

Both the Danish Safety Technology Authority and the Environmental Protection Agency indicate that they cooperate with authorities in other countries on a monthly basis. The main tools are RAPEX, ICSMS, the Confluence wiki, joint trainings and formal/informal meetings. This is supplemented with regional (i.e. Nordic) meetings with authorities from the other Nordic countries.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Both authorities have systems and methods in place to ensure that unsafe products are notified via RAPEX as rapidly as possible. This normally means a couple of days. However, it may take time to determine whether a product is unsafe; the investigations and tests may be time-consuming and the legal processes take time.

Both authorities enter information about dangerous products directly into RAPEX. If the information comes from the Danish Environmental Protection Agency, it will be checked by the Danish Safety Technology Authority in its capacity as the national RAPEX contact point for Denmark.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Both authorities involve stakeholders (business organisations) in their work:

The Danish Environmental Protection Agency consults business organisations when new legislation is being passed. Moreover, they meet with the industry in different fora (e.g. for toys, HFC gases, cosmetics, etc.). The flow of information goes both ways – the Agency receives feedback and comments from the industry, and the Agency informs or advises the industry.

The Danish Safety Technology Authority also meets with the industry regularly (monthly). This includes formal as well as informal meetings. The Authority may also involve the industry when they are developing new approaches to issues. One example mentioned was the recent development of an approach for the surveillance of online traders. Moreover, the Danish Safety Technology Authority have implemented a new regular market surveillance activity called "company-based market surveillance" where they visit companies to discuss issues related to compliance ("compliance assistance").

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Both authorities use tools like press releases, publishing of unsafe products on their websites and information campaigns in traditional media as well as on social media.

The Danish Environmental Protection Agency has furthermore participated in the development of a number of applications for consumers where the user can scan the barcode of a product and immediately get access to

various information about the contents and dangerous chemicals in the product.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Denmark (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

The common practice in both authorities is to encourage business to take action "voluntarily", and both authorities are prepared to impose mandatory measures when necessary.

The Danish Environmental Protection Agency requests the economic operator to produce a recall plan. The plan has to be approved by the Agency. It shall describe what the economic operator will do to recall the product, which communication channels will be used, what messages will be given, what the timeline will be, how recalled products will be handled (destroyed), etc. The Agency does not have a "best practice guide" as such, but the letter imposing the measure on the economic operator includes a number of "recommendations" on how to conduct the recall. The economic operator will normally follow these.

The Danish Safety Technology Authority asks the economic operator to provide an overview of the messages that will be given to the consumers, lists of economic operators involved in the supply chain, the timeline and the recall effectiveness. The Authority has a section in its website about recalls and how to conduct them.[142] The Authority refers to the Blue Guide and the website has links to the Recall Guide from PROSAFE and the European Commission's guidelines[143]. Moreover, the Authority links to the Business Alert Gateway[144] and runs campaigns for businesses on how to recall an unsafe product.

Both authorities "assist" the recall by communicating information about the recall to consumers. This goes out via their websites, but also via social media if this is found to be useful.

Monitoring of effectiveness of product recalls by market surveillance authorities

The two authorities follow up in different ways:

The Danish Safety Technology Authority requires the economic operator to provide information about the number of items that have been returned by customers. They then evaluate the number and share of products recalled. Spot checks may be relevant for certain product categories, e.g. fireworks.

The Danish Environmental Protection Agency normally follows up by undertaking spot checks in shops.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Denmark that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Both authorities produce an annual report about their activities that include statistics on the number of cases, number of infringements, number of recalls, etc.

Both authorities also operate schemes where consumers can report unsafe products:

The Danish Safety Technology Authority runs a web-based system through a "button" on the website that gives the consumer access to a form where unsafe products can be reported.[145] It is also possible for a consumer to report unsafe products on the telephone. Either way, the complaint ends up in the Authority's market surveillance information system.

The Danish Environmental Protection Agency operates two platforms depending upon the type of complaint. One platform is used for reporting potentially illegal chemicals and products.[146] Another platform is used for consumers to report incidents and injuries that may be caused by chemicals or cosmetics. On top of this, the Agency cooperates with the Danish hospital in Bispebjerg that operates the "poison line" which records all kinds of poisoning including poisoning caused by chemicals.

[142] See: https://www.sik.dk/erhverv/produkter/vejledninger/generelle-vejledninger-om-produkter/tilbagetraekning-og-tilbagekaldelse-produkter
[143] See: https://www.sik.dk/erhverv/produkter/vejledninger/generelle-vejledninger-om-produkter/sadan-tilbagekalder-du-farligt-produkt
[144] See: https://www.sik.dk/erhverv/produkter/vejledninger/generelle-vejledninger-om-produkter/hvad-gor-jeg-hvis-jeg-har-solgt-farligt-produkt
[145] See: https://www.sik.dk/farlige-produkter
[146] See: https://mst.dk/kemi/tilsyn-og-haandhaevelse/indberet-mulige-overtraedelser/

The sources that provide injury data are product-specific injury databases (e.g. the annual statistics on fireworks accidents), the fire brigade registers, the occupational safety registers, systems for recording accidents with cosmetics or chemicals as described above, and others.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Denmark (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The overall impression from both authorities is that the market surveillance works "pretty well". However, it is noted that the emergence of online trade has disrupted the whole market surveillance process and left the authorities with some challenges when it comes to methods and tools that can be used to intervene in the sales process. Both authorities have used the "Product Safety Pledge" and find it to be a very useful tool that has solved several issues.

The Danish Safety Authority also indicates that it would be helpful to require that online traders display the CE-marking and the mandatory warnings together with the product. This would allow for an easier screening of products presented on websites through the use of automatic tools ("WebCrawler").

Areas to make market surveillance of consumer products in Denmark/the EU more effective

In general, the impression is that market surveillance in Denmark works well. The authorities seem to be well aware of the issues related to online trade and they try to cope with them as best they can.

The idea of requiring traders to display the product's marking (CE-marking, identification of manufacturer, product name, type name, etc.) next to the product on the website is worth pursuing as it can potentially enable the automatic screening of products offered for sales online.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Denmark since 2013

The general impression is that the safety level is unchanged or has increased. The Danish Safety Technology Authority notes however that the increasing sales of low-cost products may have had an adverse effect on the safety level.

This is based on "gut feelings" as the market surveillance process has changed so much in the period that it is impossible to compare numbers from "before" and "after".

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Denmark whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Both authorities find that they have the tools in place they need.

The Danish Safety Technology Authority is developing a WebCrawler solution that shall help identify online sellers of products notified via RAPEX or subject to a safeguard clause. The idea is that the WebCrawler shall deliver a list every week with addresses of websites that sell the concerned products.

The project application was recently approved by the European Commission that will support the project financially. Currently 14 Member States participate in the project.

The Danish Environmental Protection Agency is involved in developing an image recognition tool that can be used to check whether an unsafe product appears to be sold in other online shops.

Views of market surveillance authorities whether approaches in Denmark can be considered best practice implementation of the GPSD, which could be of interest to other countries

The Danish Safety Technology Authority has developed an approach called "Strakskontrol" ("immediate inspection"). The idea is that the inspector can settle a case immediately after inspection and submit the conclusion

in an electronic letter to the economic operator. It is applied in the company-driven surveillance approach.

The way that it works is that the inspector brings an iPad tool to the company and checks markings on products on the spot. It is also possible to check technical documentation on site and immediately decide whether it is necessary to sample products for testing. The iPad tool is linked to the Authority's document management system, meaning that all records are updated automatically. It also means that requests for e.g. more documentation can be delivered immediately to the economic operator.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*4.3*	*32.5*	*36.8*
Total (country)	***4.3***	***32.5***	***36.8***
Of which staff allocated to market surveillance activities regarding products sold online	n.a.	n.a.	n.a.
Notes:	*Data are estimated for 2020 for the Danish Safety Technology Authority* *No data are available regarding Number of staff (FTE) working with online trade*		

B. Number of <u>inspections</u> of consumer products (2018)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**approx. 400 *)**	**approx. 100 *)**	**approx. 500 *)**
Total number of consumer products inspected	approx. 2.200	approx. 300	approx. 2.500
Total number of dangerous consumer products found	approx. 450	approx. 80	approx. 520
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	20 **)	23 **)	43 **)
Notes:	*All figures are combined from the Danish Safety Technology Authority and the Danish Environmental Protection Agency unless otherwise indicated.* **) figures for Danish Environmental Protection Agency only* ***) figure for the Danish Safety Technology Authority only*		

C. Number of <u>recalls</u> of consumer goods (2018)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	44	18	62
Total number of mandatory recalls	3	0	3
Notes:	*Figures for the Danish Safety Technology Authority only.*		

D. Key sources	
Legislation	Consolidation Act no. 3 of January 3, 2019 on Product Safety, which consolidates Act No. 1262 of December 16, 2009 on product safety with the amendments that follow from Sec. 53 of Act No. 1231 of December 18, 2012 and Sec. 42 of Act No. 525 of April 29, 2015 and Order no. 545 of May 29, 2017 on the Assignment of Powers to the Security Agency, and Order no. 243 of March 16, 2012 on notification, cooperation and coordination relevant to consumer products between producers, distributors and control authorities and on the application of the Community system for the rapid exchange of information.
Websites	The Danish Safety Technology Authority: www.sik.dk The Danish Environmental Protection Agency: www.mst.dk The Danish Customs: www.toldst.dk
Interviews	The Danish Safety Technology Authority The Danish Environmental Protection Agency Danish Customs

8. Estonia

COUNTRY REPORT ESTONIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Estonia, the General Product Safety Directive is implemented by the Product Conformity Act (hereinafter PCA, entered into force 01.10.2010) and by Regulation No 122 of the Government of the Republic, dated 26.08.2010, the Procedure for Notifying European Commission of Restrictions on Placing on Market of Products (entered into force 01.10.2010).

The PCA is a result of revision and systematisation of norms which previously were included in three separate acts (Product and Service Safety Act, Technical Norms and Standards Act and Product Conformity Certification Act).

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Estonia

Article 5(1) of the GPSD is implemented almost verbatim by article 11 of the PCA which states the following:

§ 11. Obligations of manufacturers

(1) Manufacturers provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

(2) The presence of warnings does not exempt any manufacturer from compliance with the other requirements laid down in this Act.

(3) Manufacturers take measures commensurate with the characteristics of the products they supply, enabling them to:
1) be aware of risks these products might pose;
2) choose to take appropriate action to avoid these risks, such as withdrawal of the products from the market, warning consumers or recall of the products from consumers.

(4) The measures referred to in subsection (3) of this section include:
1) an indication, by means of the product or its packaging, of the identity or trademark and contact details of the manufacturer, with reference to the type, batch or serial number of the product or another mark, except where not to give such information is justified;
2) the carrying out of sample testing of products placed on the market and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring;
3) other relevant measures.

(5) Action such as that referred to in clause (4) 2) of this section is undertaken by the manufacturer on a voluntary basis or at the request of the market supervision authority.

(6) Where other measures laid down in this Act do not suffice to prevent the risk, a product will be recalled from a consumer if:
1) the manufacturer considers it necessary, or
2) the market supervision authority orders the manufacturer to do so.

(7) If the manufacturer is not established in the European Union, the provisions of this section apply to the manufacturer's representative. If the manufacturer does not have a representative in the European Union, the provisions of this section apply to the importer.

The list of traceability measures in PCA is not exclusive (as indicated by article 11 section 4, point 3) and can thus be considered as an example of relevant measures. More detailed (and binding) requirements on packaging or labelling of products are often provided in other legal acts.

In a similar manner, Art 5(2) of the GPSD has been implemented by article 12 of the PCA:

§ 12. Obligations of distributors

(1) Distributors act with due care to ensure the conformity of products with requirements. Distributors must not make any products available on the market:
1) that they know, on the basis of the information in their possession and as professionals, are not safe;
2) that they know, on the basis of the information in their possession and as professionals, do not comply with the requirements, or
3) whose non-conformity with requirements should have been foreseen.

(2) To avoid these risks, distributors, among other things:
1) within the limits of their respective activities, participate in monitoring the safety of products placed on the market;
2) pass on information on product risks to the manufacturer;
3) keep the documentation necessary for tracing the origin of products.

There are no legal norms requiring application of barcodes as a traceability measure.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

According to article 6 section 3 point 5 of the PCA, the state of the art of science and technology is one of the criteria to be taken into account when assessing product safety in the absence of EU rules or standards. However, so far no specific definition of safety has been applied specifically in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

So far, the Estonian legislation does not contain specific provisions concerning emerging threats related to new technologies. The existing provisions of the PCA are sufficiently abstract to cover all possible threats, including those that may emerge in the future.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

In the absence of European standards, article 6 section 3 of the PCA refers to the following criteria for assessment of safety:

1) The standards of the European standardisation bodies adopted by Estonia, which are not harmonised standards;

2) Original Estonian standards;

3) Recommendations of the European Commission which contain guidelines for the assessment of product safety;

4) The best practices in product safety in the specific industry;

5) The state of the art of science and technology;

6) The reasonable expectations of consumers regarding safety.

Experts have also referred to international standards and/or standards from non-EU/EEA countries as one of the relevant criteria in assessing the safety of a product.

On 21.06.2017, the administrative chamber of the Tallinn Circuit Court in its decision in administrative matter no. 3-16-861 confirmed that if the product is in conformity with the requirements arising from an EU directive (Directive 2014/35/EU in this particular case), its safety can be assumed. National standards cannot be regarded as additional requirements to those arising from the EU directive but merely alternative requirements which are to be applied only in the absence of relevant EU standards.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Estonia in case there are consumer product(s) on the market which are found unsafe under the GPSD

Pursuant to article 54 section 1 of the PCA, the market supervision authority has the right to check the required

extent of safety and conformity of each product placed on the market before the product has reached the end-consumer as well as in cases where the product has been placed on the market as a conforming and safe product.

Administrative measures which the market surveillance authorities may take include the following:

A. General measures listed in the Law Enforcement Act (LEA):
    a. questioning and requiring of documents (article 30 of LEA);
    b. summons and compelled attendance (article 31 of LEA);
    c. establishment of identity (article 32 of LEA);
    d. examination of movable property (article 49 of LEA);
    e. entry into premises (article 50 of LEA) - the market supervision authority may enter the premises where a product is made, stored or offered for sale;
    f. examination of premises (article 51 of LEA);
    g. taking into storage of movable property (article 52 of LEA)

B. Specific measures listed in the PCA:
    a. test transaction (PCA article 54, sections 3-7). The official making a test transaction does not have to introduce themselves upon making the transaction, wear a uniform or present their identification before attaining the purpose of the test transaction;
    b. publication of information concerning the risks arising from products and information regarding identification of products, the characteristics of the risk arising from products, and the measures taken (PCA article 55 section 1);
    c. obliging economic operators to disclose information about the risks arising from a product (PCA article 55 section 2);
    d. if a product may pose a risk under certain conditions, demand that it be labelled with clear warnings in Estonian about the risks that the product may cause or establish prior conditions to placing the product on the market, which ensure safety (PCA article 56 section 2 p 1);
    e. if a product may pose a risk to certain persons, demand that these persons are warned of the risk in a suitable manner and at a suitable time, including by publishing separate warnings (PCA article 56 section 2 p 2);
    f. if a product may be dangerous, demand the temporary withdrawal of the product from the market or prohibit the presentation of the product for a period that is necessary for assessment and checking of its safety (PCA article 56 section 2 p 3);
    g. prohibit the placing of a product on the market and take measures that ensure compliance with the prohibition (PCA article 56 section 2 p 4);
    h. demand and organise the immediate withdrawal of a dangerous product from the market (PCA article 56 section 2 p 5);
    i. demand, coordinate and organise jointly with economic operators the recall of a dangerous product from consumers and, where necessary, the destruction of the product. A product must be recalled from consumers if other measures are insufficient (PCA article 56 section 2 p 6);
    j. obtain samples of products placed on the market from economic operators free of charge for the purpose of checking their safety or conformity and, where necessary, commission an expert assessment in order to identify the safety or conformity of products. If it is established that the product is not safe or does not conform to the requirements, the economic operator will pay the documented costs of the expert assessment (PCA article 56 section 7);
    k. in the event of a serious risk, the Tax and Customs Board, with the approval of the appropriate market supervision authority, has the right to prohibit making the product available on the market or exporting the product (PCA article 56, section 5).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other

relevant provisions (types of penalties, their level/amount)

Market surveillance authorities may apply

a) a penalty payment or

b) administrative penalties (fines which are imposed in misdemeanour proceedings).

A penalty payment is an amount of money which the addressee has to pay if it has failed to perform the obligation imposed by a rule of an administrative authority. This measure may be applied repeatedly until the objective sought by a rule is achieved, and pursuant to the Substitutive Enforcement and Penalty Payment Act, it is not deemed to be a punishment. The maximum amount of penalty payment which may be imposed under the PCA is 10 000 euros (PCA article 58 section 5).

Administrative penalties which may be applied by the Consumer Protection and Technical Regulatory Authority, the Health Board, the Maritime Administration, the Agricultural Board, and the Environmental Inspectorate are the following (PCA articles 59-61):

1) The penalty for violation of the conditions of placing a product on the market or making a product available on the market is a fine of up to 300 fine units[147]; the penalty for the same act committed by a legal person is a fine of up to 3 200 euros;

2) The penalty for failure to give notice of risks arising from products already placed on the market is a fine of up to 200 fine units; the penalty for the same act committed by a legal person is a fine of up to 2 000 euros;

3) The penalty for the misuse of a conformity marking is a fine of up to 200 fine units; the penalty for the same act committed by a legal person is a fine of up to 2 000 euros.

The administrative penalties (fines) are not very often applied in practice (for instance, during the last two years, the Consumer Protection Board has imposed fines on two addressees only). Instead, the authorities prefer to impose the penalty payments described above, and this type of measure is applied much more often.

As indicated above, the penalty payment may be applied repeatedly and thus it may turn out to be more efficient than fines. Another reason for preferring the penalty payments by the authorities may be the simplicity and speed of the administrative procedure in contrast to the misdemeanour procedure to be followed in imposing fines.

For small enterprises, the obligation to remunerate the costs for testing the product is often a sufficient disciplinary measure which positively affects the future practices of that entrepreneur.

Recent case law in Estonia with respect to or relevant for the GPSD/the national implementation legislation.

In Estonia, product safety issues are usually solved in the course of administrative procedures applied by the market surveillance authorities. Therefore, the court practice on product safety issues is rare. Recent case law includes the following:

1) Based on RAPEX notification no A12/0861/16 concerning children's car seats with the fastening mechanism type E8 04 44596 and sold under a certain trademark, the Consumer Protection and Technical Regulatory Board in 2018 requested an Estonian entrepreneur to recall the car seats with the same fastening mechanism but sold under a different trade mark. The entrepreneur refused to recall the products and pay the penalty payments, arguing that the product under the dispute differs from the one mentioned in the RAPEX notification. On 29.04.2019, the Tallinn Administrative Court decided in the administrative matter no 3-18-1801 that both types of car seats did not differ significantly and the product sold in Estonia must therefore be recalled. It also found that the measures requested by the Consumer Protection and Technical Regulatory Board were appropriate and enough time (3 weeks) was given for taking the measures, and the amount of the penalty payment (8 000 euros) imposed on the addressee was reasonable and justified.

2) On 29.06.2018, the administrative chamber of the Tallinn Circuit Court made a decision in the administrative matter no 3-16-1698. In 2013, the Technical Regulatory Board had issued a prescript on temporary withdrawal or presentation prohibition of a product (certain polystyrene foam boards) for a

[147] One fine unit = 4 euros (article 47, section 1 of Penal Code)

period of assessment of its safety under PCA article 56 section 2 p 3. In addition, the Board published this information on its website and sent letters to the professional unions concerned, informing them of the prohibition. The entrepreneur demanded compensation for damages suffered because of the decrease in turnover. The court found that the temporary withdrawal of a product is not unlawful and therefore publishing information concerning that measure cannot cause a damage which should be compensated under the State Liability Act.

3) In the court practice, there have been disputes regarding the question as to who has the right to request the regulatory authority to check the safety of a product and challenge the outcome of that process. On 18.12.2017, the Tallinn Administrative Court in the administrative matter no 3-17-990 had to establish the scope of persons who have the right to file complaints regarding product safety. The court stipulated that it is important to refer to the relevant EU legislation, since the PCA is based on EU law, and assess more broadly the general objectives of establishing conditions for the marketing of products (and hence market surveillance) in the European Union. The court referred to p. 17 of the decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products which states that "products that are placed on the Community market should comply with the relevant applicable Community legislation, and economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and of the environment, and to guarantee fair competition on the Community market". The court concluded that the tasks of the Technical Regulatory Board in its capacity of market surveillance authority include both the protection of the public interest and the protection of the market operators against unfair competition. This means that an entrepreneur may challenge the findings of the market surveillance authority with the purpose of preventing dangerous (and cheaper) products being imported by the competing entrepreneur.

4) On 21.06.2017, the administrative chamber of the Tallinn Circuit Court in its decision in administrative matter no 3-16-861 focused on two issues. Similarly to the dispute mentioned above, the court decided that an entrepreneur who imports and sells certain products (electrical cables) has the right to request the supervisory authorities to investigate the safety of a product imported by a competing entrepreneur. In addition, the court found that if the product is in conformity with the requirements arising from an EU directive (Directive 2014/35/EU in this case), its safety can be assumed. In that case, the national standards cannot be regarded as additional requirements but merely alternative requirements which are to be applied only in the absence of EU standards.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Estonia concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

In practice, there are cases where information on the manufacturer, the model number or other relevant details can be found only on the packaging of the product but not on the product itself. This means that after the removal of packaging, the information may get lost, which in turn may impede conducting an expertise or recalling the product from the market.

Also, there have been problems in the process of assessing the conformity of a product with the required standards and norms in cases where the documents concerning the product appear to be manipulated (for example, different fonts used in the text regarding technical information). There have been cases where the origin or correctness of the documents raises doubts, but the experts do not have competence and skills necessary to prove the forgery of the documents.

Possible improvements to make the implementation of the GPSD in Estonia more effective

Estonian legislation does not permit the market surveillance authorities to conduct mystery shopping. This has been pointed out by the experts as an impediment to effective implementation of product safety on the market.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Estonia.

In Estonia, market surveillance is conducted on a sector-by-sector basis and the surveillance activities are exercised

by seven authorities which are allocated to four ministries:

1) Ministry of Economic Affairs and Communications (Consumer Protection and Technical Regulatory Authority, Road Administration, Maritime Administration);
2) Ministry of Social Affairs (Health Board, Labour Inspectorate);
3) Ministry of Rural Affairs (Agricultural Board);
4) Ministry of Environment (Environmental Inspectorate).

Market surveillance authorities cooperate closely with the Tax and Customs Board[148] in order to prevent non-compliant products from reaching the EU internal market.

In 2019, the Consumer Protection Board and the Technical Regulatory Authority were merged into one institution (the Consumer Protection and Technical Regulatory Authority).[149] The objective of the merger was to improve the effectiveness of market surveillance. In the process of merging, the competences and responsibilities of both authorities as well as the possible overlap of tasks with other authorities was analysed and changes were made on the basis of this analysis. For example, the surveillance tasks in the field of personal protective equipment were moved from the Labour Inspectorate to the Consumer Protection and Technical Regulatory Authority.

In order to reduce duplication of competences of public bodies, the Ministry of Economic Affairs and Communications will in 2020 conduct an analysis regarding the merger of authorities engaged in supervision of transportation matters.

Plans/programmes in place which define priorities for market surveillance of consumer products

The priorities for market surveillance of consumer products are based on yearly market surveillance programmes drawn up by the Ministry of Economic Affairs and Communications in cooperation with the Environmental Inspectorate, the Road Administration, the Agricultural Board, the Consumer Protection and Technical Regulatory Authority, the Health Board, the Labour Inspectorate and the Maritime Administration.

In drafting the market surveillance plans, different sources of information are used, for example analysis conducted on the basis of RAPEX notifications, information received through ICSMS, surveillance outcomes of the Estonian authorities, laboratory testing results, market surveillance projects (PROSAFE), complaints, questions and information received from consumers and businesses, information concerning accidents (for example, poisoning), problems dealt with in the mass media, and information retrieved from social media (for instance, on newest trends in the consumer goods market, etc).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Estonia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

No special market surveillance activities can be mentioned with respect to products containing new technologies.

As to the products sold online, the experts do conduct regular surveillance activities on products offered for sale in the web shops (checking the existence of warnings, testing the products).

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Many regular shops also sell their products in their web shops. Where that is the case, the experts prefer inspections on site. In their statistics of inspections, the authorities do not distinguish between activities concerning products sold online and products sold in traditional shops. The experts of the Consumer Protection and Technical Regulatory Authority estimate that the percentage of inspections regarding online shops is rather low (max 5 %).

Mystery shopping is not allowed in Estonia and the experts point to that as one of the impediments to efficient market surveillance.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-

[148] See https://www.emta.ee/eng
[149] See https://www.ttja.ee/en

border

Functioning of cooperation with other relevant authorities in Estonia (except customs) with respect to product safety

The cooperation between different Estonian market surveillance authorities is good. There are regular bilateral and multilateral meetings either dealing with specific topics or focusing on overviews and setting the general strategies. For example, each year the Ministry of Economic Affairs and Communications organises a meeting involving all authorities dealing with product safety surveillance (the Market Surveillance Board) with the objective to review the activities that have taken place during the year, to exchange experiences and practices, and to discuss current market surveillance issues. There are also regular meetings (once every month or two) between the representatives of the Ministry and the Consumer Protection and Technical Regulatory Authority.

The representatives of different authorities which exercise supervision on certain product groups also meet bilaterally or multilaterally to exchange information, share experiences and discuss opportunities for cooperation. As of 2013, the surveillance authorities also have concluded cooperation agreements where necessary.

In addition, the experts from different authorities communicate with each other as needed, most often by e-mail or by phone.

Cooperation with customs authorities in Estonia with respect to product safety

The surveillance authorities have a close cooperation with customs. When the customs authorities find, upon examination of the goods declared for free circulation, that the characteristics of the product are such that, when properly installed, maintained and used, the product presents a serious risk to human health, safety, the environment; or the product is not accompanied by the written or electronic documents required by the relevant Community acquis or is not marked in accordance with such legislation; or the CE marking has been affixed in an incorrect or misleading manner to the product, the customs authorities suspend the product and immediately inform the national market surveillance authority.

The Tax and Customs Board organises meetings once a year with the representatives of the market surveillance authorities. In these meetings, the participants discuss ways to enhance cooperation and analyse problems encountered in the course of cooperation, as well as share information on product groups that could potentially be addressed in customs controls.

Some market surveillance authorities have concluded a cooperation agreement with customs (for instance, the Consumer Protection and Technical Regulatory Authority, the Health Board, the Environmental Inspectorate). These agreements specify the tasks, rights and obligations of the parties in exercising surveillance over the products listed in agreements. In order to facilitate and speed up communication, a contact list of officials in charge and the channels and procedure of information exchange are provided.

The experts from different market surveillance authorities and customs also communicate as needed (ongoing issues, either by phone or email) in the process of dealing with specific cases.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with surveillance authorities of other EU countries functions in different forms. For example:

1) In conducting joint surveillance activities in international projects (PROSAFE projects involving market surveillance authorities of other countries) which provide an opportunity to exchange experience and to improve the knowledge of experts in a particular area;
2) Cooperation projects – for example, the Estonian Consumer Protection and Technical Regulatory Authority has good experiences with Baltic cooperation projects;
3) Regular exchange of information, especially with the surveillance authorities of other Baltic states (in the form of joint meetings once a year);
4) Cooperation and communication in individual cases.

Several experts have pointed out the positive experience of the Baltic cooperation projects concerning the safety of air trampolines and the safety of adventure parks (2017). The experts inspected two adventure parks in each of the three countries, mapping the current situation. Based on that, the expert group drafted guidelines for safety in adventure parks. This document also contains a self-check questionnaire which gives the operators of adventure

parks the opportunity to evaluate the current state of the adventure park and make necessary corrections. The Safety Guide for Adventure Parks is available on the website of the Consumer Protection and Technical Regulatory Authority.[150]

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

A national RAPEX network has been set up in order to ensure the effective operation of the RAPEX system in Estonia. Market surveillance authorities as well as customs have access to the RAPEX system and monitor it with respect to the product groups for which they are responsible.

In Estonia, the Consumer Protection and Technical Regulatory Authority is operating as a RAPEX Contact Point. Information and assistance on the operation and updates of the RAPEX system are provided to other surveillance authorities both in electronic channels and in face-to-face meetings.

After detection of a dangerous product, in practice, the notification to RAPEX may take more than two weeks. This period is estimated as rather long by the experts and is said to be a result of a) lack of personnel and the heavy workload of the existing personnel; b) number of activities required in a specific case which have effect on the length of the proceedings; and c) time needed to collect necessary data.

If non-safety risks are notified to RAPEX, the Consumer Protection and Technical Regulatory Authority either deals with the issue itself (for example in cases of environmental risks) or notifies another authority which has the competence to proceed the matter.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Market surveillance authorities inform and consult consumer organisations and business associations regarding amendments of laws. There are also specific events organised where the market surveillance authorities meet and discuss with the representatives of the Estonian Chamber of Commerce and Industry,[151] and the Estonian E-Commerce Association.[152]

Cooperation also takes the form of specific projects. For instance, in the framework of the above-mentioned Baltic cooperation project from 2017 on safety of adventure parks, the adventure park operators were informed and consulted on the safety issues, and two adventure parks from each of the three Baltic countries were involved in the project.

One of the forms of cooperation includes joint training sessions or information days which are organised by surveillance bodies for businesses and experts of other surveillance authorities. For example, recently (October 15th 2019), an information day was conducted by the Health Board regarding the safety of chemical products.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Market surveillance authorities organise information days and roundtables in order to explain product specific requirements or the functioning of RAPEX.

In the seminars organised by consumer organisations, business associations or municipalities, experts give presentations on the product safety issues. Recent examples of such events include seminars organised by the Estonian Consumers' Union,[153] the Estonian Traders Association[154] or Board of Entrepreneurship of the City of Tallinn.

Experts also write articles in the traditional media (newspapers and magazines, paper and online issues) and on social media. Information is also published on the websites of the market surveillance authorities.

[150] At https://www.ttja.ee/sites/default/files/failid/dokumendid/seikluspargi_ohutuse_juhised_0.pdf
[151] See https://www.koda.ee/en
[152] See https://e-kaubanduseliit.ee/
[153] See https://tarbijakaitse.ee/
[154] See https://kaupmeesteliit.ee/liidust/english-summary/

In addition, surveillance authorities organise public campaigns which focus on certain safety issues (either specific products or services such as leisure services for children, e.g. play rooms, air trampolines, adventure parks). These campaigns aim to raise both consumers' and businesses' awareness of product safety issues.

Finally, individual entrepreneurs who have questions are consulted both in writing as well as by phone. Also, experts regularly provide consumer advice at the information points located in the municipalities.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Estonia (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

PCA article 56 section 2 point 6 gives the market supervision authority the right to demand, coordinate and organise jointly with economic operators the recall of a dangerous product from consumers and, where necessary, the destruction of the product. A product must be recalled from consumers if other measures are insufficient. Such a right may be exercised even if the product complies with the requirement of the law but there is evidence that the product is dangerous (PCA article 56 section 3).

When a market supervision authority identifies a dangerous product on the market, the business will be first given an opportunity to voluntarily take necessary measures, such as the recall of a product. In this process, the experts of the market supervision authority advise and instruct the business on the nature of a recall, how and in which timeframe to conduct a recall, and how to inform the consumers. Many businesses use their websites for announcing the recall; in some occasions even separate websites are created.[155]

Should the business choose not to cooperate, the market supervision authority can issue an instruction which lists the measures to be taken. If the recall is not carried out effectively (for instance, because of insufficient information sharing), the market supervision authority reinforces the recall by informing the public (for example, in the social media and on its own website).[156]

Penalty payments are imposed on businesses which do not conduct recalls with sufficient efficiency. In deciding on penalty payments or fines, information on the effectiveness of the recall and the willingness of the business to cooperate is taken into account.

Monitoring of effectiveness of product recalls by market surveillance authorities

The market supervision authorities inspect the process of the recall conducted by a business. The business must present evidence on how the consumers are informed and on how many products have been returned, and if relevant, destroyed.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Estonia that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Market surveillance authorities themselves collect statistics on complaints received, inspections conducted, products tested and the number of dangerous products found on the market, and the number of notifications received from customs. In addition, the information derived from the EU Consumer Conditions Scoreboard is monitored. These data are taken into account when the risk forecast is made and surveillance activities are planned.

Information on injuries is not systematically collected; the hospitals are not obliged to notify the market surveillance authorities regarding accidents caused by dangerous products. Such information rather stems from the victims who lodge complaints to the market surveillance authorities. Regarding poisoning incidents caused by products (for example, chemicals), the Health Board receives information from the Poisoning Information Centre.[157]

Market surveillance authorities do not collect separate statistics regarding the inspections of products sold online, or surveillance activities concerning non-harmonised products. Data on the percentage of returned products compared to the number of products sold to consumers is not systematically collected, although the experts

[155] For example, a website for recalling children's car seats: https://spelitagastus.ee/
[156] See for instance https://www.ttja.ee/et/uudised/palume-taas-lapsevanematel-ule-kontrollida-kasutusel-olevad-turvatoolid
[157] See https://www.16662.ee/eng/

indicate the number of products returned by the consumers as one of the criteria of evaluating the efficiency of a recall.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Estonia (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

One of the biggest problems is the lack of personnel which in turn impacts the workload and thus the capacity of the existing staff to effectively monitor the safety of all product groups. Due to this, so far no specific attention has been paid to the emerging issues related to new technologies, or to the more rigorous surveillance of products sold in webshops only. The experts have also pointed out the difficulties of adapting the surveillance activities to changes in the nature of products and commercial practices. The complexity of products challenges the experts who do not always possess specific knowledge for assessing all the risks.

Pursuant to article 54 section 4 of the PCA, in making the test transaction it is not allowed to use a person involved in secret collusion, to pretend to be a legal person, to use an undercover agent or covert measures. This means that Estonian market surveillance authorities do not have the right to conduct mystery shopping (that is, making transactions using a cover identity). Nor can the surveillance authorities block the websites used for marketing dangerous products. Both deficiencies are marked by the experts as obstacles to guaranteeing product safety on the market.

In general, the RAPEX system functions well, but there are cases where the notifications should be more detailed. Examples include notifications concerning specific risks identified in products with certain model numbers while the same risk is present in identical products of different colour (and which thus carry a different model number).

From the technical side of RAPEX, some problems have occasionally occurred in creating public pdf versions for the transmission of information to the competent supervisory authority.

Concerning the recalls, practical problems emerge in cases of recalling products that are rather cheap – the consumers find it too cumbersome to return the product and instead throw it away or stop using it. This means that it is difficult to estimate the effectiveness of the recall.

Judging by the yearly market surveillance programmes, there seems to be some room for development regarding data collection, such as unifying the principles of collecting statistics and presenting data with sufficient detail which would allow for more sophisticated analyses on the efficiency of product safety surveillance.

Areas to make market surveillance of consumer products in Estonia/the EU more effective

The experts of the Consumer Protection and Technical Regulatory Authority observe a growth in the number of enquiries from businesses who prefer to clarify safety issues before starting to import certain products. This can be seen as a positive trend. However, the awareness of Estonian businesses on the nature, aim and process of a recall needs to be raised. The Consumer Protection and Technical Regulatory Authority thus plans to draft relevant guidelines.

Another area for improvement which cannot be directly influenced by the surveillance authorities is the level of self-regulation of businesses with respect to product safety.

In Estonia, statistical data concerning injuries caused by dangerous products are not systematically collected at the moment because the hospitals and emergency rooms do not have the duty to inform the surveillance authorities of the relevant cases. Availability of such data could improve the effectiveness of market surveillance and thus the safety of consumers. Also, there is no central point for statistics regarding the safety of products (both harmonised and non-harmonised). Relevant data are available on harmonised products and are only kept and analysed by each market surveillance authority individually.

In some areas, the responsibilities of Estonian market surveillance authorities overlap or are not divided in the most efficient way (for example, one authority inspects certain products by the manufacturers while on the retail market the same product group is monitored by a different authority). This issue has been already addressed by the responsible ministries, which have initiated the process of analysing the problems and improving the efficiency (the merger of the Consumer Protection Board and the Technical Regulatory Authority in 2019 being one of the results of this process).

Concerning RAPEX, it should be ensured that the information given in the notifications is detailed and sufficient.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Estonia since 2013

Market surveillance authorities estimate that the level of safety of consumer products shows no clear trend, which means that the safety level has been largely left unchanged. It has been brought up that the monitoring needs to be consistent and frequent; the awareness of businesses decreases and the number infringements of product safety rules increases as soon as a certain product group receives less attention.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Estonia whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

In Estonia, the market surveillance authorities lack tools for addressing new challenges. From the technical point of view, there is need for IT tools which would screen websites with the aim to detect dangerous products sold online, or new products which should be inspected. From the legal point of view, the market surveillance authorities could have the right to conduct mystery shopping and to block websites if needed. There's need for training on issues related to new technologies.

Views of market surveillance authorities whether approaches in Estonia can be considered best practice implementation of the GPSD, which could be of interest to other countries

The Estonian Consumer Protection Board (now the Consumer Protection and Technical Regulatory Authority) has good experiences with projects which target certain product groups. Such projects aim to raise the awareness of both businesses and consumers, and improve the level of the safety of products. At the beginning of a project, the information on it is shared with public; the businesses dealing with the products in question are checked and individual feedback of the deficiencies found are given along with recommendations. In the case of smaller infringements, the business is given a deadline for eliminating the problems. At the end of the project, findings are summarised and introduced to the businesses and to the public. For example, in 2019, information was published on the safety of public playgrounds.[158]

A cooperation project between the market surveillance authorities of Baltic countries may be named as another example of good practices. This project (described in more detail above) focused on the safety of adventure parks (2017) and resulted in the drafting of guidelines for safety in adventure parks and a self-check questionnaire for adventure park operators. The Safety Guide for Adventure Parks has been made available on the website of the Consumer Protection and Technical Regulatory Authority.[159]

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	49	n.a.	49
Total (country)	***49***	n.a.	***49***

Notes: Source: Ministry of Economic Affairs and Communications (2019), Market

[158] See https://www.ttja.ee/sites/default/files/contenteditors/Ehitus/Manguvaljakud/avalike_manguvaljakute_seisukord_2018_2019.pdf
[159] At https://www.ttja.ee/sites/default/files/failid/dokumendid/seikluspargi_ohutuse_juhised_0.pdf

	Surveillance Programme 2019. Estonia.

B. Number of inspections of consumer products (last available year)			
	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	1188	n.a.	1188
Total number of consumer products inspected	8317	n.a.	8317
Total number of consumer products tested in laboratories	183	n.a.	183
Total number of dangerous consumer products found	46	n.a.	46
Notes:	*Source: Ministry of Economic Affairs and Communications (2019), Market Surveillance Programme 2019. Estonia. Statistical data are available for the first 9 months of 2018.*		

C. Number of recalls of consumer goods (last available year)			
	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of mandatory recalls	10	n.a.	10
Notes:	*Source: Ministry of Economic Affairs and Communications (2019), Market Surveillance Programme 2019. Estonia. Statistical data are available for the first 9 months of 2018.*		

D. Key sources	
Legislation	Directive 2001/95/EC, *Official Journal L 11, 15.11.2002, p 447-462* Product Conformity Act, State Gazette RT I 2010, 31, 157, available in English at https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/518012019009/consolide Regulation No 122 of the Government of the Republic (26.08.2010), The Procedure for Notifying European Commission of Restrictions on Placing on Market of Products, State Gazette RT I 2010, 61, 424, available in Estonian at https://www.riigiteataja.ee/akt/110042019015 Law Enforcement Act, State Gazette RT I, 22.03.2011, 4, available in English at https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/525032019010/consolide Substitutive Enforcement and Penalty Payment Act, State Gazette RT I 2001, 50, 283, available in English at https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/522012015001/consolide Code of Misdemeanour Procedure, State Gazette RT I 2002, 50, 313, available in English at https://www.riigiteataja.ee/en/eli/ee/Riigikogu/act/508042019014/consolide Penal Code, State Gazette RT I 2001, 61, 364, available in English at https://www.riigiteataja.ee/en/eli/513012020005/consolide
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Interviews	Consumer Protection and Technical Regulatory Authority Ministry of Economic Affairs and Communications

9. Finland

COUNTRY REPORT FINLAND

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Finland, the GPSD has been transposed through the Consumer Safety Act[160] 920/2011. The Consumer Act is supplemented by the Government Decree on Information to be Supplied with Respect to Consumer Products and Services (613/2004).

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Finland

Traceability requirements are provided in the Government Decree on Information to be Supplied with Respect to Consumer Products and Services no. 613/2004, issued by virtue of Act no. 75/2004, which entered into force on 1 January 2005.[161] § 3 of the Decree (on consumer product information) stipulates that:

"As a minimum, the following information shall be provided on consumer goods:

(1) the commercial name;

(2) the name of the manufacturer, manufacturer or importer.

If the information referred to in paragraph 1 is not clearly visible without opening the sales package, it shall be provided on the sales package.

If the surface of the unit package is insufficient or if the unit package is otherwise unsuitable for the labeling provided for in this Regulation, the label may be affixed to a separate label or other similar notice on the unit package."

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the legislation in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The Finnish Safety and Chemicals Agency (Tukes, or 'the Agency') considers that the national legislation transposing the GPSD likely covers threats posed by embedded software in a product. However, it is considered to be "more or less unclear at the moment" whether other emerging threats related to new technologies would be covered by the current legislation.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

For assessing the safety of a product where European standards referenced in the EU Official Journal do not exist, the following other benchmarks are used: Other European standards (not referenced in the EU Official Journal); national standards (not based on European standards); international standards and/or standards from non-EU/EEA countries; Commission recommendations setting guidelines on product safety assessment; codes of good practice in force in the sector concerned; and reasonable consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

[160] *Kuluttajaturvallisuuslaki*
[161] General Product Safety Directive (GPSD) – Comparative Inventory, p. 68, 2006 (by Baker & McKenzie)

Administrative measures at the disposal of market surveillance authorities in Finland in case there are consumer product(s) on the market which are found unsafe under the GPSD

Administrative measures are the most common consequence for an economic operator for a violation of compliance. Market surveillance authorities may prohibit the sale of a non-compliant product, or the batch, and obligate the operator to withdraw or recall the product causing the risk. If necessary, market surveillance authorities may intensify the effect of an order or prohibition by imposing a conditional fine, or by having measures taken at the expense of the defaulting respondent, if the operator does not take actions voluntarily.

Market surveillance authorities can charge the economic operator for the purchasing price as well as the testing costs of a product if the product is found non-compliant. This procedure functions as an incentive for the economic operator to ensure the compliance of their products.

In case there are consumer product(s) on the market which are found to be unsafe, the following administrative measures are at the disposal of the authority:

- Require businesses to provide relevant information on the product, on the supply chain and the distribution of the product;
- Require businesses to provide relevant information to ascertain the ownership of websites;
- Carry out unannounced on-site inspections and physical checks of products; acquire product samples;
- Require economic operators to undertake recalls of products or other corrective measures (such as restrictions for placing products on the market or bringing products into compliance, stopping products from being placed on the market, withdrawal of products).

The Decree make no express provision for administrative powers to do mystery shopping under a cover identity, or to require businesses to block websites; or to reclaim the costs of the working time of the officers involved in administrative measures. As mentioned above, the authority can reclaim the testing and sampling costs from economic operators if the product is found to be non-compliant.

There are penalties and sanctions that can be issued for serious violations of non-compliance. For example, regarding toys and consumer products, the penalty for a consumer safety offence as laid down in The Finnish Consumer Safety Act's (920/2011) section 50 is a fine. The penalty for a health offence (laid down in The Finnish Criminal Code's (39/1889) Chapter 44, section 1), is at minimum a fine and at maximum a 6-month imprisonment.[162]

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The national implementation legislation of the GPSD does not provide provisions on administrative sanctions or fines (only criminal sanctions are possible, which are never used). The authority may impose an obligation to take an action within the period and in the way determined by the supervising authority. It may also impose a conditional sanction if the operator did not follow the instructions of the authority.

Recent case law in Finland with respect to or relevant for the GPSD/the national implementation legislation.

The Agency is not aware of any case law in Finland with respect to or relevant for the GPSD or the national implementation legislation.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Finland concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The Agency reported that in relation to traceability, it has encountered practical problems in terms of the non-availability of traceability information. Without the information, for example in form of a batch number, it is impossible to trace the product in the market.

With respect to the definition of safety in the GPSD, the Agency states that it is lacking clarity, which leads to

[162] Market Surveillance Programme, 2019, p.13

practical problems, especially in cases where safety and security issues are closely interlinked due to the integrated application of the Internet of Things (IoT) and artificial intelligence (AI) in all kinds of products.

The function of the GPSD as a safety net is good but the application in practice with respect to new products is difficult.

Possible improvements to make the implementation of the GPSD in Finland more effective

With respect to the GPSD, the most urgent need for improvement would be aligning the traceability requirements for all consumer products. The Agency expressed a preference for the following traceability requirements for all consumer products (harmonised and non-harmonised): to indicate the name and contact details of the producers on the product or its packaging; to indicate product reference or, where applicable, the batch of products to which it belongs; and the requirement for business operators to keep supply chain records (one-up-one-down traceability).

Furthermore, for efficient traceability, a machine readable or other type of digital "code" such as a QR code would be most desirable, according to Tukes. Search this code could, for example, lead the authority to a website or a database where all traceability information of a product could be retrieved immediately. Economic operators could store all the information/documentation of the products in this database which could be required by the harmonisation legislation.

The Agency also observed that there needs to be a more clear distinction between the GPSD and the new Mutual Recognition Regulation (2019/515/EU). Art. 7 of the Regulation might give an impression that an economic operator could appeal to mutual recognition also in cases where a GPSD product is found to be dangerous. Therefore, it would be desirable, if and when the GPSD is amended or reformed, that it be clearly stipulated that consumer products with risks covered by the GPSD do not fall under the presumption of mutual recognition, and that with respect to Member States' actions towards these dangerous products, the Regulation 2019/515/EU does not apply.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Finland.

In Finland, the Ministry of Economic Affairs and Employment is responsible for the coordination of the national implementation of Regulation 765/2008/EC and for the cooperation of market surveillance related tasks between the different ministries. Each ministry is responsible for market surveillance in their respective sector(s). Market surveillance is mostly conducted at the central authority level. Market surveillance authorities in Finland operate in several administrative sectors.[163] These are:

- Finnish Food Authority (Ministry of Agriculture and Forestry)

- Finnish Transport and Communications Agency, Traficom (Ministry of Transport and Communications, Ministry of the Environment)

- National Police Board (Ministry of the Interior)

- National Supervisory Authority for Welfare and Health, Valvira (Ministry of Social Affairs and Health)

- Medical Devices, In Vitro Diagnostic Medical Devices (Finnish Medicines Agency, Fimea)

- Department for Work and Gender Equality at the Ministry of Social Affairs and Health as well as Regional State Administrative Agencies' occupational health and safety areas of responsibility

- Radiation and Nuclear Safety Authority, STUK (Ministry of Social Affairs and Health)

- Finnish Environment Institute, SYKE (Ministry of the Environment)

- Finnish Safety and Chemicals Agency, Tukes (Ministry of Economic Affairs and Employment, Ministry of Social Affairs and Health, Ministry of the Environment, Ministry of Agriculture and Forestry, Ministry of the Interior and

[163] Market Surveillance Programme 2019.

Ministry of Transport and Communications)

- Finnish Competition and Consumer Authority, KKV (Ministry of Economic Affairs and Employment)

- Finnish Customs (Ministry of Finance)

Of these authorities, the relevant market surveillance authorities for consumer products falling under the GPSD are Tukes (the Finnish Safety and Chemicals Agency) and Finnish Customs (which has a standalone role as a market surveillance authority).

Plans/programmes in place which define priorities for market surveillance of consumer products

Market Surveillance in Finland is based on a national surveillance plan/programme covering all product sectors (consumer and professional products) as well as sectoral surveillance plans/programmes.

Tukes is responsible for sectoral surveillance plans regarding products within its competence. Ministries compile sectoral plans to be included in national programmes[164].

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Finland with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance activities with respect to the safety of products containing new technologies are conducted similarly to other products, as they still need to comply with the relevant legislation. The sales channel (online or offline) also does not make a difference regarding the requirements applicable to the product or the competence of the market surveillance authority. No market surveillance regarding C2C products is conducted.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The Agency conducts market surveillance regarding products sold online about once a week within its territory, occasionally (once every three months) in the EU/EEA, and very rarely (once a year) in non-EU/EEA, focusing on retailers' websites, online market places, and social networks. Due to its territorial competence, market surveillance activities are targeted at sellers located in Finland. In some cases, the Agency takes samples from non-EU/EEA-country-based platforms and uses the Product Safety Pledge for enforcement. The share of market surveillance activities conducted by the Agency that focus on products sold online is around 30-40% of total inspections (considering all online sales channels and types of online shopping).

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Finland (except customs) with respect to product safety

With respect to product safety, the Agency cooperates with other relevant authorities through the common use of RAPEX, ICSMS, and through the inclusion of other market surveillance authorities (MSAs) in preparing the national market surveillance programme, in addition to regular meetings and exchange of information as well as through the Advisory Council on Consumer Safety.

A national Market Surveillance Forum was founded by the Ministry of Economic Affairs and Employment in 2016, consisting of relevant market surveillance authorities (mentioned above), which provides a forum for informal discussion and sharing of information. The Forum is chaired by the Ministry of Economic Affairs and Employment. Through the Market Surveillance Forum, it is expected that the coordination and discussion will provide new ways of horizontal cooperation.

Cooperation with customs authorities in Finland with respect to product safety

Market surveillance authorities cooperate regularly with customs authorities using common selection criteria and risk rules placed in the declaration systems of the customs. Customs also operates as a competent surveillance

[164] See https://tem.fi/en/market-surveillance-programmes

authority in the sectors of toys, chemicals, cosmetics and consumer products, having the power to decide on whether the import, export or transit of certain products is allowed. This possibility of customs taking its own decisions was indicated by the Agency to be a major advantage, ensuring quicker and more efficient decisions.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The market surveillance authorities cooperate actively with other European authorities. Cooperation is carried out on both a bilateral and multilateral basis, *inter alia* in the form of joint surveillance projects and various types of information exchange. Significant cooperation between the authorities of Member States is conducted in the sectoral Administrative Cooperation groups (ADCOs) and in the Enforcement Forum of the European Chemicals Agency. Market surveillance authorities also take part in PROSAFE projects and other European and Nordic projects.

Cooperation with other Member States and non-Member States is mostly conducted on a sector-specific level.

In cases where the operator is in the EU, the responsible market surveillance authority cooperates directly with the relevant authority in the other Member State. If the operator is located outside of the EU/EEA, the authority uses the Product Safety Pledge.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

According to the General Product Safety Directive and Regulation 765/2008, the MSAs in Finland have an obligation to make notifications, as required by the legislation, to the European Commission via the RAPEX and ICSMS systems. The Agency is the national contact point for RAPEX, and validates the notifications and feeds it into the RAPEX system. The average duration between the detection of a dangerous product and its notification to RAPEX is estimated to be two weeks. Tukes notes that there is a significant degree of variation in the notification time, as submitting authorities want to serve the decision to the relevant economic operator first.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

MSAs cooperate often (once a week) with businesses and business associations through regular exchange of information, regular meetings, and providing advice to businesses where needed. Tukes is building a learning platform for businesses. At the first stage, it will include an assessment test revealing how well the company knows about requirements related to its product group. At a later stage, the platform will provide more material and detailed information on its webpage.

In practice, the Advisory Board of Conformity Assessment Affairs (attached to the Ministry of Economic Affairs and Employment) supports the Ministry in the coordination of the tasks related to market surveillance. In the Advisory Board, market surveillance authorities from different administrative sectors as well as stakeholders are represented.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

MSAs organise Consumer Safety meetings two to three times a year.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Finland (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

With respect to recalls, the Agency provides information for businesses on its website.[165] It emphasises that carrying out an effective recall is the obligation of the business, not of the authority. The Agency requires businesses to provide the following information in the case of a recall: Information activities targeted at consumers; information activities targeted at/cooperation with other businesses involved in the supply chain (e.g. distributors,

[165] See https://tukes.fi/en/products-and-services/dangerous-products

online marketplaces); and a list of other businesses involved in the supply chain (e.g. distributors, online marketplaces).

Market surveillance authorities inform consumers about an unsafe product via information bulletins and press releases. MSAs may also oblige the relevant economic operator to inform the consumers at the economic operator's own expense.

Monitoring of effectiveness of product recalls by market surveillance authorities

The Agency reported that only mandatory recalls are monitored. While not all mandatory recalls are monitored, spot checks are conducted in which the economic operator conducting the recall is asked to provide information on the recall's effectiveness in terms of the number of items placed on the market and the number of items returned by consumers (both in terms of absolute numbers of products collected and as a percentage of recalled products actually collected). Furthermore, the recall action is required to remain in place until all the products placed or made available on the market are accounted for.

The authority publishes information on products found dangerous on their website.[166]

6. Availability of statistics relevant for market surveillance

Availability of statistics in Finland that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The Agency collects data on consumer complaints in relation to dangerous products (outside the RAPEX system) and collect all notifications made by consumers in a national register (including those specifically related to dangerous products).

The National Institute for Health and Welfare collects injury data systematically. However, the injury data that is available is considered to be too general and difficult to use.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Finland (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

In relation to market surveillance in general, the Agency identified the following practical problems as being most relevant in the country:

1. Limited staff resources for market surveillance;
2. Lack of financial resources for testing of consumer products;
3. Unclear distribution of competences for market surveillance at the national level (especially regarding new products/technologies);
4. Lack of suitable product testing laboratories;
5. Lack of awareness among businesses with respect to product safety requirements;
6. Lack of awareness of consumers with respect to product safety;
7. Problems to take effective action when the responsible operator is in another EU/EEA country, or outside the EU/EEA.

The Agency faces several impediments regarding market surveillance online. As mentioned above, in addition to a lack of staff resources, the Agency is often not able to take action against rogue economic traders when they are not established in Finland, even if the website is in Finnish.

In relation to the RAPEX system, the following impediments were encountered:

- Insufficient human/financial resources: The agency has only one staff member (not full time) assigned to the national contact point. It also has no dedicated inspectors for notified products.

- Difficulties with risk assessment: Assessing the probability of risk with the help of the RAG tool is not always very helpful. Technical issues arise as in some cases the system crashes. It would be helpful to open the RAPEX database for web-crawling or use of applications.

[166] See https://marek.tukes.fi/

- Difficulties with national protection legislation: In some cases, removing personal data from the notification as required by the EC legislation could make a notification not very helpful at all. In the case of a notification regarding tattoo ink, for example, the personal data of tattoo artists were removed from the notification where the same persons were the supplier of this product.

- In some cases, notification classification does not function well: For the notification to be rated as a serious risk (under Article 12 of the GPSD), RAPEX requires information on the manufacturer. If this information is missing, the notification needs to be downgraded regardless of the risk category (an example being an Army Surplus Gas Mask from the former USSR that lacked information on the manufacturer, with asbestos in it, sold to collectors and for role plays). The Agency would also appreciate being consulted by default before a notification is amended by the EC RAPEX team.

Areas to make market surveillance of consumer products in Finland/the EU more effective

Suggestions for possible improvements with respect to the RAPEX system include:

The Agency raised an issue with regards to the functionality of sorting notifications by country of origin/delivery, which is no longer available in the system (which was considered very user-friendly for retrieving information). They consider it essential to have this functionality again in the system.

In addition, in case of a notification, the Agency recommends having a functionality for direct communication with other relevant competent authorities in other countries via the RAPEX system, including the possibility to limit communications to only the relevant authority, if needed.

With respect to product recalls and market surveillance more generally, the Agency suggests making use of customer data mandatory where possible. Furthermore, a measure to make market surveillance more effective would be the establishment of EU testing laboratories working on non-profit basis.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Finland since 2013

The Agency noted that the level of safety of consumer products very much depends on the type of products and the sales channel. They also observed that the use of non-EU/EEA-country online shopping has increased significantly in the recent years, affecting the level of product safety.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Finland whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

In relation to tools for market surveillance, the Agency considered that it does not have the tools at its disposal to address new challenges related to emerging technologies at present. It lacks both the competence and resources needed. Competences are not clearly defined relating to e.g. new products such as refrigerators connected to the Internet, which requires coordination within institutions. If the competence of an authority is not clear, its enforcement powers can be challenged in court, which creates uncertainty for the institution.

The Agency is participating in developing IT tools for market surveillance online. For example, the Agency is participating in data mining/web-crawler projects.

Views of market surveillance authorities whether approaches in Finland can be considered best practice implementation of the GPSD, which could be of interest to other countries

Where consumer products are concerned, in some sectors (toys, chemicals, cosmetics and consumer products), customs also operates as a competent surveillance authority and has the power to decide on the import, export or transit of these products. As mentioned above, Finnish customs and market surveillance authorities cooperate regularly in the field of market surveillance using the selection criteria and risk rules placed in the declaration systems of customs authorities.

The Agency also considers it to be best practice that it issues a decision in all cases where actions are needed and

do not rely on the own initiative of an economic operator. This creates legal certainty for operators, and makes it easier for them to obtain compensation from the MSA (should it make a mistake), or reimbursement from a supplier.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*2*	*n.a.*
Total (country)	*n.a.*	*2*	*n.a.*
Notes:	*Data from 2019*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of consumer products inspected	*n.a.*	85	*n.a.*
Total number of dangerous consumer products found	*n.a.*	31	*n.a.*
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	*n.a.*	6	*n.a.*
Notes:	*Data from 2019*		

C. Number of recalls of consumer goods (last available year)

The total number of product recalls based on GPSD was 17

D. Key sources

Legislation	The Act Kuluttajaturvallisuuslaki 22.7.2011/920, from: http://plus.edilex.fi/tukes/fi/lainsaadanto/20110920 (Google translation into English) Decree "Valtioneuvoston asetus kulutustavaroista ja kuluttajapalveluksista annettavista tiedoista 23.6.2004/613" from: http://plus.edilex.fi/tukes/fi/lainsaadanto/20040613?toc=1) (Google translation)
Studies/reports/articles	Market Surveillance Programme 2019, Finland General Product Safety Directive (GPSD) – Comparative Inventory, p. 68, 2006 (by Baker & McKenzie)
Websites	https://marek.tukes.fi/
Interviews	Questionnaire filled in by Finnish Safety und Chemicals Agency (Tukes) and interviews conducted with the same Agency

10. France

COUNTRY REPORT FRANCE

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In France, the Directive on General Safety Products (GSPD) was initially implemented in French Law by Order n°2004-670 dated 9 July 2004 that came into force on 11 July 2004.

This was then supplemented by in French Law by Order n° 2008-210 dated 22 August 2008.

There was also a reform of the Consumer Code by virtue of Order n° 2016-884 of 29 June 2016.

This legislation was consolidated in codified form in the Consumer Code under Articles L. 411-1 and following; and in Consumer Code under Articles L. 421-1 and following.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in France

The general obligations with respect to producers providing the necessary information for tracing the origin of a product, such as an indication of the identity and details of the producer and the product reference or the batch of products to which it belongs, is applied in a contextual way in France, depending upon the products concerned.

As was stated by the DGCCRF,[167] the traceability obligations are "determined with respect to the characteristics of the products (potential risks and modalities / extent of the distribution) on a case-by-case basis." These obligations are thus determined on a case by case basis by the DGCCRF rather than being laid down specifically. It is unclear whether any guidelines have been produced for specific product categories.

This case-by-case approach can pose problems, however, and generate uncertainty for business. It was moreover noted by the DGCCRF that it was "sometimes difficult to explain to an economic operator that the characteristics of their product required that it was specifically identified and was traceable in the distribution chain."

Issues have also been raised concerning the specific position of online platforms, which have posed many difficulties for the French authorities in terms of traceability. With respect to these platforms, the products sold do not necessarily satisfy the traceability obligations because the seller may be established abroad, often in the Far East, and may not be subject to applicable standardisation obligations in their home jurisdiction. There have thus been many issues concerning traceability with respect to products purchased via these online platforms, such as where the product does not have a barcode at all.

Another related problem is that the online platforms consider that they are neither the seller nor importer of the products, as they solely host the marketplace as service providers, but they are often the entities which hold the relevant information to be able to organise recalls effectively (e.g. customer names and contact details). In order to respond to this difficulty, the DGCCRF has proposed that in case of a failure of the original manufacturer or seller to undertake the relevant GPSD obligations such as a recall, then that obligation should fall on the online platform.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

Articles L. 421-3 of the Consumer Code[168] provides that "products and services must, under the normal conditions of use or under other circumstances which may be reasonably foreseeable by the professional, offer the safety that can legitimately be expected, and must not be a danger to public health."

[167] *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*
[168] *Code de la consommation*

This is a somewhat open-ended definition, as recognised by authorities and commentators.

Professor Julien has thus written that "the definition of Article L 421-3 is general, vague, and no doubt a source of difficulty for professionals"[169], recognising however, that the imprecision is the feature "which is the strongpoint of this article, which due to the general nature of its terms can apply to all manner of scenarios"[170].

As was noted by the DGCCRF, "The notion of security that the consumer can legitimately expect is subject to interpretation, particularly in non-referential sectors."

Certain precisions have been made to this definition in Articles 421-5 and 421-6 of the Consumer Code.

Article 421-5 Consumer Code:

"A product is considered to satisfy the general safety requirement laid down in Article L. 421-3 when it complies with the specific regulations applicable to it with the aim of protecting the health or safety of the consumers."

Article 421-6 Consumer Code: "A product is presumed to fulfil the general safety obligation provided for in Article L. 421-3 with regard to the risks and risk categories covered by the standards applicable to it when it complies with the non-mandatory national standards transposing European standards published by the European Commission in the Official Journal of the European Union pursuant to Article 4 of Directive 2001/95 / EC of 3 December 2001 on general product safety."

Article 421-7 Consumer Code:

"In cases other than those mentioned in Articles L. 421-5 and L. 421-6, the conformity of a product with the general safety requirement is assessed by taking into account the following elements in particular, when they exist:

1. Non-mandatory national standards transposing European standards applicable to the product other than those whose reference is published in the Official Journal of the European Union pursuant to Article 4 of Directive 2001/95/EC of 3 December 2001 on general product safety;

2. Other French standards;

3. The recommendations of the European Commission setting guidelines for the evaluation of product safety;

4. The guide of the good practice in terms of product safety in effect in the concerned sector;

5. The current state of knowledge and technology;

6. The security that consumers can legitimately expect."

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Yes.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Various benchmarks are used in France for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist. These include:

- Other European standards (not referenced in the EU Official Journal)
- National standards (not based on European standards)
- International standards and/or standards from non-EU/EEA countries
- Commission recommendations setting guidelines on product safety assessment
- Codes of good practice in force in the sector concerned
- State of the art and technology

[169] Julien, J, (2019) *Droit de la consommation*, Paris: Domat para 354
[170] Ibid, para 352.

- Reasonable consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in France in case there are consumer product(s) on the market which are found unsafe under the GPSD

Various administrative measures are available in France in case there are consumer products on the market which are found unsafe:

- Require businesses to provide relevant information on the product(s)
- Require businesses to provide relevant information on the supply chain and the distribution of the product(s)
- Require businesses to provide relevant information to ascertain the ownership of websites, where relevant
- Carry out unannounced on-site inspections and physical checks of products
- Acquire product samples, including under a cover identity (mystery shopping)
- Block websites if needed
- Require from economic operators recalls of products and other corrective measures (such as restrictions for placing products on the market or bringing products into compliance, stopping products being placed on the market, withdrawal of products etc)
- Reclaim from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s) (e.g. for carrying out testing, storage etc).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Putting an unsafe product on the market can result in a substantial fine (maximum of 375 000 Euros) and/or a prison sentence (of maximum 3 years imprisonment). Notifications are regularly passed on to prosecutors, and cases are often brought forward.

Recent case law in France with respect to or relevant for the GPSD/the national implementation legislation.

There has been litigation with respect to decisions taken by the market surveillance authorities in terms of product safety such as:

- Conseil d'État, Juge des référés, 12 Juillet 2019 – n° 431523 (expedited case concerning alleged toxic products in certain babies nappies, in respect of which the French authorities had made various recommendations to the manufacturers concerned, and specific regulations were to be taken in respect of those products. The claimants had asked for the sale of such products to be suspended and for public warnings to be given as to those products. The challenge was rejected as the element of urgency, necessary for an expedited claim was not present).Cour administrative d'appel, PARIS, Chambre 3, 4 Octobre 2012 - n° 11PA05141 (administrative court rejected the challenge by the manufacturer of a sofa-bed of a decision of French market surveillance finding the product as breaching the product safety obligation and warning the producer of the fire risks of its product and requiring it to make changes to the product).

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in France concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

As noted above, there is an element of uncertainty related to Articles L. 421-3 of the Consumer Code. Similar comments were also made by the DGCCRF regarding the notion of state of the art and technology.

The case-by-case approach to traceability requirements has also generated some uncertainty. It was thus noted by

the DGCCRF that "it was sometimes difficult to explain to an economic operator that the characteristics of their product required that it was specifically identified and was traceable in the distribution chain."

As noted, there are also issues concerning online platforms, which have posed many difficulties in terms of traceability.

Another related problem is that the online platforms consider that they are neither the seller nor importer of the products, as they solely host the marketplace as the service providers, but they are often the entities which hold the relevant information to be able to organise recalls effectively (e.g. customer names and contact details). In order to respond to this difficulty, the DGCCRF has proposed that in case of a failure of the original manufacturer or seller to undertake the relevant GPSD obligations such as a recall, then that obligation should fall on the online platform.

There are also some emerging safety issues concerning particular types of consumer products which pose problems in the context of the current regulatory framework:

- **Childcare articles** have been identified as creating issues, for similar reasons to that concerning toys: the large number of such products and vulnerability of consumers. The DGCCRF raises the point that a harmonising instrument in this area at the EU level would be useful.
- **Button batteries.** In view of the inadequacies with respect to normalisation, the DGCCRF points out that labelling requirements might be useful.
- **Electrical appliances under the Low Voltage Directive. UV Sun beds.** These are subject to the Low Voltage Directive, but no action has been taken at a European level with respect to the risk of skin cancer, despite reports such as SCHEER.
- **Baby nappies.** Issues were raised here about potentially dangerous substances. French authorities are planning to make submission concerning a REACH restriction.
- **Siphons à crème** (whipped cream makers). Several serious cases have occurred in France in past few years.
- **Toys:** Mentioned as a priority area because of the vulnerability of consumers and the difficulties experienced with toys sourced from certain countries.

Possible improvements to make the implementation of the GPSD in France more effective

The DGCCRF has indicated that improvements could be made with respect to products sold on online platforms. As noted above, the DGCCRF has proposed that in case of a failure of the original manufacturer or seller to undertake the relevant GPSD obligations such as a recall, then that obligation should fall on the online platform.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in France.

At the national level:

Market surveillance is mainly carried out by officials of the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF) in the case of products intended for consumers, and by officials of the Directorate-General for Customs and Indirect Taxation (DGDDI)[171] in the case of products imported from non-EU/EEA countries.

The French customs authority is also a market surveillance authority. Depending on the applicable rules and where an import prohibition is provided for, customs officials can take samples, have them tested in a laboratory, and, based on the results obtained, decide on how to proceed.

Other departments assist with market surveillance, either by performing checks directly or with the support of services on the ground. These include:

[171] *Direction Générale des Douanes et Droits Indirects*

– The Direction Générale des Entreprises (DGE) for measuring instruments;

– The Directorate-General for Risk Prevention (DGPR)[172] for gas appliances, pressure vessels (pressure equipment, simple pressure vessels, transportable pressure equipment), chemicals, explosives and equipment for use in potentially explosive atmospheres;

– The Vehicle Market Surveillance Department (SSMV)[173] for vehicles;

– The Directorate for Maritime Affairs (DAM)[174] for recreational crafts and marine equipment;

– The Directorate-General for Labour (DG Labour)[175] for professional personal protection equipment and machines;

– The office for occupational health and safety of the Ministry of Agriculture and Food (MAA) for agricultural and forestry vehicles and machinery;

– The Technical Service for Cableways and Guided Transport (STRMTG)[176] for cableway installations designed to carry persons;

– The French National Agency for Medicines and Health Products Safety (ANSM)[177] for medical devices and cosmetics;

– The French National Agency for Frequencies (ANFR)[178] for radio equipment.

At the sub-national (regional/provincial/local) level:

The DGCCRF and the DGDDI are supported by a regional network.

Plans/programmes in place which define priorities for market surveillance of consumer products

There are indeed sectoral surveillance plans/programmes and regional surveillance plans in place.

The DGCCRF establishes a national plan on an annual basis, which determines priorities for controls and/or enquiries depending upon the types of product, types of economic actors involved and based upon the type of distribution of the product in question. There are also regional variants so as to take account of the specificities at a regional or local level.

There is also an extensive customs network at the regional and local level implementing regional surveillance plans.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in France with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance activities are undertaken in France with respect to the safety of products containing new technologies (such as the Internet of Things, connected devices), though the focus is on the safety of the product and not on data protection or cyber fraud issues.

The French customs authority, which is also a market surveillance authority, is also involved in this activity. It works on such issues, often in tandem with the relevant sectoral authorities (e.g. the French National Agency for Frequencies), with whom it coordinates. The French customs authority has a policy of reinforcing controls in this area. There is evidence that new technology products have created product safety issues.

Regarding products sold online via e-commerce that fall within the scope of market surveillance undertaken by the DGCCRF, there are various challenges in this area, including difficulties where the online platforms are not selling the products directly (not liable for the product), but are simply hosting them as a service provider, so it is not possible to undertake a control at that distribution level.

There are also practical difficulties in terms of accessing the product, as in e-commerce the controls often require

[172] *Direction Générale de la Prévention des Risques*
[173] *Service de Surveillance du Marché des Véhicules*
[174] *Direction des Affaires Maritimes*
[175] *Direction Générale du Travail*
[176] *Service Technique des Remontées Mécaniques et des Transports Guidés*
[177] *Agence nationale de sécurité du médicament et des produits de santé*
[178] *Agence Nationale des Fréquences*

the purchase of the product in question (extra cost).

There was some scepticism expressed about the effect of the EC Notice on market surveillance of online products and the Product Safety Pledge, which were considered to be only moderately helpful and limited in impact (because the Product Safety Pledge is voluntary, and not all platforms abide by it) and also because of the legal issues concerning the lack of liability of online platforms.

The work of the DGCCRF does not concern C2C products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance of products sold online falls within the remit of the DGCCRF where the products can be purchased in France and delivery is possible in France.

Controls are undertaken and there is an internal specialist unit within the DGCCRF dedicated to e-commerce.[179]

It is not possible to state the frequency of control, as a control will occur when there is a specific problem (e.g. a complaint concerning a specific product) or as part of a planned programme of controls.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in France (except customs) with respect to product safety

Cooperation occurs regularly, through formal agreement, inclusion of other authorities in preparing national market surveillance plan/programme, joint processes for dealing with dangerous products, joint training sessions, regular exchange of information, regular meetings and informal cooperation.

Cooperation with customs authorities in France with respect to product safety

There is regular cooperation between the DGCCRF and the customs authorities which is facilitated by a cooperation protocol, including at a local level. The protocol sets out an annual plan and sets common priorities. An annual review is conducted.

There are also streamlined processes so as to ensure that information on dangerous products is shared quickly and easily, with appropriate follow-up. There is a centralised customs point that provides and coordinates the dissemination to actors at a local or regional level.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with authorities in other countries functioning reasonably well.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Coordination between RAPEX and national market surveillance systems functions well.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

There is regular (weekly) cooperation between central market surveillance authorities and business associations/businesses, and/or an exchange of information with them on market-related topics or to notify a dangerous product of a competitor.

There is also regular (monthly) cooperation with consumer organisations on product safety. There are meetings with consumer associations, and any issues related to products will be discussed with them and any product testing they have undertaken will be reviewed by the DGCCRF, and separate tests undertaken if necessary. Consumer organisations are brought together with business representatives so as to have an exchange on topical issues.

[179] *Le Centre de surveillance du commerce éléctronique du Service National d'Enquete*

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Business is informed through a regular exchange of information, through meetings and through informal cooperation.

Awareness raising with consumers is done by means of online information, press releases and social media campaigns.[180]

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in France (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and other corrective measures are undertaken in France. Businesses can be asked to conduct voluntary or mandatory recalls and other corrective measures, if needed. Business can also be required to use their available customer information for recalls and other corrective measures. Online marketplaces are also involved in the recall process.

The DGCCRF prioritises voluntary measures, and verifies that the measures proposed by the given business are adequate and appropriate, and will require changes if need be.

Monitoring of effectiveness of product recalls by market surveillance authorities

Recalls are monitored by market surveillance authorities. The DGCCRF verifies that the measures undertaken by business are appropriate, and requires changes if need be. The business will be asked regularly to explain the results of the undertaken recall.

There have however been problems with the effectiveness of recalls, particularly with respect to e-commerce.

6. Availability of statistics relevant for market surveillance

Availability of statistics in France that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

There are statistics available in France concerning dangerous products, and these are collected in a DGCCRF database. All complaints received by the DGCCRF and regional representatives are registered and categorised. As for injury data, this can be gained from the national health system information ("EPAC") but this is only based on a sample of cases registered in hospital emergency departments, and thus only contains limited information about the product concerned and whether this played a causal role in the injury.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in France (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

A number of challenges have been identified:

- Emerging risks can sometimes prove difficult to address, especially where there may not be enough or any scientific basis on which to act;
- Issues have been raised concerning the general position of online platforms. Many of these problems derive from the fact that online platforms consider that they are neither the seller nor importer of the products, as they solely host the marketplace as service providers. This can produce difficulties in terms of traceability, in undertaking effective recalls, etc.;
- The costs of lab testing can be disproportionately high with respect to the product concerned;
- Customs controls in certain countries for products entering the EU are too weak, and this effects all other countries due to the principle of free movement;

[180] See: www.economie.gouv.fr/dgccrf/infos-presse-0; https://www.economie.gouv.fr/dgccrf/securite; https://twitter.com/dgccrf?lang=en; https://www.facebook.com/DGCCRF/

- Data linking accidents to specific products is either absent or only fragmented;
- In some sectors, companies are not sufficiently aware of their obligations;
- Consumers overlook or do not pay attention to product warnings and security information.

Areas to make market surveillance of consumer products in France/the EU more effective

- Internet online platforms should be obliged to inform the authorities of what measures the seller has taken in terms of product safety;
- There should be a legal obligation on online platforms to undertake recalls where the original seller fails to do this.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in France since 2013

The authorities have different reactions. The national customs considered that the overall trend was positive (safety improved), and the sub-national customs authorities confirmed this trend, whereas the national DGCCRF considers that safety has deteriorated.

The view of the DGCCRF is more nuanced, however, because their view would be more positive with respect to traditional distribution channels (due to the effect of standardisation, etc.) and they consider that the negative trend derives principally from e-commerce offerings with products originating from third parties without an EU importer and sent directly to individuals in France.

E-commerce has also posed issues with respect to traceability. On online platforms, the products sold do not necessarily satisfy the traceability obligations because the seller is established abroad, often in the far east, and in the absence of applicable standardisation. There have thus been issues concerning traceability where the product does not have a barcode at all.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in France whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

The market surveillance authorities in France do not have all the tools and resources necessary for addressing new challenges, particularly as regards e-commerce. There were issues about resources for testing, though it was felt however that mystery buyer controls via online marketplaces worked well.

Views of market surveillance authorities whether approaches in France can be considered best practice implementation of the GPSD, which could be of interest to other countries

The mystery buyer controls via online marketplaces have worked particularly well, accompanied by media publicity.

Note also the new central customs authority's service created in 2016, the SARC,[181] which centralises the analysis of risk, and which has been very helpful in assisting in the harmonisation of the practice of local and regional customs. The SARC provides coordinated expertise on sensitive issues and helpful coordination work, which has made a real difference to sub-national customs authorities.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

[181] *Service d'Analyse de Risque et de Ciblage*

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	n.a.	57.5	n.a.
Total (country)	n.a.	57.5	n.a.
Notes:	This is a DGCCRF estimation as at 2016. The DGCCRF has indicated that the data concerning harmonised consumer products will be communicated in the exercise relating to the evaluation of Regulation *765/2008.*		

B. Number of <u>inspections</u> of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	n.a.	**3980**	n.a.
Total number of consumer products inspected	59.2 million of articles inspected by customs	n.a.	n.a.
Total number of consumer products tested in laboratories	2 188 205 products tested by customs	365	n.a.
Total number of dangerous consumer products found	14.3 million articles found by customs.	760	n.a.
Notes:	With respect to the 2nd column, this is a DGCCRF estimation as of 2016. The line relating to "*Total number of consumer products inspected in cooperation with customs*" is not relevant in France as customs is a market surveillance authority, able to undertake controls without recourse to another authority. With respect to the 1st column, this is information from the customs authority for 2018. The DGCCRF has indicated that the data concerning harmonised consumer products will be communicated in the exercise relating to the evaluation of Regulation *765/2008.*		

C. Number of <u>recalls</u> of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*n.a.*	100	*n.a.*
Notes:	The DGCCRF has indicated that the data concerning harmonised consumer products will be communicated in the exercise relating to the evaluation of Regulation *765/2008*		

D. Key sources

Legislation	In France, the Directive on General Safety Products (GSPD) was initially implemented in French Law by Order ("*Ordonnance*") n°2004-670 dated 9 July 2004. It came into force on 11 July 2004. This was then supplemented by in French Law by Order ("Ordonnance") n° 2008-210 dated 22 August 2008. There was also a reform of the Consumer Code by virtue of Order ("Ordonnance") n° 2016-884 of 29 June 2016. This legislation was consolidated in codified form in the Consumer Code under Articles L. 411-1 and following; and in Consumer Code under Articles L. 421-1 and following to L. 423-4.

Studies/reports/articles	Baghestani-Perrey, Le principe de précaution, nouveau principe fondamental régissant les rapports entre le droit et la science, D. 1999. Chron. 457. Boy (1999), La nature juridique du principe de précaution, Nature, Science, Société, vol. 7, no. 3. Bruggemeir et Micklitz (1991), Product safety legislation in France and the United Kingdom, Institut européen de Florence. Calais-Auloy, J. (2015), Droit de la consommation, Paris: Dalloz. Favret (2001), Le principe de précaution ou la prise en compte par le droit de l'incertitude scientifique et du risqué virtuel, D 2001. Chron 3462. Favro (2004), La commission de la sécurité des consommateurs, vingt ans après, D. aff. Chron. 1886. Julien, J, (2019) Droit de la consommation, Paris: Domat. Kourilsky and Viney (2000), Le principe de précaution, la Documentation française. Lambert-Faivre (1994), Fondement et régime de l'obligation de sécurité, D. 1994. Chron. 81. Martin (2000), Apparition et définition du principe de précaution, LPA, no 239. Paisant (1997), L'obligation de sécurité et le droit de la consommation, Gaz. Pal. Doctr. 15 Picod, Y (2018), Droit de la consommation, Paris: Sirey. Raymond, G (2019) Santé et Sécurité des Consommateurs, Fascicule 950, Jurisclasseur Concurrence – Consommation (Paris). Viney and Jourdain (1998), Les conditions de la responsabilité, LGDJ, nos 499 s., nos 550 s. Whittaker, S. (2005), Liability for Products: English Law, French Law, and European Harmonization: Oxford University Press.
Websites	European Consumer Centre France, https://www.europe-consommateurs.eu/en/consumer-topics/health/safety/product-safety/ https://www.oulah.fr/ http://www.pourquery.fr/ https://www.bureauveritas.fr/nos-marches/biens-de-consommation-retail-commerce-de-detail/produits-de-consommation https://signalconso.beta.gouv.fr/
Interviews	Direction Générale des Douanes et Droits Indirects DGCCRF Direction Générale des Douanes et Droits Indirects Direction des Douanes du Havre

11. Germany

COUNTRY REPORT GERMANY

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The GPSD was first implemented with the Equipment and Product Safety Act (GPSG)[182] of 2004,[183] which replaced two earlier pieces of legislation, the Equipment Safety Act (GSG)[184] of 2001 (the predecessors of which date back to 1968[185]) and the Product Safety Act (ProdSG)[186] of 22 April 1997.[187] When the New Legislative Framework of 2008, consisting of Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products, Decision 768/2008/EC on a common framework for the marketing of products, and Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country, made reforms of the German product safety law necessary, the GPSG was replaced by the Product Safety Act (ProdSG) of 2011,[188] which is currently in force. Where the specific Regulations do not set out rules, the ProdSG applies. Other EU product safety directives, such as the Medical Devices Directive 93/42/EEC, have been entirely implemented in special legislation; thus, the ProdSG does not apply to them, § 1 para. 4 ProdSG. There is an academic discussion in Germany as to whether or not § 1 para. 4 ProdSG correctly implements the GPSD and its relationship to sector-specific legislation. According to Article 1 no. 2 GPSD, each of its provisions shall apply insofar as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned. Where products are subject to specific safety requirements imposed by Community legislation, the GPSD shall apply only to the aspects and risks or categories of risks not covered by those requirements. In German law, this reads slightly differently: The provisions of this ProdSG shall not apply where other legal provisions provide for corresponding or more far-reaching provisions. This seems to imply that the ProdSG still applies where the sector-specific legislation provides for rules but at a lower standard of protection, whereas some authors argue that Article 1 no. 2 GPSD also establishes the prevalence of lower-standard rules in sector-specific legislation.[189] According to the market surveillance authority, German market surveillance authorities tend to follow the latter approach.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Germany

According to § 6 para 1 sent. 1 no. 2 ProdSG, the manufacturer, its authorised representative and the importer shall have the obligations when making a consumer product available on the market, to ensure that the names and contact address of the manufacturer or, if it is not domiciled in the European Economic Area, of the name and contact address of its authorised representative or the importer are affixed to the product. Moreover, they must affix unambiguous markings allowing the identification of the consumer product, § 6 para. 1 sent. 1 no. 3 ProdSG. In contrast, these obligations are not directly imposed on the distributor by § 6 para. 1 sent. 1 ProdSG.[190] According to § 6 para. 5 ProdSG, however, the distributor has to contribute to making only safe consumer products available on the market. In particular he shall not make any consumer product available on the market of which he knows or should know on the basis of the information or experience available to him that it does not comply with the requirements under § 3 ProdSG. According to the German Federal Supreme Court (BGH),[191] the information about

[182] Geräte- und Produktsicherheitsgesetz
[183] Bundesgesetzblatt (Federal Gazette; BGBl.) 2004 I, p. 2.
[184] Gerätesicherheitsgesetz
[185] See the Gesetz über technische Arbeitsmittel of 24 June 1968, BGBl. 1968 I, p. 717.
[186] Produktsicherheitsgesetz
[187] BGBl. 1997 I, p. 934.
[188] BGBl. 2011 I, p. 2178. An English translation of the Act is available at http://www.gesetze-im-internet.de/englisch_prodsg/englisch_prodsg.html#p0119.
[189] See Schucht, in: Klindt (ed.), Produktsicherheitsgesetz, 2nd ed. (Munich, C.H. Beck, 2015), § 1 paras 87 ff., with further references.
[190] See BGH, 12/1/2017, I ZR 258/15, Neue Juristische Wochenschrift –Rechtsprechungsreport 2017, p. 745, and BGH, 11/5/2017, I ZR 59/16, Multi-Media und Recht 2018, p. 239, referring to CJEU, 30/4/2009, Case C-132/08 *Lidl Magyarország Kereskedelmi bt v Nemzeti Hírközlési Hatóság Tanácsa*, ECLI:EU:C:2009:281, at para. 39.
[191] *Bundesgerichtshof*

the name and address of the manufacturer forms part of the safety of consumer products. The BGH in this respect relies on Art. 5(1) subparas 3 and 4 GPSD, where the indication of the identity and details of the producer is named as one measures that producers shall adopt.[192] Prior to these decisions, the instance courts had been divided on the matter.[193] § 6 para 1 sent. 2 ProdSG specifies that this information shall be affixed to the consumer product or, where this is not possible, to its packaging. This concretisation was introduced with the enactment of the ProdSG in 2011. The previous legislation, the GPSG of 2004, had left the choice to the manufacturer as to whether to affix the information to the product or to the packaging.[194] Exemptions are admissible if it can be justified to omit this information, in particular where it is already known to the user or where it would involve disproportionate costs to affix it, § 6 para. 1 sent. 3 ProdSG. Moreover, the ProdSG of 2011 introduced sanctions that had not been in place under the GPSG of 2004. According to § 26 para. 2 ProdSG, they can prohibit the product from being placed on the market if the relevant information is not affixed. Failure to affix a name or a contact address, or failure to affix it accurately, completely and in due time, thus violating § 6 para. 1 sent. 1 no. 2 ProdSG, is a regulatory offence under § 39 para. 1 no. 3 ProdSG, which can be punished with a fine of up to 10 000 Euros, § 39 para. 2 ProdSG.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

The ProdSG does not contain any specific definition of safety related to new technologies. The general safety requirements of § 3 para. 2 ProdSG apply. According to that provision, a product which does not come under a specific product safety law regime may only be made available on the market if its intended or foreseeable use does not put the health and safety of persons at risk. In academic literature, it is alleged that the criterion of "foreseeable use" is causing problems in practice, in particular when it comes to foreseeable misuse. One author claims that market surveillance authorities too lightly equate use that has occurred in practice with foreseeable use.[195] However, the relevant guidance document of the Committee for Occupational Health and Safety (LASI)[196] appears to be perfectly in line with EU law.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Emerging threats related to new technologies are not expressly mentioned by the ProdSG but they are covered by the general safety requirements, provided they pose a threat to health and safety. At least, this applies where software is embedded in a physical product.[197] Whether or not software as such also constitutes a "product" in the terms of product safety law, is a subject of controversy in Germany.[198] In practice, the market surveillance authorities do not deal with software "as such". As products with embedded software usually use radiocommunication, the competence for monitoring their safety lies with the Federal Network Agency.[199] However, this mainly deals with risks related to, for example, radiation. If the Federal Network Agency instead finds some risk in a smart product that is related to its physical properties, such as sharp edges in a smart washing machine, it will pass the product on to the competent market surveillance authority or a competent laboratory to deal with this issue. There is criticism that due to the new "smartness" of electrical products, the surveillance of these products have migrated to the Federal Network Agency although they do not have the experience and the

[192] See BGH, 12/1/2017, I ZR 258/15, Neue Juristische Wochenschrift –Rechtsprechungsreport 2017, p. 745, at pp. 746 f., and BGH, 11/5/2017, I ZR 59/16, Multi-Media und Recht 2018, p. 239, at p. 241.
[193] For a denial of the distributor's obligation to only sell products on which the name and address of the manufacturer were indicated, see, e.g., LG Coburg, 29/1/2015, 1 HK O 42/14, Beck-Rechtsprechung 2015, 117651.
[194] See Schucht, Das Recht der Verbraucherprodukte im neuen Produktsicherheitsgesetz, Verbraucher und Recht 2013, p. 86, at p. 90.
[195] See Reusch, Pflichtenkreis von Unternehmen im Umgang mit unsicheren Produkten – Thesen zum Produktrückruf, Betriebs-Berater 2017, p. 2248 at p. 2249.
[196] *Länderausschuss für Arbeitsschutz und Sicherheitstechnik*; LASI, Leitlinien zum Produktsicherheitsgesetz, 3rd ed. 2013, available at https://lasi-info.com/uploads/media/lv_01.pdf, at p. 16 f.
[197] See, for example, Klindt and Schucht, in: Klindt (ed.), supra n. 6, § 2 para. 164; Rockstroh and Kunkel, IT-Sicherheit in Produktionsumgebungen, MultiMedia und Recht 2017, p. 77, at p. 81; Wiebe, Produktsicherheitsrechtliche Pflicht zur Bereitstellung sicherheitsrelevanter Software-Updates, Neue Juristische Wochenschrift 2019, p. 625, at p. 626.
[198] In favour of the classification of software as a product: Runte and Potinecke, Software und GPSG, Computer und Recht 2004, p. 725, at pp. 726 f.; Zscherpe and Lutz, Geräte- und Produktsicherheitsgesetz: Anwendbarkeit auf Hard- und Software, Kommunikation & Recht 2005, p. 499 at p. 500; Gärtner, Die Rolle von Betriebssystemen im Konformitätsbewertungsprozess, Medizinprodukterecht 2014, p. 187 at p. 188. Against: Klindt and Schucht, in: Klindt (ed.), supra n. 6, § 2 para. 164; Wiebe, supra n. 13, at p. 626.
[199] *Bundesnetzagentur*; see infra, Part II Q 1.

laboratories to deal with risks stemming from the electricity, whereas the market surveillance authorities and also the Hessen Equipment Inspection Body[200] cannot monitor them any longer themselves.

Cyber security is a hot political issue in Germany (as well as at the EU level), and which institution should deal with it is currently debated. A working group of the Product Safety Commission (AfPS)[201] is also discussing product safety related issues of cyber security. When it comes to data integrity, the competent authority is the Federal Office for Information Security (BSI).[202] BSI, however, does not deal with issues of health and safety. Apparently, no authority has yet taken up the physical aspects of cyber security.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

According to § 5 para. 1 ProdSG, (non-harmonised) standards and other technical specifications may be used to assess the compliance of a product with the requirements. § 5 para. 2 ProdSG contains a presumption of compliance with § 3 para. 2 ProdSG when the product complies with standards or other technical specifications or parts thereof which have been identified by the Product Safety Commission and whose references have been published by the Federal Institute for Occupational Safety and Health (BAuA)[203] in the Joint Ministerial Gazette.[204] Registers of those national standards and technical specifications are available at the BAuA website.[205]

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Germany in case there are consumer product(s) on the market which are found unsafe under the GPSD

The administrative measures at the disposal of market surveillance authorities are set out in §§ 26 to 28 ProdSG.[206] Generally speaking, the market surveillance authorities shall take "appropriate measures" when they have reason to suspect that a product does not fulfil the general prerequisites for making products available on the market as set out in §§ 3 to 8 ProdSG and special legislation. These measures are directed to the economic operator concerned, and thus to the manufacturer, authorised representative, importer or distributor, § 2 no. 28 ProdSG. In particular, these measures include:

1. The prohibition of the exhibition of a product which does not fulfil the requirements of § 3 para. 5 ProdSG. Under that provision, the exhibitor[207] of a product that is not yet safe must clearly indicate that it does not comply with the requirements and cannot be acquired unless compliance is reached.[208] Moreover, when a product is presented, the necessary precautions for the protection of the safety and health of persons present shall be taken;

2. Measures ensuring that a product is not placed on the market unless it fulfils the safety requirements as laid down in § 3 paras 1 or 2 ProdSG (see Q 3);

3. An order that a product be checked by a notified body, a GS body or a body that is similarly suited;

4. The prohibition of a product's being made available on the market or a product's exhibition for the period necessary to carry out such checks;

5. The requirement that appropriate, clear and easy-to-understand information in German about the risks which

[200] *Hessische Geräteuntersuchungsstelle*; See infra, Part II Q 1.
[201] *Ausschuss für Produktsicherheit*
[202] *Bundesamt für Sicherheit in der Informationstechnik*
[203] *Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*
[204] *Gemeinsames Ministerialblatt*
[205] See https://www.baua.de/DE/Aufgaben/Gesetzliche-und-hoheitliche-Aufgaben/Produktsicherheitsgesetz/Normenverzeichnisse.html.
[206] It should be added that product safety law is also enforced indirectly, through unfair commercial practices law. German courts have consistently held that the requirements of product safety law are market practices, and that their breach is an unfair commercial practice. This is not barred by the Unfair Commercial Practices Directive 2005/29/EC, whose Article 3(3) and recital (9) exempt health and safety from its total harmonisation approach.[206] This opened up the opportunity for competitors[206] as well as for consumer organisations and for business organisations to challenge unsafe products or products that did not indicate the name and address of the manufacturer under the unfair commercial practices law of the Unfair Competition Act (UWG).[206] The main remedy available there is an injunction, but the law also offers the remedy of damages to competitors who have suffered (economic) damage.
[207] In German *„Wirtschaftsakteur oder Aussteller " in: § 27 Adressaten der Marktüberwachungsmaßnahmen, Gesetz über die Bereitstellung von Produkten auf dem Markt (Produktsicherheitsgesetz – ProdSG. According to §2* an "exhibitor" shall mean any natural or legal person exhibiting a product.
[208] For a case see VG Berlin, 9/2/2012, 1 L 422.11, Verbraucher und Recht 2014, p. 480.

the product represents be affixed to the product;

6. The prohibition to place a product on the market;[209]

7. The order that a product that was made available on the market be withdrawn or recalled;

8. The seizure of a product or its destruction; and

9. The order that the public be warned about the risks posed by a product available on the market. Market surveillance authorities may alert the public themselves if the economic operator fails to alert or alert in time or fails to take a similarly effective measure or fails to take it in time.[210]

This catalogue of standard measures is not exclusive, as indicated by the term "in particular". Thus, market surveillance authorities can also take other "appropriate measures". These may include the order of making a software update available where this is technically feasible and the costs are not excessive.[211] Of course, the consumer cannot normally be forced to actually implement the update, as much as they cannot be forced to return recalled goods.[212] All these measures can be taken where there is a reasonable suspicion of a risk for health and safety, which means that there must be facts that lead to the assumption that health and safety are at risk.[213] Due to that risk, measures are usually taken with immediate effect, and legal action by the addressee against such a measure does not have a suspensive effect.[214] In cases of serious risks, the choice of measures is limited to the more stringent measures. According to § 26 para. 4 ProdSG, the market surveillance authorities shall order that products presenting a serious risk to the safety and health of persons in particular, be withdrawn or recalled or shall prohibit that such products are placed on the market. The decision as to whether a product represents a serious risk shall be based on an appropriate risk assessment which takes into account the nature of the hazard and the likelihood of its occurrence; the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk. The measures under § 26 para. 2 sent. 2 nos. 6, 7, 8 and 9 ProdSG as well as those under § 26 para. 4 ProdSG, which have become unappealable or immediately enforceable, are made public by the Federal Institute for Occupational Safety and Health, see § 31 para. 1 ProdSG. They are published in the database "Dangerous Products in Germany".[215] For the year 2017, BAuA lists five measures of which it has knowledge.[216] Under § 27 para. 1 ProdSG, additional competencies exist in relation to persons other than the economic operator or exhibitor[217] concerned, but they shall only be permissible when an imminent serious risk cannot be averted otherwise. An example is a platform operator which is not itself involved in the manufacturing, exhibition or distribution of a product (see infra, Part. 2 Q 2). If that other person suffers damage from such measure, they shall receive compensation unless they can obtain compensation otherwise or unless the measure has served to protect their assets.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Administrative sanctions are set out in § 39 ProdSG, and they were strengthened in 2011 as compared to the previous regime of the GPSG. Most breaches are now a regulatory offence, which can normally be sanctioned with a fine of up to 10 000 Euro. Some regulatory offences can be sanctioned with a fine of up to 100 000 Euro. Insofar as they are under the scope of the GPSD (rather than special legislation and purely national law, namely the GS

[209] For a case see VG Köln, 17/3/2013, 21 K 2589/12, Multimedia und Recht 2013, p. 143.
[210] The public warning by market surveillance authority is seen as ultima ratio, as this is the most intensive measure and most detrimental for the reputation of an economic actor; see Tremml and Luber, Amtshaftungsansprüche wegen rechtswidriger Produktwarnungen, Neue Juristische Wochenschrift 2013, p. 262, at p. 263; Schucht, Meldungen im Internet-Schnellwarnsystem RAPEX und hoheitliche Warnungen bei gefährlichen Produkten, Betriebs-Berater 2017, p. 455.
[211] See Wiebe, supra n. 13, at p. 629.
[212] An exception is the car sector where a consumer can be prohibited from using the car unless they implement a software update. See e.g. VG München, 28/11/2018, M 23 K 18.2902, Beck-Rechtsprechung 2018, 36621, in the context of the Volkswagen Diesel scandal.
[213] See, e.g., VG Berlin, 9/2/2012, 1 L 422.11, Verbraucher und Recht 2014, p. 480.
[214] For an example, see ibid.
[215] *Gefährliche Produkte in Deutschland*; https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Produktinformation/Datenbank/Produktsicherheit_form.html?nn=8684884&meldev.GROUP=1&prodkat.GROUP=1.
[216] BauA, Gefährliche Produkte 2018, https://www.baua.de/DE/Angebote/Publikationen/Berichte/ProdSG-2018.pdf?__blob=publicationFile&v=5, p. 61.
[217] *The* German legislation uses the terms „Economic operator or exhibitor", in German *„Wirtschaftsakteur oder Aussteller " in: § 27 Adressaten der Marktüberwachungsmaßnahmen, Gesetz über die Bereitstellung von Produkten auf dem Markt (Produktsicherheitsgesetz - ProdSG). According to §2* an "exhibitor" shall mean any natural or legal person exhibiting a product.

mark), these relate to breaches of an enforceable order under § 26 para. 2 sent. 2 no. 2, 4, 6, 7 or 8 or § 26 para. 4 sent. 1 ProdSG. In addition, § 40 ProdSG provides for criminal sanctions under the scope of the GPSD for a person who persistently repeats an intentional act as mentioned, i.e. the breach of an enforceable order under § 26 para. 2 sent. 2 no. 2, 4, 6, 7 or 8 or § 26 para. 4 sent. 1 ProdSG, or who, by such an intentional act, puts at risk the life or health of a third person or third-party property of substantial value. These sanctions can amount to a term of imprisonment of up to one year or a fine. In practice, sanctions are rare. In their latest available annual reports, most states (*Länder*) do not list a single sanction.[218] Berlin and Lower Saxony listed 1 case each, Baden-Württemberg, Brandenburg and Saarland two cases each, Bremen[219] and Hessen 3 each, North Rhine-Westphalia and Rheinland-Pfalz 12 each.

Recent case law in Germany with respect to or relevant for the GPSD/the national implementation legislation.

In the vast majority of cases, economic operators voluntarily comply, and the market surveillance authority does not even need to make a formal decision.[220] Thus, in their latest available annual reports, some states (*Länder*) list only very few formal decisions. Some market surveillance authorities have issued prohibitions from putting certain products into circulation (Hamburg and Thüringen: 1 each; Berlin: 3, Brandenburg: 9, Rheinland-Pfalz: 18, Baden-Württemberg: 24, Bavaria and Hessen: 33 each, Sachsen-Anhalt: 43), published product warnings or ordered recalls (Brandenburg, Northrhine-Westphalia and Saxony: 1 each, Bavaria and Mecklenburg-Vorpommern: 2 each, Rheinland-Pfalz: 3, Hamburg: 4, Hessen and Lower Saxony: 7 each), or ordered the destruction of products (Saxony and Thüringen: 1 each, Northrhine-Westphalia and Sachsen-Anhalt: 2 each, Brandenburg: 9, Berlin: 11, Hessen: 12, Rheinland-Pfalz: 31). Challenges to measures of the market surveillance authorities and case law relating to them is extremely rare,[221] and the cases referred to above were finally determined in the first instance courts and are of no general significance, which also means that courts did not have the chance to clarify legal concepts of the ProdSG or the underlying EU legislation.[222] Usually, the market surveillance authority wins in court, as it prepares its decisions carefully. Unfair commercial practice law cases are in fact more frequent, and they have even reached the Federal Supreme Court (BGH). In fact, the BGH has made the important statement that the information about the name and address of the manufacturer forms part of the safety of consumer products and that therefore the distributor, who has to contribute to making only safe consumer products available on the market, also must make sure that the name and address of the manufacturer are affixed to the product or its packaging.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Germany concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

In relation to traceability, one market surveillance authority considered that an obligation to use barcodes would be helpful. In this respect, one would have to require manufacturers to change the barcode once they change the product. Even now, where barcodes are used voluntarily, it is sometimes difficult to understand whether manufacturers have actually reacted to safety concerns that were raised by the market surveillance authority if they keep the same barcode. Moreover, distributors sometimes replace the manufacturer's barcode with their own, or simply affix their own barcode where the manufacturer had not done so. This would have to be regulated.

In relation to the definition of safety, the individual assessment of what is an acceptable or unacceptable level of risk often differs from one official to the next. In practice, the problem is sometimes mitigated by taking the opinions of two or three officials on the same product. The definition should express more clearly the preference for a safe design over instructions or warnings, as manufacturers often try to compensate for insufficient design by way of instructions.

Concerning emerging issues with new technologies, it has become clear that the fragmentation of competencies between the federal level and the level of the states (*Länder*) is a problem, and that intense cooperation between different authorities will be necessary, including the Federal Office for Information Security, which is competent in

[218] Bavaria, Hamburg, Mecklenburg-Vorpommern, Sachsen-Anhalt, Saxony, Schleswig-Holstein and Thüringen.
[219] In the annual report of Bremen, they do not appear in table 5 on market surveillance but in table 4.1 on health and safety at work.
[220] See, for example, Vogel, Marktüberwachung – eine Aufgabe mit zunehmender Relevanz, in: Freie Hansestadt Bremen, Die Senatorin für Gesundheitsschutz, Frauen und Verbraucherschutz, Jahresbericht 2018 Gewerbeaufsicht des Landes Bremen, p. 48, at p. 51, for Bremen.
[221] For examples, see VG Sigmaringen, 27/11/2008, 8 K 1828/06, juris; VG Berlin, 9/2/2012, 1 L 422.11, Verbraucher und Recht 2014, p. 480; VG Düsseldorf, 4/9/2012, 3 L 1092/12, BeckRS 2014, 55467; VG Köln, 17/3/2013, 21 K 2589/12, MultiMedia und Recht 2013, p. 143.
[222] This may also be the reason why some case law is not reported, as it is of no general interest.

cyber security but has not yet dealt with other safety issues.

Possible improvements to make the implementation of the GPSD in Germany more effective

Beyond minor clarifications (for example, concerning the relationship between warnings and safe design), the legislative framework of the ProdSG is not regarded to be problematic. As to the European level, the fragmented system of Regulation (EC) 765/2008 caused major problems in practice. Moreover, the different market surveillance systems of the GPSD and of the sector-specific EU legislation was criticised; this was, however, remedied at the national level by way of adaptation of the general product safety law to the requirements of sector-specific legislation.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Germany.

Germany is a federal state where the enforcement of the law is, generally speaking, in the competence of the states (*Länder*). At the same time, there is a need for homogeneous application of the law in Germany and also for effective communication externally. This makes the institutional setting of the implementation and enforcement of product safety law rather complex. At the regulatory level, the competency for product safety law is with the federal state (Bund). The various areas of product safety law are allocated in different ministries. The responsibility for the GPSD lies with the Federal Ministry of Food and Agriculture, whereas the Ministry of Labour and Social Affairs is responsible for the majority of the specific sectors. The responsibility for customs lies with the Ministry of Finance.

In Germany, the enforcement of market surveillance is generally in the competence of the states (Länder), § 24 para. 1 ProdSG. Usually, the competence is allocated with the authorities that are responsible for health and safety at work.[223] The federal state is only competent for enforcement in certain sectors, in particular electrical appliances under the EMC Directive[224] and radio equipment,[225] whose enforcement is within the competency of the Federal Network Agency, and motor vehicles and tractors[226] which are within the competency of the Federal Motor Transport Authority (KBA).[227] The federal level, however, takes some coordination function in certain product sectors. The Federal Institute for Occupational Safety and Health (BAuA) is a federal authority that is not itself a market surveillance authority but fulfils important roles in product safety law. First, it has a research mandate by which it shall at an early stage identify and assess safety and health risks posed by the use of products and make proposals for the reduction of such risks, § 32 para. 1 ProdSG. In individual cases, it shall make, in consultation with the competent market surveillance authority, a risk assessment for products when there is sufficient evidence that they present a direct risk to the health and safety of persons or that they represent a serious risk, § 32 para. 2 ProdSG. The BAuA also supports the market surveillance authorities in the development and implementation of surveillance concepts that market surveillance authorities are required to adopt and to implement under § 25 para. 1 ProdSG. BAuA thereby scientifically analyses identified shortcomings in the nature of the product, § 32 para. 3 ProdSG. BAuA also operates a Product Safety Portal where it publishes its findings.[228] Finally, BAuA has its own laboratories, for example, for acoustic testing, and it organises annual meetings of market surveillance authority officials for the exchange of experience.

The ProdSG also foresees the Product Safety Commission (AfPS) at the Federal Ministry of Labour and Social Affairs, § 33 para. 1 ProdSG. It is composed of experts from market surveillance authorities, conformity assessment bodies, statutory accident insurance institutions, the German Institute for Standardisation (DIN),[229] the Commission for Occupational Health and Safety and Standardization (KAN),[230] employers' associations, trade unions and the

[223] For the full list, see European Commission, List of national market surveillance authorities by country, at pp. 67 ff.
[224] § 13 Elektromagnetische-Verträglichkeit-Gesetz (EMVG), BGBl. 2016 I, 2879.
[225] § 23 Funkanlagengesetz (FuAG), BGBl. 2017 I, 1947.
[226] § 2 para. 1 no. 5 lit. a) Gesetz über die Errichtung eines Kraftfahrt-Bundesamtes (KfBAG), BGBl. 1951 I, 488, as amended.
[227] *Kraftfahrtbundesamt*
[228] See https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/_functions/BereichsPublikationssuche_Formular.html?nn=8701932. See also Bentz, Infos für alle Akteure, baua Aktuell 3/2018, p. 8.
[229] *Deutsche Insitute für Normung*
[230] *Kommission Arbeitsschutz und Normung*

associations involved, particularly those of manufacturers, distributors and consumers. The AfPS advises the Federal Government in matters relating to the safety of products. It also identifies standards and other technical specifications where no harmonised standards for a product exists. Moreover, in 2018 the German Market Surveillance Forum (DMÜF)[231] was established. It is located at the Federal Ministry of Economy and mainly serves as a policy advisory instrument. Its purpose is to create a forum where all the administrative bodies that are involved in the enforcement of product safety law meet, including those that act outside the ProdSG on the basis of sector-specific legislation, such as the Federal Network Agency or the Federal Motor Transport Authority. Not least, in this forum common points of view shall be developed for the political debates at the EU level.[232] However, the DMÜF also serves to develop guidelines for harmonised nation-wide market surveillance, to organise trainings and exchange and to support the communication between the market surveillance authorities and the customs authorities. The DMÜF itself has no enforcement powers.

The states (*Länder*) themselves have set up a committee, the Committee for Occupational Health and Safety (LASI). Among others, LASI has published guidelines on the application of the Product Safety Act (ProdSG).[233] LASI has also set up the Working Committee on Market Surveillance (AAMÜ)[234] to decide on and coordinate action in the individual states (*Länder*). The AAMÜ's key tasks include coordinating cooperation between the market surveillance authorities of the states (*Länder*) as well as planning and coordinating inter-regional focus initiatives in Germany as part of pro-active market surveillance. The AAMÜ meets twice a year.[235]

Certain coordination and reporting tasks have been transferred by an agreement between the states (*Länder*)[236] to the Central Authority of the States for Safety (ZLS)[237] in Munich, to exploit synergies and avoid duplication of work. ZLS is financed by the states (*Länder*).[238] In particular, the ZLS is responsible for the accreditation, notification and surveillance of notified bodies, GS bodies and approved inspection bodies.[239] The ZLS also serves as a central contact for the market surveillance authorities of other Member States, the Commission and customs,[240] and it hosts the representatives of the states (*Länder*) for the individual sector-specific pieces of product safety legislation as well as a representative for the GPSD[241] that act, for example, in the Administrative Cooperation Groups (AdCos) at the EU level.[242] Moreover, ZLS is a kind of arbitrator when the market surveillance authorities of different states (*Länder*) disagree on the safety of a particular product. The above-mentioned agreement provides for two scenarios. First, the ZLS is entrusted with the enforcement of the ProdSG if a product entails a serious risk and (1) the states (*Länder*) disagree on the appropriate measure to deal with that risk, (2) the risk cannot be dealt with by one *Land* by itself and (3) the risk can only be managed through measures that are applied in a harmonised way in the whole of Germany.[243] In practice, this situation may occur when one state announces a measure (under § 26 ProdSG) against a manufacturer or distributor after another state has confirmed the safety of the product, and the manufacturer or distributor in question then produces the safety confirmation to the market surveillance authority that intends to take measures against it. Second, the ZLS enforces product safety law if 13 states (*Länder*) entrust the ZLS with this task in writing and if the advisory council of the ZLS agrees.[244]

Finally, it should be mentioned that 10 states (*Länder*) have established special institutes where equipment, in

[231] *Deutsches Marktüberwachungsforum*
[232] See Bundesnetzagentur, Deutsches Marktüberwachungsforum (DMÜF), https://www.bundesnetzagentur.de/DE/Sachgebiete/Telekommunikation/Unternehmen_Institutionen/Technik/DMUEV/DMUEF-node.html.
[233] LASI, Leitlinien zum Produktsicherheitsgesetz, supra n. 12.
[234] *Arbeitsausschuss Marktüberwachung*
[235] See Germany, National Market Surveillance Programme 2019, p. 10.
[236] Abkommen über die Zentralstelle der Länder für Sicherheitstechnik, last amended in 2016, available at http://www.zls-muenchen.de/aktuell/pdf/201608_Lesefassung_ZLS-Abkommen_7_2016.pdf.
[237] *Zentralstelle der Länder für Sicherheitstechnik*
[238] The relevant share depends on their tax income and population, see https://www.gwk-bonn.de/fileadmin/Redaktion/Dokumente/Papers/koenigsteiner-schluessel-2010-2018.pdf.
[239] Art. 2 para. 2 Abkommen über die Zentralstelle der Länder für Sicherheitstechnik.
[240] Art. 2 para. 4 Abkommen über die Zentralstelle der Länder für Sicherheitstechnik.
[241] Art. 2 para. 7 Abkommen über die Zentralstelle der Länder für Sicherheitstechnik.For the list, see https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Marktueberwachung/pdf/Richtlinienvertreter.pdf?__blob=publicationFile&v=4.
[242] See https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/administrative-cooperation-groups_en.
[243] Art. 2 para. 5 Abkommen über die Zentralstelle der Länder für Sicherheitstechnik.
[244] Art. 2 para. 6 Abkommen über die Zentralstelle der Länder für Sicherheitstechnik.

particular electric equipment, toys and machines, can be tested, also proactively, and where measuring and testing procedures are developed.[245] One of them plays a special role in the system: the Hessen Equipment Inspection Body (GUS) in Kassel, which belongs to the *Land* Hessen and which has been entrusted by the government of Hessen to test products, or rather groups of products, proactively, independently from special requests of the market surveillance authorities. The GUS also develops its own testing and measuring procedures. It is therefore much better equipped to detect unsafe products than the regular market surveillance authorities, and it has also often found insufficient safety reports of private laboratories as well as unsafe elements in harmonised standards as well as in private standards.[246]

Plans/programmes in place which define priorities for market surveillance of consumer products

Each German *Land* annually defines its priorities for market surveillance of consumer products. Informally, the states (*Länder*) coordinate their priorities so as not to duplicate the work. Beyond the general coordination and exchange within the Working Committee on Market Surveillance (AAMÜ), working groups are set up regularly to further develop market surveillance in specific areas.[247] Currently, working groups are active, for example, in the areas of products sold online and on the harmonisation of the implementation of product safety law in the practice of the states (*Länder*).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Germany with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

The general measures of market surveillance activities also relate to products containing new technology and connected devices that are, however, controlled by the Federal Network Agency. The Federal Institute for Occupational Safety and Health (BAuA) is currently conducting a scientific investigation into approaches to deal with this category of products.[248] Moreover, BAuA has finalised a project in 2018 dealing with the question of whether or not, or under what circumstances, 3D printers come into the scope of application of the ProdSG.[249]

Market surveillance on C2C products is not conducted, as they are outside the scope of application of the ProdSG.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Of course, the competent authorities have recognised the problems related to the online sale of unsafe products, particularly that they cannot take direct action against the manufacturers or suppliers, which are often outside the EU. The Federal Institute for Occupational Safety and Health (BAuA) has therefore commissioned a study on the question of how to develop the Product Safety Portal further in the light of these problems.[250] BAuA has also published a brochure addressed to consumers that gives advice on how to avoid unsafe products on the internet.[251]

The practical procedures regarding market surveillance of products sold online are laid down in the Operations Guidelines of the Committee for Occupational Health and Safety (LASI).[252] For the distinction between the distributor and neutral actors, in particular online platforms, the Operation Guidelines refer to the Blue Book and to the Commission Notice on the market surveillance of products sold online.[253] Otherwise, the Operation Guidelines

[245] Decision of 30/6/2009, Marktüberwachung im Bereich des Geräte- und Produktsicherheitsgesetzes (GPSG); Eckpunkte für eine „ Gemeinsame Strategie des Bundes und der Länder zur Stärkung der Marktüberwachung im Bereich des Geräte- und Produktsicherheitsgesetzes (GPSG)", Gemeinsames Ministerialblatt (GMBl.) 2009, 581, available at https://lasi-info.com/fileadmin/user_upload/themen/strategie-zur-marktueberwachung/2009_07_07_veroeffentlichung_gpi.pdf.
[246] For information, see https://rp-kassel.hessen.de/sicherheit/produktsicherheit/hessische-geräteuntersuchungsstelle.
[247] See Germany, National Market Surveillance Programme 2019, p. 5.
[248] See Bleyer, Wie funktioniert Produktsicherheit?, baua Aktuell 3/2018, available at https://www.baua.de/DE/Angebote/Publikationen/Aktuell/3-2018.pdf?__blob=publicationFile&v=5, p. 3, and Kasper, Neue Anforderungen an die Sicherheitsnachweisführung, baua Aktuell 3/2018, p. 6.
[249] See BauA, 3-D-Druck: Praxisgrundlagen zu Produktsicherheit und Rechtsrahmen, 2nd ed. 2019, https://www.baua.de/DE/Angebote/Publikationen/Berichte/F2389.pdf?__blob=publicationFile&v=13. See also Wanders, Neue Fragen rund um 3D-Drucker, baua Aktuell 3/2018, p. 5.
[250] See Gesmann-Nuissl, Weiterentwicklung des BAuA-Produktsicherheitsportals: Internethandel und Produktsicherheit, 2014, available at https://www.baua.de/DE/Angebote/Publikationen/Berichte/F2256.html. See also Bleyer, Mehr Aufklärung gefragt, baua Aktuell 3/2018, p. 4.
[251] BAuA, Unsichere Produkte im Onlinehandel, 2016, available at https://www.baua.de/DE/Angebote/Publikationen/Praxis/A96.pdf?__blob=publicationFile&v=4.
[252] LASI, Handlungsanleitung, supra n. 55, at pp. 91 ff.
[253] OJ 2017 C 250/1.

suggest the following procedure: 1) Identification of the relevant exhibitor or distributor and its address; 2) Identification of the competent authority; 3) Sample. In practice, market surveillance of products sold online focuses primarily on the (virtual) check of online marketplaces.[254] For specific information, the surveillance authorities also visit manufacturers' websites.

Mystery shopping is rarely used by market surveillance authorities. One reason appears to be that that power is not explicitly mentioned in the ProdSG.[255] Another reason is, according to a market surveillance authority, that normally, offline samples are retrieved free of charge, and it would be difficult to explain to offline economic operators that they have to give their products free of charge, while online economic operators receive payment. In practice, mystery shopping is rather an instrument that private actors use, and in fact it has already led to injunctions under unfair commercial practices law, prohibiting, for example, the sale of products where the name and address of the manufacturer was not indicated.[256] However, where consumer organisations engage in mystery shopping, not least of non-EU/EEA country products sold on internet (in particular, China), they only test the quality rather than safety. One additional problem is that products in the online marketplace do not necessarily correspond to the seemingly like products that are sold offline.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Germany (except customs) with respect to product safety

At the national level, cooperation between the market surveillance authorities works through the use of ICSMS. The other institutions that serve to foster communication and exchange, not least with the federal level.. The most important actors in this regard are the Central Authority of the States for Safety (ZLS) and the Federal Institute for Occupational Safety and Health. Of course, there is also informal communication if, for example, one market surveillance authority finds an unsafe product that is manufactured within another state (*Land*), and thus in the geographical competence of another market surveillance authority. Moreover, neighbouring states (*Länder*) sometimes coordinate their market surveillance activities.

Cooperation with customs authorities in Germany with respect to product safety

Under § 24 para. 2 sent. 1 ProdSG, the market surveillance authorities shall cooperate with the authorities in charge of external border controls in accordance with Articles 27 to 29 of Regulation (EC) No. 765/2008, the latter being the customs authorities, § 2 no. 31 ProdSG. In addition, § 24 para. 2 sent. 2 ProdSG states that the customs authorities may, on request of the market surveillance authorities, transmit information which they obtained in connection with the release of products for free circulation and which are necessary for the performance of the tasks of the market surveillance authorities. Thus, according to § 24 para. 2 sent. 2 ProdSG, it is firstly the market surveillance authorities that can request information from the customs authorities but not *vice versa*, and secondly, the customs authorities would not need to transmit information of their own accord but only on request.[257] This does not, however, reflect practice, where, of course, market surveillance authorities also give information to customs authorities about what they might want to look for. Formally, so-called risk profiles are communicated by the market surveillance authorities to the ZLS that passes them on to the General Directorate Customs,[258] which then communicates them to the various customs authorities,[259] through a separate database of the customs authorities (ATLAS).[260] In the future, all customs authorities will also be included in ICSMS, which is not currently the case. In addition, there is regular communication at least between market surveillance authorities and customs authorities in states (*Länder*) with important ports, i.e. Bremen and Hamburg. For example, Hamburg reports that

[254] For an example, see ibid., pp. 98 ff.
[255] See, in contrast, § 23 para. 2 no. 1 FuAG (on the powers of the Bundesnetzagentur in relation to radio equipment) that expressly confers the power to make anonymous test purchases. The Bundesnetzagentur actually engages in mystery shopping.
[256] See BGH, 11/5/2017, I ZR 59/16, Multi-Media und Recht 2018, p. 239.
[257] See Schucht, in: Klindt, supra n. 6, § 24 para. 19.
[258] *Generaldirektion Zoll*
[259] Whereby risk profiles not only relate to product safety but to all kinds of risks, including weapons, drugs, products violating intellectual property rights and so on. In E-commerce, about one third of objections relate to product safety.
[260] *Automatisiertes Tarif- und Lokales Zoll-Abwicklungs-System*; based on Art. 6 of Regulation (EU) No. 952/2013 laying down the Union Customs Code, OJ 2013 L 269/1. See Weerth, ATLAS, in: Gablers Wirtschaftslexikon, https://wirtschaftslexikon.gabler.de/definition/atlas-27056.

the customs authorities notified 1 211 products in 2018, which were then controlled by the market surveillance authorities.[261] In Bremen, where the market surveillance authority and the customs office are in contact at least once per week, the vast majority of the reactive measures by the market surveillance authority were triggered by notifications from the customs authorities.[262] It is clear, however, that only a very small part of imported products can be inspected by the customs authorities.[263] However, there have been reports of "customs shopping" in the EU. Germany appears to be a preferred port of entry, generally because customs fees are lower than in other countries. It has, however, happened in the past that German customs authorities have denied entry of products into Germany that have then been taken to the port of another Member State and entered the EU there. Generally speaking, the number of customs officers and therefore the number of controls of imported goods is higher than in some of the neighbouring Member States.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Market surveillance authorities do not communicate or cooperate formally with the authorities of other Member States but only via the Federal Institute for Occupational Safety and Health (BAuA), which is the RAPEX contact point. Before passing on the notifications of market surveillance authorities, BAuA assesses the formal correctness of the notification and the plausibility of the risk assessment (but does not perform its own risk assessment). In rare cases, BAuA has contacted the notifying authorities because of doubts concerning the risk assessment, which has occasionally led to downgrading the risk category. When it comes to the usefulness of RAPEX for their own work, interviewed authorities mentioned that the first problem is a language problem. Not only are the RAPEX notifications only in English but more importantly, the accompanying documentation is in the national language of the notifying authority and therefore often not useful. Moreover, it was mentioned that some Member States appear to notify far more products than those that pose a "serious risk",[264] thereby "flooding" RAPEX.[265] This leads to a tendency to pay less attention to notifications from those Member States. The control that the European Commission exercises before a RAPEX notification is made public seems insufficient.

It was also mentioned that cultural differences exist between Member States. For example, when it comes to the assessment of risks for children, some Member States seem to be more protective than others. Finally, the RAPEX system is barely useable for long-term risks stemming from the toxicity of products where there is a breach of the Restriction of certain Hazardous Substances Directive 2011/65/EU but no imminent risk for health and safety. It is suggested that RAPEX should be extended to cover these risks.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Nationally, RAPEX notifications are also in ICSMS. RAPEX notifications from other Member States are first dealt with by the ZLS. In practice, the ZLS clusters RAPEX notifications and passes them on to a limited number of market surveillance authorities (usually three), which then investigate whether the product in question is available in Germany. In parallel to that, ZLS conducts online research. BAuA as the RAPEX contact point is notified of voluntary recalls but cannot produce RAPEX notifications on serious risks itself, as it only has the competency to feed the notifications of the market surveillance authorities into RAPEX.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

There is no structured cooperation with either business associations or consumer organisations. The regional consumer organisations do not normally deal with product safety at all (except with food safety and related issues,

[261] See Hamburg, Behörde für Gesundheit und Verbraucherschutz, Marktüberwachungskonzept (2019), https://www.hamburg.de/produktsicherheit/3887550/marktueberwachungskonzept-produktsicherheit.
[262] See Vogel, supra n. 32, pp. 48 ff.
[263] The inspection quota is less than 3%, whereby this still seems by far higher than the inspection quota in other Member States with big ports.
[264] See also, generally, Wende, in: Klindt (ed.), supra n. 6, § 30, at para. 29. Concerning the notion of serious risk, see Commission Implementing Decision (EU) 2019/417 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system, OJ 2019 L 73/121.
[265] Actually, one interviewee raised doubts as to whether all the notifications from Germany of 2018 concerning cars were really justified by "serious risks".

such as the safety of food packaging). Only at the federal level, the Federation of German Consumer Organisations (vzbv)[266] sometimes takes part in meetings, but rather at the political level. One example is cyber security where the head of vzbv participates in a high-level group on digitalisation of the federal government. In principle, vzbv as well as the regional consumer centres cooperate with authorities in the framework of the 'Market Guardians'[267] project. In that project, which is financed by the federal state, the consumer organisations monitor markets to discover structural problems and share their insights with the competent authorities. This happens, for example, in the area of financial services. In contrast, no product safety case has ever been reported to the market surveillance authorities, not least because vzbv and the consumer centres have not specialised in product safety until now. Conversely, market surveillance authorities do not use vzbv or the consumer centres as a channel to reach out to consumers. The consumer organisation *Stiftung Warentest* would in principle be best suited to pass on information to market surveillance authorities about safety issues related to the products that they test. Their business model, however, is to be the first to publish test results concerning products. Therefore, market surveillance authorities only learn of such issues from *Stiftung Warentest*'s publications. In turn, the BAuA website provides for a link to *Stiftung Warentest*.[268]

Individual consumers very rarely come to the market surveillance authorities with products that they regard to be unsafe. There seems to be little awareness in the population, and individual consumers will often think of their particular problem as a one-off problem rather than a safety issue. The same applies, generally speaking, to contacts with business associations. Only the state Baden-Württemberg seems to organise regular roundtable meetings with businesses. Otherwise, market surveillance authorities have sometimes contacted business associations in the beginning of a surveillance project related to a particular group of products, for example, gardening products. Occasionally, businesses approach market surveillance authorities to report competitors that manufacture allegedly unsafe products, which then usually leads authorities to investigate.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

According to § 31 para. 2 ProdSG (corresponding to Article 16(2) of Regulation (EC) 765/2008), market surveillance authorities and the Federal Institute for Occupational Safety and Health (BAuA) shall inform the public, preferably by electronic communication, of any other findings available to them relating to products which present a risk to the health and safety of persons. This shall apply in particular to information for the identification of the products, the type of risks and the measures taken. More generally, the BAuA website offers some information for consumers, including a brochure concerning online sales. The same applies to the states (*Länder*). However that information is difficult to find for the average consumer. Individual market surveillance authorities have made attempts to raise awareness of product safety in the population, for example through a topical exhibition in Bremen, which again received very little attention. Use of social media is by and large non-existent, but has been named by one authority as a possible channel for the future. In fact, there is a mobile application that lists all recalls but that is run by a private person.

Businesses should have an intrinsic interest in the matter and should therefore be better suited to find relevant information at BAuA's website, for example BAuA's recommendations on how to organise recalls,[269] which summarises the key points of the EU Commission's document "Product Safety in Europe: A Guide to corrective action including recalls" and provides a link to them. BAuA also has an online tool that businesses can use to report a recall.[270] The Committee for Occupational Health and Safety (LASI) also made an exhibition at a business fair in order to raise awareness of product safety.[271]

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Germany (including cooperation and information exchange

[266] *Verbraucherzentrale Bundesverband e.V.*
[267] *Marktwächter*
[268] See BAuA, Geprüfte technische Arbeitsmittel und Produkte, https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Produktinformation/Gepruefte-Produkte_node.html.
[269] BAuA, Handlunsempfehlungen für das Rückrufmanagement, https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Rueckrufmanagement/Handlungsempfehlungen.html.
[270] See BAuA, Das Rückruf-Formular der BAuA, https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Rueckrufmanagement/Rueckrufformular/Rueckrufformular_node.html.
[271] See Bimmermann, Troia and Hocevar, Der LASI-Messestand im Rahmen der Arbeitsschutz aktuell in Stuttgart, in: Hessisches Ministerium für Soziales und Integration, supra n. 62, pp. 42 ff.

with businesses, existence of codes of good practice on product recalls)

First of all, it is the manufacturer who is responsible not only for ensuring the safety of products before they are put into circulation, but also for reacting if there is a safety risk in products that are already available on the market, § 6 para. 2 ProdSG. The measures must be appropriate with respect to the product's characteristics and include the withdrawal, adequate and effective warning and recall. Thus, the withdrawal, warnings or recall is only necessary if the problem cannot be solved otherwise, but if the product has already reached the consumer, or even children, the recall is indispensable. BAuA has a recommendations on its website on how to organise recalls,[272] which summarises the key points of the EU Commission's document "Product Safety in Europe: A Guide to corrective action including recalls" and provides a link to them. The manufacturer must also inform the competent market surveillance authority immediately about the safety problem and about the measures it has taken to prevent this risk, § 6 para. 4 ProdSG (implementing Article 5(3) GPSD). Thus, market surveillance authorities will usually request a list of distributors and possibly of the brands under which the product is distributed. Importantly, such information shall not be used for criminal proceedings against the informant or for the purpose of starting proceedings in accordance with the Code of Administrative Offences (OWiG)[273] against the informant. Thus, the threat of sanctions shall not act as a disincentive to comply with the duties under § 6 para. 4 ProdSG. This does not mean, however, that the information could not lead to investigations that then lead to administrative or criminal sanctions, for example, for negligently causing the death or physical injury of victims.[274] The market surveillance authorities shall ensure that the manufacturer complies with these duties. Thus, they can order the manufacturer to publish a recall, and they can also fine the manufacturer if it fails to inform the competent market surveillance authority or fails to inform the authority accurately, completely or in due time with up to 10 000 Euro, § 39 para. 1 no. 4 ProdSG. The market surveillance authority for its part has to inform BAuA (the Federal Institute for Occupational Safety and Health) immediately about the facts, in particular in the event of recalls, § 6 para. 4 sent. 2 ProdSG. In addition, the manufacturer can report a recall directly to BAuA, for example by using an online form that is available on the BAuA website.[275] That website also refers to the European Commission's Product Safety Business Alert Gateway.[276] BAuA then publishes the relevant information in the database "Dangerous Products in Germany",[277] see § 31 para. 2 ProdSG.

Monitoring of effectiveness of product recalls by market surveillance authorities

Market surveillance authorities only monitor mandatory recalls. Economic operators have to submit a copy of the recall letter to their customer, which will normally be a trader, as well as information for publication, information on the number of products that were delivered and returned, on the supply chain and on the fate of the recalled products. In the case of voluntary recalls (which are the vast majority of recalls), the market surveillance authorities do not systematically monitor to what extent products are actually returned or destroyed, due to lack of resources. Many consumers are not aware of recalls, and it is possible that often recalled products are not destroyed but rechannelled to non-EU/EEA countries.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Germany that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The states (*Länder*) report data concerning the activities of the market surveillance authorities in their annual reports, which are then collected and consolidated by the ZLS for the purpose of reporting to the EU Commission. In addition, BAuA reports that in 2017, 89 complaints by private actors and traders were submitted via ICSMS to the various German market surveillance authorities, whereas there were 90 complaints in 2016, 75 complaints in 2015, and 131 complaints in 2014. Statistics about fatal accidents or injuries stemming from consumer products are not collected in Germany. Moreover, hospitals and the medical profession in general are under no obligation to report

[272] BAuA, Handlunsempfehlungen für das Rückrufmanagement, https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Rueckrufmanagement/Handlungsempfehlungen.html.
[273] *Ordnungswidrigkeitsgesetz*
[274] See Kapoor, in: Klindt, supra n. 6, § 6 para. 90.
[275] See BAuA, Das Rückruf-Formular der BAuA, https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Rueckrufmanagement/Rueckrufformular/Rueckrufformular_node.html.
[276] https://webgate.ec.europa.eu/gpsd.
[277] https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Produktinformation/Datenbank/Produktsicherheit_form.html?nn=8684884&meldev.GROUP=1&prodkat.GROUP=1.

product safety related injuries to market surveillance authorities.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Germany (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The market surveillance authorities almost consistently complain about scarce resources both in terms of staff and in terms of financial resources, which, for example, stops them by and large from mystery shopping. This is why, for example, some states (*Länder*) want to have the ZLS do the mystery shopping on request by the market surveillance authorities, as they do not have the budget themselves to buy products online. Another problem that was mentioned is the small number of laboratories in the hands of the federal state, which means that it can be very difficult and time consuming to have a product tested. Far more products need to be tested in the authorities' own laboratories rather than having to rely on test documentation produced by manufacturers or in privately run laboratories, at least in cases where the privately run laboratories' tests are commissioned and paid for by the manufacturer, which may create adverse incentives.[278]

The fragmentation of market surveillance over about 70 market surveillance authorities not only leads to scarce resources for each authority but also to small case numbers and therefore a lack of routine in each individual market surveillance authority. As an example for an area where centralisation led to better coordination and more routine, the Federal Network Agency was mentioned, with its responsibility for the enforcement of the Radio Equipment Directive. In terms of timely notification, a certain tension between speed and thorough investigation was pointed out. Before a RAPEX notification can be made, testing in a laboratory may be necessary, and due to a scarcity of laboratories – some states (*Länder*) do not have any themselves – it may take a while until the tests can be conducted and a "serious risk" can be ascertained, which is required for the use of RAPEX. Another source of failure to notify is the situation in which a safety risk concerns the GPSD and sector-specific legislation at the same time. Here, market surveillance authorities may only report the sector-specific issue in the safeguard clause procedure but may not make a RAPEX notification, in particular if the competencies for the sector-specific legislation and for the GPSD lie with different market surveillance authorities. A further complication lies in the fact that a market surveillance authority that has prematurely notified a serious risk and then, after further investigations, finds out that there is no risk or it is not serious, or is actually overturned by a court,[279] cannot easily withdraw the notification, as only BAuA can do this; this may make market surveillance authorities even more cautious to notify a product to BAuA for notification in RAPEX. It is nearly impossible to get a notification deleted from the list of the European Commission even if it has proven to be incorrect.

Incorrect notifications, for example notifications that are based on insufficient risk assessment, may even lead to state liability, which is often emphasised in academic literature.[280] At the EU level, the judgment of the Court of Justice in the *Lehtinen* case has shown the risk of state liability for warnings by a public official.[281] Specifically due to that risk, but also for the general use of RAPEX, there was a strong opinion that market surveillance authorities that have reported a serious risk should have the right to withdraw that notification. Also, it was mentioned that currently there is no clear rule on what happens if the European Commission refuses to delete an entry in the RAPEX database which the notifying authority (and the manufacturer) regard as incorrect. In this situation the EU should become responsible and liable rather than the market surveillance authority that has made an attempt to correct its erroneous notification.[282] Most importantly, however, market surveillance authorities often do not even get to the stage where a serious risk is ascertained that could be reported because most economic actors voluntarily and immediately react once they are confronted by the market surveillance authority with the suspicion of a risk, and do not put the product into circulation (in Germany) in the first place. Thus, voluntary reactions including recalls often never reach the RAPEX database of serious risks, as the seriousness of the risk has not yet been ascertained. Also, the fact that an unsafe product is recalled and is therefore not available on the market

[278] See the experience with the control by notified bodies of medical devices, which led to a major reform of EU medical devices law.
[279] The risk evaluation can be controlled by the court, see VG Sigmaringen, 27/11/2008, 8 K 1828/06. See also Schucht, supra n. 20, at pp. 458 f.
[280] See, for example, Tremml and Luber, supra n. 20. Concerning public warnings, see Schieble, Öffentliche Warnungen vor unsicheren Verbraucherprodukten: Behördliche Befugnisse und Haftungsrecht, Verbraucher und Recht 2007, p. 401, at pp. 406 ff.
[281] ECJ, 17/4/2007, Case C-470/03 *A.G.M.-COS.MET Srl v Suomen valtio and Tarmo Lehtinen*, ECLI:EU:C:2007:213; on which see Reich, A.G.M. COS.MET oder: Wem dient das EU-Produktsicherheitsrecht?, Verbraucher und Recht 2007, pp. 410 ff.
[282] In Germany, in the famous *Birkle noodles* case that was decided in 1990,[282] the warning of the public by a public authority of noodles had led to state liability which cost the *Land* Baden-Württemberg 6.5 million Euro. These were not RAPEX cases, but they might still have a chilling effect on market surveillance authorities, not least due to their lack of financial resources.

anymore has an impact on the likelihood of damage, which is a criterion within the assessment of the seriousness of risk. Thus, some market surveillance authorities barely produce RAPEX measures, although they may be highly successful in preventing unsafe products from entering the market or in achieving recalls of unsafe products.[283]

Areas to make market surveillance of consumer products in Germany/the EU more effective

In principle, most actors agree that the fragmentation of market surveillance in Germany between the states (*Länder*) but also between the states (*Länder*) and the federal level causes problem. This is, however, a problem that is caused by the constitutional setting of Germany and that therefore cannot be solved entirely but only mitigated through coordination, working groups, meetings and so on, and a lot has been done to achieve coordination. As to RAPEX, quality should go before quantity, and that the system does not ensure that attention is focused on serious risks. It was therefore suggested to focus RAPEX on what it was at the outset: a system to rapidly report serious risks, rather than flooding the system with all sorts of notifications. Moreover, it was criticised that it is extremely difficult to delete an incorrect notification from RAPEX, which has repercussions on the preparedness to rapidly notify a risk, the seriousness of which has not yet been confirmed, for example, through extensive testing – not least as an incorrect notification may trigger state liability. In relation to recalls, tighter control of the recall process is hampered by data protection laws, and an improvement would require data protection to be relaxed accordingly. Better traceability, in particular through bar codes that traders should not be allowed to replace, would also be helpful. Finally, it was mentioned that recalled unsafe products should have to be destroyed, rather than sold elsewhere. Other potential improvements, such as more intense control of imports into Germany, more laboratory tests and better control of the effectiveness of voluntary recalls, all depend on the availability of more resources.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Germany since 2013

The level of safety of consumer products in Germany is generally regarded to be consistently high, moreover, manufacturers sometimes compensate for insufficient safety design through the use of instructions. In contrast, the rise of direct imports to consumers of products sold online gives reason for concern, as mentioned above. Statistics concerning injury or death caused by consumer products are not available.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Germany whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

New technologies are a problem that German market surveillance authorities and their supporting infrastructure are only beginning to approach and where appropriate solutions are not yet in place. For C2C sales, there is not even the legal competency to act. In the area of B2C products, control of the online market is not yet fully developed, and comprehensive testing (rather than testing by individual institutions of different types of safety issues) is not yet being pursued. A new approach that is, however, not necessarily related to new technologies or products sold online, is the use of web crawlers that search, for example, rating platforms for relevant combinations of words, such as a particular product and “fire”. According to a market surveillance authority, this has already led to the detection of safety risks in products that would not have been discovered otherwise. BAuA is conducting research on how this can be used more effectively to detect product risks.[284]

Views of market surveillance authorities whether approaches in Germany can be considered best practice implementation of the GPSD, which could be of interest to other countries

One important feature of German product safety law is that the national legislator has extended the system of the

[283] The practice between market surveillance authorities appears to differ but there are no statistics available, not least as there is no intention to initiate a notification competition among market surveillance authorities.
[284] See Bleyer, Mehr Aufklärung gefragt, supra n. 58, p. 4.

New Legislative Framework to general product safety law so that a uniform market surveillance system is in place, which avoids confusion. The same is intended for the implementation of the new Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products, and indeed the German government pursues the goal of achieving harmonisation at the EU level as well. Moreover, Germany could serve as an example for other federal systems concerning the many ways by which the fragmentation of market surveillance competencies can be mitigated through cooperation between the competent authorities but also through coordination and support from the federal level. At the same time, the example of smart products shows the difficulties that come with the exclusive competence of one particular authority that is not equipped to exercise fully-fledged control over all safety aspects of a product.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

Notes: As in the past, the German authorities do not provide data on staff working on market surveillance of consumer products. This kind of data is not collected at the national level either. The figures cannot be obtained from the statistics of the states (Länder) either as they do not distinguish health and safety at work and product safety, which are dealt with, in most of the states (Länder), by the same public authorities.

B. Number of inspections of consumer products (2018)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections			
Total number of consumer products inspected	n.a.	n.a.	27,541
Total number of consumer products tested in laboratories	n.a.	n.a.	1,234
Total number of consumer products inspected in cooperation with the customs	n.a.	n.a.	12,465
Total number of dangerous consumer products found	n.a.	n.a.	12,715
Notes:	*The figures refer to ALL products tested in 13 sectors covered by the German Product Safety Act - there is no distinction between consumer and non-consumer products or between the different sectors*		

C. Number of recalls of consumer goods (2017)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	119	49	168
Notes:	*The figures relate to recalls that have been made public. The statistic does not distinguish between voluntary and mandatory recalls.*[285]		

D. Key sources

Legislation	Produktsicherheitsgesetz (Product Safety Act; ProdSG), Bundesgesetzblatt (Federal Gazette)

[285] For more details, see BAuA, Gefährliche Produkte 2018, supra n. 26, pp. 43 ff.

	2011 I, 2178, as amended, English translation at https://www.gesetze-im-internet.de/englisch_prodsg/index.html.
Studies/reports/articles	Klindt, Thomas (ed.), Produktsicherheitsgesetz, 2nd ed. (Munich, C.H. Beck, 2015). Annual reports of the states (Länder): Baden-Württemberg: Gewerbeaufsicht Jahresbericht Arbeitsschutz 2017 Bayern: Die Bayerische Gewerbeaufsicht. Mit Sicherheit für Bayern, 2015 Berlin: Ein Auftrag. Ein Ziel. Mehr Arbeitsschutz. Jahresbericht 2018 der Berlin Arbeitsschutzbehörden Brandenburg: Arbeitsschutz – Jahresbericht 2017 Bremen: Jahresbericht 2018 – Gewerbeaufsicht des Landes Bremen Hamburg: Statistischer Jahresbericht 2017 des Amtes für Arbeitsschutz Hamburg Hessen: Hessischer Jahresbericht – Arbeitsschutz und Produktsicherheit 2018 Mecklenburg-Vorpommern: Tätigkeitsbericht 2017 der Behörden für Arbeitsschutz und technische Sicherheit in Mecklenburg-Vorpommern Niedersachsen: Jahresbericht 2018 der Staatlichen Gewerbeaufsicht des Landes Niedersachsen Nordrhein-Westfalen: Statistischer Jahresbericht der Arbeitsverwaltung NRW 2018 Rheinland-Pfalz: Jahresbericht 2017 Gewerbeaufsicht Saarland: Jahresbericht der saarländischen Gewerbeaufsicht 2017 Sachsen: Jahresbericht der Gewerbeaufsicht des Freistaates Sachsen 2018 Sachsen-Anhalt: Jahresbericht 2017 Arbeitsschutzverwaltung Sachsen-Anhalt Schleswig-Holstein: Gesund leben und arbeiten in Schleswig-Holstein, 2019 Thüringen: Jahresbericht 2018 der Thüringer Arbeitsschutzbehörden
Websites	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin: https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/_functions/BereichsPublikationssuche_Formular.html?nn=8701932. Zentralstelle der Länder für Sicherheitstechnik, http://www.zls-muenchen.de.
Interviews	Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Bundesministerium für Arbeit und Soziales Bundesnetzagentur Freie Hansestadt Bremen, Die Senatorin für Gesundheit, Frauen und Verbraucherschutz Geräteuntersuchungsstelle Kassel Customs Verbraucherzentrale Bundesverband e.V.

12. Greece

COUNTRY REPORT GREECE

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The national legislation implementing the GPSD in Greece is:

a) Joint Ministerial Decision (JMD) Z3-2810/2004 'General Safety of Products', Government Gazette (GG) B' 1885/ 20.12.2004, transposes the General Product Safety Directive into the Greek legal order.

b) Law 2251/1994 'On consumers' protection', GG A' 191/16.11.1994, as amended and recently codified by Ministerial Decision 5338/2018, GG B' 40/17.01.2018. More specifically:

Article 7 on the health and safety of consumers:

§1-§4: These paragraphs repeat the provisions included in the JMD on the General Safety of Products. More specifically, they stipulate that for the implementation of article 7, the definition of producer and distributor of the JMD on general safety of products applies. The definitions of the JMD regarding 'product' and 'safe product' are also applicable.

§5: This paragraph stipulates that manufacturers and distributors must comply with European and Greek legislation, the standards that have been adopted for the health and safety of consumers, the recommendations of the European Commission for the evaluation of product safety, the code of practice and ethics that is applicable to particular fields and existing safety knowledge and techniques which consumers reasonably expect to be met. The paragraph also provides a mandate for the issuance of two ministerial decisions: one ministerial decision that will regulate any remaining specific issue or detail regarding the compliance with general product safety requirements, and another ministerial decision that shall provide for relevant inspection procedures, sampling, product laboratory testing, measures regarding product disposal, a list of sample testing laboratories and product certification bodies and will regulate any other remaining specific issue or detail relevant to the above.

Article 13a on (administrative) sanctions: The article describes the administrative sanctions that are imposed in case of violation of the GPSD.

c) Ministerial Decision (MD) 91354/2017 'Codified rules for the trading of products and rendering of services', GG B' 2983/30.08.2017, also known as DI.E.P.P.Y. rules in Greece. The MD contains provisions regarding the labelling and traceability of products. In the absence of other, more specific rules, these rules are applied for non-harmonised products and for products for which EU legislation does not provide specific requirements. More specifically:

Article 50 on labelling of non-food products: The article describes traceability requirements for harmonised products (batch number etc.) but only labelling requirements (name of product and producer, quantity, contact details) for non-harmonised products.

d) Law 4177/2013 'Product and Services regulation and other provisions', GG A' 173/08.08.2013. More specifically:

Article 18 on inspections, sampling and laboratory testing: In the absence of a more specific rule, the article is applicable for the processes, sampling and testing of products falling under GPSD.

e) Presidential Decree (PD) 147/2017 'On the organisation of the Ministry of Economy and Development', GG A' 192/ 13.12.2017). The PD defines the competences and responsibilities of the Ministry's departments. Articles 42-57 describe in detail the competences and responsibilities of the departments dealing with the GPSD. (These provisions explain why the competence and responsibility for the implementation of the GPSD currently falls to the Secretariat General of Industry and not the Secretariat General for Consumers as the JMD transposing the GPSD stipulates. Note that the Ministry of Economy and Development has now been renamed as the Ministry of Development and Investments).

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Greece

There is currently a significant legal gap with regards to the traceability of non-harmonised consumer products as there are no legal provisions that stipulate traceability requirements for such products.

Given that the national implementation legislation of the GPSD transposes the content of the GPSD with identical wording, it therefore does not contain a mandatory specification of the traceability requirement. More specifically, in line with the GPSD, the national implementation legislation (JMD on the General Safety of Products) contains indicative and not binding traceability requirements for producers. With regards to product distributors, the national implementation legislation again follows the GPSD wording stipulating that distributors shall keep and provide the necessary documentation for tracing the origin of products. Traceability obligations such as barcodes or other machine readable codes are therefore not required in the context of the GPSD.

The national rules for the trading of products, the so-called DI.E.P.P.Y. rules, which apply in parallel to the national implementation legislation of the GPSD, stipulate mandatory traceability requirements only for harmonised consumer products, such as indicating on the product packaging or in the accompanying documentation the type, batch or serial number of the product (art. 50). For non-harmonised consumer products, the national rules for the trading of products do not stipulate traceability requirements but a general requirement to indicate name of the product, name and contact details of the producer (as well as quantity of content, composition, use and maintenance instructions) that pertain to the labelling of the product and not its traceability (art. 50).

To address this issue, the national market surveillance authority is currently preparing a Joint Ministerial Decision promoting technical regulation for product categories where instances of non-compliance have been found. The draft JMD introduces traceability requirements for manufacturers (e.g. requirement for batch number etc.).

There is a strong interest in introducing more requirements for non-harmonised consumer products that would allow them to better trace these products and facilitate market surveillance. They propose e.g. a requirement to indicate the product batch on packaging, a requirement for the economic operator to keep supply chain records and/or adding a barcode or other machine readable identification on the product's packaging.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used in the application of the national legislation on general product safety in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The legislation implementing the GPSD in the Greek legal order does not explicitly cover emerging threats related to new technologies. The wording of the national implementation legislation is identical to the wording of the Directive and hence does not include provisions with respect to cyber security or software-related threats. Other legislation (irrelevant to the implementation of the GPSD) exists that cover some of these threats, e.g. threats related to private data protection. See e.g. Ministerial Decision 31619 οικ./2017 'Code of Conduct for E-commerce', GG B' 969/22.03.2017.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

If European standards do not exist, the following benchmarks are used in practice by the national market surveillance authority for assessing the safety of a specific product, in order of priority:

i) Other European standards not referenced in the EU Official Journal that are applicable for other products from which they can derive requirements for the product at hand;

ii) EU Commission recommendations setting guidelines on product safety assessment, e.g. for eco-design;

iii) International standards, i.e. standards from non-EU/EEA countries e.g. standards from NSF International, American Society for Testing of Materials (ASTM), etc.;

iv) Level of scientific and technological progress;

v) Justified and reasonable consumer expectations regarding product safety.

Even though it was indicated that codes of good practice in force in the sector concerned are also used as benchmarks, it was not further specified. Legislation and practices of other European Member States that have been notified in TRIS database are also taken into account to the extent possible, if available.

Regional market surveillance authorities on the other hand indicated that they take into account those national standards that are not based on European standards.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Greece in case there are consumer product(s) on the market which are found unsafe under the GPSD

Market surveillance authorities have the following administrative measures at their disposal if consumer products are found unsafe under the GPSD:

The National Market Surveillance Authority, depending on the level of violation i.e. the level of risk imposed by the product, may:

- Require businesses to provide relevant information on the product;
- Require businesses to provide relevant information on the supply chain and the distribution of the product;
- Require from economic operators to take corrective measures including:
  a) Restrictions for placing the product(s) on the market or bringing products into compliance;
  b) Stopping products being placed on the market;
  c) Recalling products;
  d) Withdrawing products.

In the case of products sold online, the National Market Surveillance Authority may require businesses to provide relevant information with regards to the ownership of the website where the product is sold.

The regional market surveillance authority (Department of Trade of the regional unit), depending on the level of violation, may:

- Require businesses to provide relevant information on the product;
- Require businesses to provide relevant information on the supply chain and the distribution of the product;
- Conduct unannounced on-site inspections and physical checks of products.

Both national and regional market surveillance authorities can take product samples in order to subject them to safety tests (by sending them to appropriate laboratories). National market surveillance authorities can also publish special warnings to inform the public through press releases.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The penalties foreseen by the national implementation legislation of GPSD are applicable in case of violation of the obligations of producers and distributors (art. 5 of Directive 2001/95 as transposed in the Greek legal order by art. 5 of JMD Z3-2810/2004) or if they fail to comply with the administrative measures imposed. It should be noted that the national legislation implementing the GPSD stipulates that the provisions of Law 2251/1994 on consumer protection, and more specifically art. 13a, set out the penalties to be imposed on violators. The same penalties are therefore imposed in practice for violations of the GPSD and for other violations pertaining to consumer protection (e.g. unfair commercial practices, misleading advertising etc.).

The following administrative penalties can be imposed, independently or in combination, only after a decision of the Minister of Development and Investments:

i. A recommendation for compliance within a specified period, and omission of the infringement in the future.
ii. A fine ranging from EUR 1 500 to EUR 1 000 000. If more than three fine decisions are issued against the same supplier, seller, producer or distributor, the fine is doubled.
iii. Temporary suspension of the business or part of it for a period of three months to one year if more than three fine decisions are issued against the same supplier, seller, producer or distributor.

If the producer, distributor, or seller does not reply to consumers' complaints as required, then the Minister may

i. Issue a recommendation for compliance within a specified time period to the producer/supplier that fails to reply to consumers' complaints.
ii. Impose a fine ranging from EUR 500 to EUR 5 000 to the producer/supplier that fails to reply to

consumers' complaints.

Depending on the nature and significance of violation and the potential consequences for the general consumer public, the Minister may decide to publish by press or other appropriate means the penalties that have been imposed as well as the administrative measures that have been taken by market surveillance authorities against specific suppliers, producers, distributors, or sellers with respect to consumer products in violation of the GPSD.

Recent case law in Greece with respect to or relevant for the GPSD/the national implementation legislation.

Desk research in national jurisprudence databases[286] revealed that relatively few cases exist in relation to the national implementation legislation of the GPSD, especially when considering that a significant amount of time has elapsed since this legislation entered into effect in 2004 until today.

The small number of relevant cases can be justified by the fact that if more specific legislation is available for the case at hand, it will be implemented instead of the legal provisions pertaining to the general safety of products. This was the opinion that was expressed by the Legal Council of State in 2009, according to which: "In case of violation of the provisions of JMD Z3-2810/2004 on general safety of products, it should be examined whether there is more specific Greek or Community legislation regarding the safety of the product concerned, which also provides for relevant penalties in case of violations. If so, this legislation shall be implemented instead of the JMD on general safety of products [...] if the more specialised legislation covers only specific risks or risk categories, the rest of the risks will be covered by implementation of the JMD on general safety of products."

The following case law pertains to violation of the requirement that producers and distributors should immediately inform the market surveillance authorities in case of a product safety risk:

- Decision 2869/2009 Council of State (StE). In this case, the Council of State dismissed the application for annulment that had been submitted by a company against the decision of the Deputy Minister of Development which imposed on the company a fine of EUR 58 694 because it did not immediately inform the competent market surveillance authorities of the risk of the products it had placed on the market (violation of art. 5§3 of JMD Z3-2810/2004 'General Safety of Products', GG B' 1885). The company had imported from China and supplied to the Greek market an electric iron which led to the death of one consumer and of one of the company's employees. The fine was imposed because the company failed to immediately inform the national market surveillance authority about the product risks and only notified the authority after having taken actions to withdraw and recall from the market the electronic irons.
- Decision 3076/2010 Council of State (StE). In this case, the Council of State dismissed the application for annulment that had been submitted by a company against the decision of the Secretary General for Consumer Affairs of the Ministry of Development which imposed on the company a fine of EUR 20 000 because it did not immediately inform the competent market surveillance authorities of the risk of the products it had placed on the market (violation of art. 5§3 of JMD Z3-2810/2004 'General Safety of Products', GG B' 1885). The company had imported from Austria two models of motorcycles that had technical problems. The company was aware of the risks of the particular motorcycle models, given that it had already taken steps to inform consumers of the risks posed by these models and had initiated their recall procedure. However, at the same time, it failed to immediately notify the market surveillance authorities about the potential risks posed to the consumers and only informed them after it was invited by the General Secretariat of Consumers to provide information following a RAPEX alert.
- Decision 2593/2011 Council of State (StE). In this case, the Council of State dismissed the application for annulment that had been submitted by a company against the decision of the Secretary General for Consumer Affairs of the Ministry of Development which imposed on the company a fine of EUR 29 347 because it did not immediately inform the competent market surveillance authorities of the risk of the products it had placed on the market (violation of art. 5§3 of JMD Z3-2810/2004 'General Safety of Products', GG B' 1885). The company had imported into Greece a vacuum cleaner model originating from China, but later found out from German press publications that the vacuum cleaner was dangerous for consumers. The company took steps to withdraw the products from its stores and to recall the items already sold and to publish the recall notice in the daily press, but without informing the competent authority at the same time (General Secretariat of the Ministry of Development) on the risk of the product in question, as required.

[286] NOMOS and ISOKRATIS databases

The following case law echoes the opinion of the Legal Council of State, as it stipulates that the penalties that were imposed based on the (general) provisions of product safety should be annulled as other specific legislation exists to impose penalties for specific product safety violations.

- Decision 207/2013 Council of State (StE). The Council of State accepted the application for annulment that had been submitted by a company against a decision of the Secretary General for Consumer Affairs of the Ministry of Development which imposed on the company a fine of EUR 20 000 for placing unsafe diesel on the market. The court accepted that the fine that was imposed based on the (general) provisions of product safety (art. 13a of law 2251/1994 'on consumers' protection', GG A' 191) should be annulled as other specific legislation existed to impose penalties for the specific product safety violation.
- Decision 208/2013 Council of State (StE). In a similar case to the one above, the Council of State accepted the application for annulment that had been submitted by a company against a decision of the Secretary General for Consumer Affairs of the Ministry of Development which imposed on the company a fine of EUR 15 000 for placing unsafe diesel on the market. The court accepted that the fine that was imposed based on the (general) provisions of product safety (art. 13a of law 2251/1994 'on consumers' protection', GG A' 191) should be annulled as other specific legislation existed to impose penalties for the specific product safety violation.
- Decision 3351/2011 Council of State (StE) and Decision 3352/2011 Council of State (StE) are of the same topic as the above two decisions 207 and 208 and have the same argumentation.
- Decision 4670/2013 Athens Administrative Court of Appeal. The Administrative Court of First Instance accepted the appeal of a gas station owner against a decision of the Secretary General for Consumer Affairs of the Ministry of Development imposing a fine for placing unsafe diesel in the market based on the provisions of general product safety. According to its decision, for violations that relate to the quality of petroleum products applicable provisions are the provisions of Law 3054/2002, which prevail as being more specific to those of law 2251/1994, which establish a general obligation to comply with all Community and national consumer protection provisions. In its appeal, the State sought the annulment of the appealed decision arguing that the fine at issue imposed by the SG Consumer Affairs under the general product safety provisions of Law 2525/1994 is independent of the fine imposed by the Minister of Development based on the provisions of Law 3054/2002, since the imposition of the above fines are based on different grounds. The Administrative Court of Appeal rejected the State's plea and ruled that the provisions of the most specific law are valid and should be the basis of the imposed penalty.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Greece concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Market surveillance authorities in Greece (both national and regional) have encountered traceability issues. The lack of specific traceability requirements for non-harmonised products in national legislation creates shortcomings in the effective tracking of products. Authorities have indicated the lack of tracking methods/tools as well as the lack of a list or categorisation of the types of non-harmonised products as a problem. A specific issue has been encountered with regards to furniture, as the traceability of raw material (e.g. timber) that has been used in manufacturing the furniture cannot be ascertained. As a result, proper administrative fines and corrective measures cannot be imposed in case of violations. Water filters was reported as another product category with which authorities have recently encountered traceability issues.

National market surveillance authorities consider that the existing definition of safety in the GPSD, which has been transposed in identical wording in the Greek legal order, overlooks some crucial issues. More specifically, it does not explicitly cover environmental risks, cyber security risks, safety risks for persons with disabilities and safety risks due to the child-appealing character of products. The authorities consider that a lack of clarity with regards to some characteristics that increase risk (e.g. child-appealing character), could lead to these characteristics being treated differently by Member States and leading to different results per country. Another issue is that the current definition of safety leaves a lot of room for uncertainty between authorities and producers/distributors with regards to what products can be considered safe.

The national market surveillance authority identifies emerging safety issues with regards to particular categories of consumer products that are not addressed by current safety legislation. More specifically, safety issues have been identified with the following products:

- Personal care articles: may contain foreign bodies, e.g. insects, or create allergies;
- Childcare articles, baby/children's beds, baby car seats: safety requirements of these products are not always complied with;
- Furniture: traceability of raw material used (timber) is not easy or not possible;
- Button batteries;
- Rubber floor tiles for playgrounds: do not comply with REACH regulation and playground equipment and surfacing standards.

The regional market surveillance authority which is responsible for the market surveillance of both non-harmonised and harmonised products at the level of the regional unit identifies emerging safety issues with the following categories of products:

Non-harmonised consumer products: furniture, electrical appliances and equipment outside the scope of the Low Voltage Directive.

Harmonised consumer products: toys, cosmetics, electrical appliances and equipment under the scope of the Low Voltage Directive.

Possible improvements to make the implementation of the GPSD in Greece more effective

The lack of traceability requirements of consumer products is at the centre of focus of national market surveillance authority officials, who consider that improvements in the legislative framework, such as the promotion and adoption of technical regulations for specific product categories with reference to mandatory/voluntary standards, including also requirements for the quality management system of economic operators, would improve the effectiveness and efficiency of the implementation of the General Product Safety Directive as well as of the horizontal legislation on market surveillance and mutual recognition (Regulations 764/2008 and 765/2008 as currently in force and EU Decision 768/2008). Both economic operators and consumer associations would be involved in the drafting of technical regulations, leading to increased legitimisation and compliance with the requirements included therein.

Furthermore, to deal with product categories that fall under complex legal frameworks (grey zones), national market surveillance authorities propose the issuance of guidelines and/or codes of conduct regarding the general safety of products, labelling, presentation and promotion of products and services, in cooperation with other competent authorities, market stakeholders, universities and relevant non-profit organisations, as the best way to complement the existing legal framework.

The Director of the regional market authority considers the complexity of the current legal framework to be the most important hindrance for the effective implementation of the GPSD and therefore considers that a codification of the legal provisions on these topics would improve it.

Another suggestion for improvement would involve amending the existing national implementation legislation of the GPSD to include provisions pertaining to the regulation of product safety issues emerging due to new technologies, e.g. Internet of Things (IoT), connected products, etc. One such amendment may for instance involve updating the existing concept/definition of a 'safe product' to cover risks that are generated through the connectivity of products and the risk to be hacked.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Greece.

At the national level:

The Secretariat General (SG) for Industry of the Ministry of Development and Investments exercises market surveillance over the majority of products (harmonised and non-harmonised). It consists of three Directorates: the Directorate for Technical Industrial Legislation, which exercises market surveillance for industrial products, the Directorate for Technical Professions and Installation safety, which is responsible for lifts and cableways, and, finally, the Quality Policy Directorate, which is the Safety Gate (RAPEX) contact point, is member to the Consumer Safety Network and is responsible for the implementation of the GPSD.

Other authorities responsible for market surveillance at the national/central level are:

- The General Chemical State Laboratory is responsible for supervision of chemical substances (REACH, detergents etc.) and conducts chemical laboratory testing as or if necessary;
- The National Organization of Medicines (EOF) is responsible for medical devices;
- The Ministry of Rural Development and Food (DG plant production) that is responsible for fertilizers;
- The Ministry of Infrastructure and Transport, the Ministry of Environment and Hellenic Recycling Agency are responsible for waste, and others;
- The central authority of customs supervises the border and other (airport/port) custom authorities.

At the level of the regional unit:

- The Directorate of Development is responsible for exercising market surveillance competences regarding the products supervised by the SG for Industry at the level of the regional unit. It is therefore the regional authority that is most heavily involved with market surveillance. In some cases, the SG for Industry may also delegate some of its own competences to regional Directorates of Development through programming agreements. The Directorate of Development conducts inspections regarding consumer products following requests for cooperation from the SG for Industry or consumer complaints, imposes administrative measures in the case of unsafe products, provides advice to businesses regarding recall procedures and cooperates with other authorities as needed.
- Customs authorities at the border, airports, ports etc. in practice exercise market surveillance mostly for harmonised products.
- The regional chemical services of the General Chemical State Laboratory.
- Other departments involved with market surveillance at the regional level, but with regards to specific Products only, e.g. the Department of Environment and Spatial Planning is responsible for waste.

Plans/programmes in place which define priorities for market surveillance of consumer products

The SG for Industry creates an annual national market surveillance programme covering all consumer product sectors. The programme includes priorities for market surveillance based on product risks (e.g. products widely consumed, products consumed by vulnerable consumers, categories of products that are frequently reported on RAPEX, etc.). The SG for Industry requests regional authorities to conduct targeted market surveillance activities on specific products (regional surveillance plan).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Greece with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

No market surveillance activities are organised in Greece with respect to the safety of products containing new technologies or C2C products.

Market surveillance activities with regards to products sold online are an important percentage of market surveillance activities of the Quality Policy Directorate of the SG for Industry, reaching approximately 21-30% of total activities. These activities may also take place due to the participation of the Quality Policy Directorate in European market surveillance programs or after consumer complaints. According to the replies of the Directorate's officials, the market surveillance activities regarding products sold online are not different from the activities that take place for other products, given that the vast majority of online sellers have a physical store location so that e.g. on-site inspection can take place, administrative measures for recall or withdrawal can be imposed, etc.

On the other hand, according to the regional authority, market surveillance activities for products sold online are undertaken rarely (less frequently than once a year) and only after a consumer complaint or following a request for cooperation by the Ministry of Development and Investments.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The national market surveillance authority conducts market surveillance of products sold online from sellers established in Greece once a week, from sellers established in the EU once every three months and from sellers established outside the EU once every six months. The sales channels covered are retailer websites, online marketplaces and comparison websites. Market surveillance activities are usually conducted for online marketplaces and retailer websites that also have a physical store location.

To organise market surveillance of products sold online, the following process is followed:

Risk assessment is initially conducted using the information that has been collected through research, complaints, publicity (media etc.) in order to allow for targeting specific products. The basic criterion in the risk assessment is the inherent risk of the products (e.g. laser pointers, child care articles) with potential high impact for the health of vulnerable groups of consumers/citizens. The frequent use of these products is also a criterion, e.g. the frequent use of soothers and soother holders for babies.

For both online marketplaces and retailer websites, officials browse the relevant website and check the product sold online. By looking at the pictures of the product it is sometimes possible to detect if there is a problem with the product. Then, after locating the physical store of the seller, officials proceed to the physical inspection at the store premises where they check the actual product and take samples as or if necessary. Mystery shopping cannot be used as a method to conduct market surveillance, given that the Greek legislation currently in force requires officials to always disclose their identity when conducting inspections/market surveillance activities.

After inspection and findings of non-compliance with EU or national legislation of a specific product, all companies selling this product through electronic websites are controlled either by physical inspection and sampling or by requiring the companies to share technical documents/certification and other technical data. These actions have been recently undertaken for jewellery without the necessary marking (national legislation), for water filters lacking required certification, for playground floors (EU REACH legislation), etc.

The regional authority conducts market surveillance activities for products sold online rarely and only after a request for cooperation by the Ministry of Development and Investments or after a consumer complaint. This is the case also for other regional authorities. More specifically, the regional authority conducts market surveillance of products sold online from sellers established in Greece less than once a year and has had less than 10-15 relevant cases over the last decade, so the percentage of the market surveillance activities that focus on products sold online is very low.

The discrepancy in the percentage of market surveillance activities that focus on products sold online between the national and regional market surveillance authorities can be easily explained by taking into account that the competence of the regional market surveillance authority is local by definition and hence the regional authority does not take up relevant cases unless the location of the producer, supplier, distributor, or seller is within its territory.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Greece (except customs) with respect to product safety

Market surveillance authorities at the central level (national authorities) cooperate more frequently with other relevant authorities than regional market surveillance authorities. More specifically, the national market surveillance authority (Quality Policy Directorate) of the Ministry of Development and Investments indicated that it cooperates with authorities more than once a week. Cooperation takes place through formal agreements, through the inclusion of other authorities in the preparation of the annual national market surveillance plan, through regular exchange of information and/or informal cooperation e.g. in the case of an emergency.

The regional market surveillance authority (Department of Trade) cooperates with other authorities approximately once every three months. Most frequent is the cooperation with the Ministry of Development and Investments in the context of sampling programmes, more specifically with the General Secretariat for Trade and Consumer Protection, which is responsible for the implementation of the DI.E.P.P.Y. rules. The Department of Trade also cooperates with the Quality Policy Directorate in sampling programmes and through joint processes for dealing with dangerous products.

Cooperation with customs authorities in Greece with respect to product safety

Cooperation of the national market surveillance authority with customs falls short of what would have been expected to efficiently implement the GPSD. Cooperation of the national market surveillance authority with customs occurs less than once a year while the regional authority cooperated with customs only once over time with regards to a case involving quality of fuel.

To achieve cooperation between the national market surveillance authority (SG for Industry, Ministry of Development and Investments) and customs, a formal agreement is required through the issuance of a ministerial decision (legislation), which needs to be issued before cooperation can take place (see for instance JMD Z3/7835/2011 'on furniture, decorative objects and their raw material', GG B' 2650/09.11.2011, which in article 3 stipulates the authorities that shall cooperate and the way they shall cooperate in order to undertake market

surveillance activities regarding these products). As a result, there is no actual cooperation or timely provision of information to and from customs with regards to dangerous non-harmonised products.

The situation is different with regards to harmonised consumer products (with CE mark), for which customs cooperation is provided for by the EU regulation and the national legislation (e.g. see Law 4072/2012, GG A' 86/11.04.2012 for industrial products).

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

No cooperation takes place between regional market surveillance authorities and authorities in other countries. The regional authorities inform the national market surveillance authority immediately as soon as they detect a dangerous consumer product originating from another country. If the national market surveillance authority identifies or is notified of a dangerous product that has been manufactured outside Greece, the following steps are taken depending on whether the economic operator is located in the EU/EEA or outside the EU/EEA:

If the dangerous product originates from another EU/EEA country, the national market surveillance authority communicates with the respective national market surveillance authority of the other Member State where the operator is located, and provides all the relevant information that has been collected with regards to the product.

If the product has been manufactured outside the EU and is imported into the EU for the first time by another Member State, the responsibility for the product lies with the importer of the product. In this case, the national market surveillance authority contacts the authorities of the Member State in which the product was initially imported and provides all the information that has been collected with regards to the product.

RAPEX and ICSMS as well as other European networks and programs are excellent for facilitating information exchange in these cases.

If Greece is the first country importing the dangerous product, the national market surveillance authority would search for the importer of the product. At the same time it would notify the European Commission through RAPEX. The European Commission services would use the information provided to establish communication with the relevant authorities of the non-EU/EEA-country where the operator is based, and complete the procedure for the dangerous product. Such a case has not been encountered so far.

Apart from RAPEX and ICSMS, cooperation with other EU/EEA authorities may take place through the Wiki confluence platform and through coordinated actions on the safety of products organised at the EU level.

The national market surveillance authority cooperates informally with the respective authorities of Cyprus but has never cooperated with authorities located in non-EU/EEA countries.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Before a dangerous product can be notified in RAPEX, the following steps need to be taken:

Once a dangerous product has been identified, the national market surveillance authority cooperates with other authorities to collect all necessary information (photos, test reports, information on imposed measures) as soon as possible. An inspection is conducted during which samples may be taken as or if needed for laboratory testing and the relevant documentation is checked. The economic operator is notified of the results, based on which the economic operator takes voluntary or compulsory measures as or if necessary. After this process, during which the relevant information for RAPEX has been collected, the national market surveillance authority proceeds with collecting any other information that is needed so that the notification to RAPEX can be performed.

It follows from this description of the pre-notification stage that the notification to RAPEX does not occur very quickly. On average, the duration between the detection of a dangerous product and its notification to RAPEX is one week. There exist cases for which this time period may be much longer due to objections submitted by the economic operators or due to objective difficulties stemming from the legislative system in order to finalise the actions required. For instance, there has been a case for which the time that elapsed between the detection of the dangerous product and the notification to RAPEX was one and a half years. In other cases when, for instance the economic operator itself indicates a dangerous product, the notification to RAPEX may take place within the same day.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations

on product safety (regarding businesses: other than for requesting corrective action)

The exchange between market surveillance authorities and businesses/business associations is irregular. The national market surveillance authority cooperates with businesses/business associations approximately once a month. The authority provides information ad hoc when requested by businesses, e.g. frequently economic operators inquire information regarding the circulation of products such as furniture, clothes, childcare articles, shoes, lighters, etc. Regional market surveillance authorities rarely cooperate with businesses/business associations. This occurs only when asked by businesses to provide guidance.

Consumer organisations usually refer to the national market surveillance authority and not the regional authorities. Cooperation does not occur on a regular basis; it takes place once or twice a year, e.g. when consumer associations become aware of a dangerous product, they forward the relevant information to the Secretary General of Industry of the Ministry of Development and Investments or when they participate in working groups with officials from the national market surveillance authority to develop technical legislation for certain categories of products. The signing of a partnership agreement between the national market surveillance authority and a consumer organisation of Northern Greece is currently being discussed as another possibility for cooperation.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Market surveillance authorities provide guidance to businesses if requested. Authorities try to raise consumer awareness with regards to product safety by:

- Issuing press releases for dangerous/problematic products;
- Having the portal with RAPEX notifications translated into Greek and accessible to the public;
- Organising information campaigns in traditional media (e.g. newspapers);
- Uploading all information regarding product recalls, weekly RAPEX notifications, consumer awareness announcements, press releases etc. in Greek onto the Ministry's website;[287]
- Uploading information regarding dangerous products onto the website of the Attica Region (for the regional market surveillance authority).

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Greece (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and other corrective administrative measures in Greece are organised as follows:

A voluntary recall is performed either by an initiative of the business itself when there is a problem or after the national market surveillance authority communicates to the business its recommendation for a recall. Businesses are required to use all their available customer information for recalls. However, if the business is not aware of how the recall can be effectuated, the market surveillance authority provides relevant information e.g. about issuing a press release, contacting the consumers, etc.

In the case of a mandatory recall, the national market surveillance authority issues a decision which is signed either by the Secretary General for Industry or the Minister for Development and Investments, according to which a recall should take place. The businesses and the market surveillance authority agree on the information channels to inform consumers and businesses are required to use all their available customer information for recalls and other corrective measures (including from customer databases, etc.). If the business does not recall its product or if it does not cooperate with the authorities, measures can be taken, including fines. These measures can be imposed regardless of a recall or a withdrawal decision.

In the case of a recall, the national market surveillance authority requires businesses to provide information about activities targeted at consumers as well as information about activities that are targeted at or that occur in cooperation with other businesses involved in the supply chain (e.g. distributors, online marketplaces). The authority may also request a list of the other businesses involved in the supply chain (e.g. distributors, online marketplaces), a timeline of the recall process, as well as information regarding the destruction/disposal of the

[287] See: http://www.ggb.gr/deltia-all-view

products collected. The above pieces of information are considered to be elements of the case file, and economic operators are expected to provide them. The national market surveillance authority does not monitor the effectiveness of the recall; however, if a product that has been recalled or withdrawn is later found in the market, the above information will be used to impose the appropriate sanction on the concerned business.

The national market surveillance authority uploads the relevant press releases and recalls on the website of the Ministry of Development and Investments[288] and uses traditional media channels to inform consumers. Codes of good practice or other types of information documents such as guidelines on recalls have not been developed so far.

The regional market surveillance authority will deal with a recall only when the recall involves products within its territory. In this case, the regional market surveillance authority will provide guidance and cooperate with the respective business with regards to the recall as or if needed. When the products are found elsewhere or are seized elsewhere, the relevant regional department becomes responsible for cooperating with the respective business.

In the case of a recall, the regional market surveillance authority requires businesses to provide information regarding activities targeted at consumers, a list of other businesses involved in the supply chain (e.g. distributors), as well as information pertaining to the destruction and/or disposal of the collected products. The regional market surveillance authority may also require other documentation such as shipping/transportation documents in order to assist in the recall by notifying the respective parties (e.g. distributors) about the recall. These documents are also used to monitor the effectiveness of the recall as they are used by the regional authority to compare whether the amount of products collected correspond to the expected/required amount. To monitor the effectiveness of the recall, the regional authority will also check the market by conducting on-site checks in shops to ascertain that the product has been removed from market circulation.

To inform the public, the regional market surveillance authority uploads relevant recall information on the website of the Attica Region.

Monitoring of effectiveness of product recalls by market surveillance authorities

Effectiveness of the product recalls is difficult to monitor. In practice, the national market surveillance authority does not monitor the effectiveness of the recall, while the regional market surveillance authorities conduct on the spot checks in shops to ascertain if the recall has been effective. Regional market surveillance authorities also notify authorities in the neighbouring regional units to alert them in case they detect a product that has been recalled in their local market.

The effectiveness of the recall cannot be established by asking the economic operator for information because due to the lack of traceability for non-harmonised consumer products, the economic operator is not in the position to ascertain where the product is.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Greece that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The only statistic that is systematically collected from market surveillance authorities pertains to consumer complaints. At the central level, a database of consumer complaints exists that contains the complaints submitted with regards to products to the General Secretariat of Trade and Consumers through the telephone number 1520 and the email address 1520@efpolis.gr.

At the regional level (Attica), all the complaints that are submitted online on the website of the Attica region[289] or by telephone to the phone number 1539 of the Attica region are stored on the website of the Region. The website includes the number of submitted complaints, the authority handling the specific complaint, and how much time it took to deal with it.

There is no systematic and consolidated injury data collection in Greece pertaining to products (or inflicted by other means). Data is fragmented between different authorities that collect the data they are interested in, e.g. the labour inspectorate collects data on workers accidents due to mechanical equipment, each hospital collects data regarding patients' type of injuries and cause, etc. There used to be a national database regarding children's

[288] See: http://www.ggb.gr/deltia-all-view
[289] See: https://www.pattikis.gr/citizen/frmCitizenPopup.zul?sid=e6eaa8de-1cbe-4cad-aa18-324718d62234

accidents (including product-related accidents) that was kept by the Children's Hospital, but it is no longer active today.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Greece (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Several practical problems and impediments exist in Greece, creating hindrances to exercising effective market surveillance of consumer products. The most important and commonly accepted issues that have been identified as problematic are:

- The lack of financial resources and the limited staff resources for market surveillance;
- The lack of expertise in online market surveillance;
- The lack of financial resources for testing consumer products;
- The lack of expertise in new technologies; and
- The lack of cooperation with customs authorities.

The national market surveillance authority also highlights the lack of suitable product testing laboratories, the lack of statistics/data to set priorities for market surveillance, the lack of cooperation with consumer organisations and the difficulty in controlling products from non-EU/EEA countries directly reaching consumers as very important issues, while the regional authority also stresses the lack of coordination at the national level and the unclear distribution of competences as significant problems.

The impediments related to the lack of financial and staff resources also affect online market surveillance. In addition, legal impediments (e.g. the legal requirement to always identify oneself when acquiring product samples, which precludes the use of the mystery shopping method) and other impediments such as the problem experienced by the regional market surveillance authority when the Attica region blocked access to commercial websites so that officers do not waste time by surfing the web etc., make effective online market surveillance difficult.

Even though RAPEX is functioning rather well, human and financial resources for RAPEX are insufficient, and other national authorities frequently do not provide information that would allow for notifications to RAPEX. At the same time, in several instances the information provided in order to trace notified products has been insufficient. Another impediment for RAPEX is the fact that due to existing legal provisions that require a series of actions, it may take a long time before a notification can be submitted to RAPEX. Another frequent problem is when a test report indicates that the product is dangerous but the importer also holds a report based on which the product is compliant. In that case, the market surveillance authority is required to have the product examined by a third laboratory, which causes a significant delay.

Finally, as far as recalls are concerned, due to the absence of relevant data, it is not possible to ascertain their effectiveness.

Areas to make market surveillance of consumer products in Greece/the EU more effective

Several steps could be undertaken to improve the market surveillance of consumer products in Greece.

With regards to the functioning of RAPEX, the national market surveillance authority highlighted that the Greek translation of the weekly RAPEX reports should be improved, especially regarding the description of the products and/or related risks. A requirement to include more information in A12 notifications is also viewed as being necessary to facilitate better traceability of the relevant products.

Lack of information provision to consumers and economic operators regarding recalls and other administrative measures as well as the lack of a commonly followed process or procedure for implementing these measures (including recalls) were emphasised as shortcomings of market surveillance in Greece and are considered to be very important weaknesses. The development of such documents is therefore essential for the improvement of market surveillance in Greece.

One such document would be a set of guidelines on recalls and other administrative measures for the economic operators that would enable them to go through the process step by step without violating any of the requirements and risking the imposition of penalties due to their ignorance of the procedure (which has occurred in several cases as can be deduced by the case law analysed above).

Another necessary document would be a code of conduct or good practices for the officials working in market

surveillance. The code of conduct would guide and facilitate officials in the correct and systematic implementation of market surveillance activities, including recalls and other administrative measures, and would make sure that homogeneous practices regarding market surveillance are followed throughout the country. The code of conduct could also be used as self-training material for young officials if it includes some additional background regarding risk assessment and priority setting in market surveillance.

With regards to consumers, more efforts should be taken to make information regarding product safety more visible and accessible. Information campaigns should therefore not be restricted to traditional means (press, uploading onto the Ministry's website) as is presently the case, but also make use of other means of communication that have not been used so far, e.g. TV and social media.

Finally, the lack of cooperation between market surveillance authorities and customs with regards to general product safety needs to be addressed. This cooperation can only occur through the issuance of legislation. There exist other, less rigid, ways (e.g. establishing protocols of cooperation, allowing access to online databases information etc.) through which cooperation between customs and market surveillance authorities could also be effectuated.

Both national and regional market surveillance authorities stressed the need to clarify the responsibility and competence of different authorities with respect to market surveillance, as there seems to be lack of clarity or overlapping of competences between authorities with respect to some product categories, which reduces the effectiveness of GPSD implementation. A law was relatively recently passed in Greece (Law 4512/2018 'on establishing a framework for the supervision of economic activities and the market for products', GG A'/17.01.2018) with the aim to deal with these problems as they exist and have been identified, including in other areas of supervision (e.g. food safety, technical safety, etc.). The law stipulates that secondary legislation shall be issued to clarify competences and strengthen cooperation between said authorities.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Greece since 2013

The lack of systematic statistical data on product safety does not allow for providing a substantiated answer to this question. However, the overall impression is that the level of product safety has improved. This is supported by the fact that the number of consumer complaints about product safety has decreased and inspections in the market indicate that the number of unsafe products circulating has also been reduced (clothes, lighters, wooden products). However, additional evidence is needed to make a definite conclusion with regards to an improvement.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Greece whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Market surveillance authorities in Greece do not have the tools to respond to market surveillance challenges related to new technologies, connected devices, Internet of Things, C2C sales etc. Unfortunately, they also do not have the necessary resources to develop relevant technological approaches and tools that would help them address these challenges.

Views of market surveillance authorities whether approaches in Greece can be considered best practice implementation of the GPSD, which could be of interest to other countries

The development of technical regulations, with reference to mandatory/voluntary standards for specific product categories, has been indicated as a best practice implementation of the GPSD which could be of interest to other countries. However, given that these technical regulations are currently in the drafting stage and have not yet been issued, it remains to be seen whether these regulations will facilitate GPSD implementation; this will depend on their content and their implementation.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available

year).			
	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*5*	*n.a.*
Responsible authorities at the sub-national level (regional/provincial/local)	*n.a.*	*55*	*n.a.*
Total (country)	***n.a.***	***60***	***n.a.***
Of which staff allocated to market surveillance activities regarding products sold online	*n.a.*	*1*	*n.a.*
Notes:	*2018 data. Data regarding harmonised consumer products could not be completed due to the unavailability of the market surveillance authority for harmonised consumer products and the lack of data in other (alternative) sources.*		

B. Number of <u>inspections</u> of consumer products (last available year)			
	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**n.a.**	**230**	**n.a.**
Total number of consumer products inspected	*n.a.*	850	*n.a.*
Total number of consumer products tested in laboratories	*n.a.*	122	*n.a.*
Total number of consumer products inspected in cooperation with the customs	*n.a.*	*n.a.*	*n.a.*
Total number of dangerous consumer products found	*n.a.*	100	*n.a.*
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	*n.a.*	0	*n.a.*
Notes:	*2018 data. Data regarding harmonised consumer products could not be completed due to the unavailability of the market surveillance authority for harmonised consumer products and the lack of data in other (alternative) sources. Officials indicated that in the context of GPSD there is minimal cooperation with customs and little (if any) information exchange.*		

C. Number of <u>recalls</u> of consumer goods (last available year)			
	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*n.a.*	130	*n.a.*
Notes:	*2018 data. Data regarding harmonised consumer products could not be completed due to the unavailability of the market surveillance authority for harmonised consumer products and the lack of data in other (alternative) sources.*		

D. Key sources	
Legislation	Directive 2001/95 EC, Official Journal L 011, 15/01/2002 P. 0004-0017. Regulation (EC) 764/2008, Official Journal L 218, 13/08/2008 P. 0021–0029. Regulation (EC) 765/2008, Official Journal L 218, 13/08/2008 P. 0030–0047. Decision 768/2008, Official Journal L 218, 13/08/2008 P. 0082–0128. Law 2251/1994 'On consumers' protection', GG A' 191/16.11.1994. Law 4072/2012, GG A' 86/11.04.2012. Law 4177/2013 'Product and Services regulation and other provisions', GG A' 173/08.08.2013. Law 4512/2018 'on establishing a framework for the supervision of economic activities and the market for products', GG A'/17.01.2018. Presidential Decree 147/2017 'On the organization of the Ministry of Economy and Development', GG A' 192/13.12.2017. Joint Ministerial Decision Z3-2810/2004 'General Safety of Products', GG B' 1885/ 20.12.2004. Ministerial Decision 31619 οικ./2017 'Code of Conduct for E-commerce', GG B' 969/22.03.2017. JMD Z3/7835/2011 'on furniture, decorative objects and their raw material', GG B' 2650/09.11.2011. Ministerial Decision 5338/2018, GG B' 40/17.01.2018.
Studies/reports/articles	Opinion 34/2019 Council of State. Retrieved on 02.12.2019, from: https://lawdb.intrasoftnet.com/nomos/nomos_frame.html Giovanni C. & Silva F. (2018), '*Cybersecurity for connected products',* ANEC-BEUC position paper, available at: https://www.beuc.eu/publications/beuc-x-2018-017_cybersecurity_for_connected_products.pdf Oliveira da Silva, F. (2019), '*Keeping consumers secure: how to tackle cybersecurity threats through EU Law',* ANEC-BEUC paper, available at: https://www.beuc.eu/publications/beuc-x-2019-066_keeping_consumers_secure_-_how_to_tackle_cybersecurity_threats_through_eu_law.pdf Ruiz J. (2018), '*An overview of EU Regulations affecting Internet of Things*', available at: https://www.openrightsgroup.org/policy/virt-eu/an-overview-of-eu-regulations-affecting-internet-of-things National Market Surveillance Programme 2019 Greece, available at: https://ec.europa.eu/docsroom/documents/36293 Case law commentary retrieved from NOMOS for decisions: Decision 2869/2009 Council of State (StE) Decision 3076/2010 Council of State (StE) Decision 2593/2011 Council of State (StE) Decision 3351/2011 Council of State (StE) Decision 3352/2011 Council of State (StE) Decision 207/2013 Council of State (StE) Decision 208/2013 Council of State (StE) Decision 4670/2013 Athens Administrative Court of Appeal
Websites	Ministry of Development and Investments, General Secretariat of Industry, market surveillance announcements, available at: http://www.ggb.gr/deltia-all-view Attica Regions, Citizens Guide, Complaint Submission webpage, available at: https://www.pattikis.gr/citizen/frmCitizenPopup.zul?sid=e6eaa8de-1cbe-4cad-aa18-324718d62234 NOMOS legal repository database, available at: https://lawdb.intrasoftnet.com/nomos/nomos_frame.html Isokratis legal repository database of the Athens Bar Association, available at: http://www.dsanet.gr/1024x768.htm European Union Agency for Cybersecurity (ENISA), available at: https://www.enisa.europa.eu/
Interviews	Ministry of Development and Investments - Secretariat General for Industry - Quality Policy

	Directorate - Department General Safety of Products (5 interviewees including the member to the Consumer Safety Network, the Safety Gate Contact Point (previously RAPEX contact point) and the authority that is the sectoral market surveillance administration covering 'other consumer products under the GPSD') North Athens Regional Unit - Directorate of Development - Department of Trade (Department of Trade supervises products in the market in all stages, before and after they reach the consumer)

13. Hungary

COUNTRY REPORT HUNGARY

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

1) Law No. CLV of 1997 on consumer protection
2) Law No. LXXXVIII of 2012 on market surveillance
3) Government Decree No. 6/2013 on detailed rules on market surveillance
4) Government Decree No. 384/2016 on the appointment of the consumer protection authorities

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Hungary

The Hungarian law requires indication of the name and contact details of the producer on the product or on the package of the product and in addition the product reference, where applicable. Indication of the batch of products to which it belongs on the product or on its packaging is also required in Hungary. Article 15(1) of Law LXXXVIIII obliges the business entities to provide the market surveillance authority with information on its suppliers and its customers.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

In Hungary, there is no specific definition in place for safety in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The Hungarian authorities indicated that they do not know whether emerging threats related to new technologies are covered by the national implementing legislation.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

In Hungary, the approach of the authorities differ in cases when European standards (as referenced in the European Official Journal) are not available for assessing product safety, depending on whether market surveillance is conducted at a central, regional or local level. The central authority indicated the use of other European standards, the state of the art and technology, the test of reasonable consumer expectations and national standards. However, at county level, only the national standards are mentioned as an alternative tool, whereas at local level the use of international standards was indicated. As the sub-national entities involved in this study represent only two such decentralised entities in charge of consumer protection-related market surveillance, the palette of the tools used at decentralised level may be more diversified.

Article 3 of Government Decree 6/2013 provides that product safety is determined by domestic rules or standards issued in compliance with EU and Hungarian laws. If safety requirements are not available or not fully covered by national rules and standards, then product safety assessment should be considering: a) international standards, harmonised standards, or national voluntary standards implementing European standards; standards of the foreign country where the product was first put on the market; guidelines of the European Commission; safety requirements of the concerned sector of the economy; the state of art of science and technology; reasonable consumer expectations concerning product safety; and recommendations of professional associations.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Hungary in case there are consumer

product(s) on the market which are found unsafe under the GPSD

The Hungarian market surveillance authorities may require the business entities to provide relevant information on the products and on the supply and distribution chain, may carry out unannounced on-the-spot inspections and physical checks of the products, may acquire product samples and may conduct mystery shopping.

The administrative measures to be taken by the market surveillance authorities in case the product is found unsafe are established in Articles 15-16 of Law LXXXVIII of 2012.

The market surveillance authority may request the business entity to indicate the dangers stemming from the use of the dangerous product, to inform the consumers in due time and in an adequate manner, if necessary by using the mass media, about the risks associated with the use of such products; may limit or interdict the commercialisation and marketing of the product and apply measures assuring the compliance with such obligations by the business entity concerned; may order the withdrawal of the product from the market and order the informing of the consumers about this; may order the recall of the product and, if necessary, in collaboration with other business entities, the collection of the products from the consumers and users and destruction of the products in compliance with the requirements of consumer protection; require the business entity to remedy the deficiencies within a deadline set for this purpose, and may condition or may prohibit the commercialisation of the product until such obligations are complied with; and may impose fines. The measures listed above may be applied cumulatively.

Such measures may be ordered immediately, before the issuance of the decision establishing the non-compliance with the safety requirements, in order to prevent a risk which may affect the life, physical integrity, health or the economic interest of large consumer groups.

The business entity may be requested to inform the market surveillance authority about the activities undertaken in compliance with the administrative measures order and may set deadlines for this. The market surveillance authority is entitled to destroy the products which present serious dangers at the business entity's expense.

The administrative measures taken by the market surveillance authorities must comply with the requirement of effectiveness, proportionality and must be sufficiently deterrent for the business entities.

The market surveillance authorities cooperate with the concerned business entities to prevent or mitigate the risks associated with unsafe products. The authorities are obliged to take all the interim measures necessary for the informing of consumers in order to protect their life, physical integrity and health.

The business entity liable for the non-conformity of the products with safety requirements may be ordered to reimburse the costs of laboratory testing and sampling in cases where the product was found to be unsafe (Article 16(4)).

Although the law does not provide for such a measure, at the sub-national level, it was indicated in addition that there is the practice of requiring the business entity to provide information on the ownership of the website offering the unsafe product and the possibility to block websites, if needed.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The penalties applied by the Hungarian market surveillance authorities are governed by Article 16 of Law LXXXVIII that provides two categories of fines: a) from 15 000 to 500 000 000 HUF[290] and b) from 15 000 to 2 billion HUF[291] in cases when infringement of the safety requirements affects or endangers the life, physical integrity or health of the consumers.

In case the life, physical integrity and health of the consumers is affected or endangered, the market surveillance authority must impose the increased level of fines mentioned above. Small and medium size enterprises may be exempted from this rule, if specific legislation issued in their support provides otherwise. (Article 16(3) of Law LXXXVIII of 2012).

In establishing the concrete level of the fines, the authority also considers whether the business entity infringed the general product safety law or the provisions of other product safety laws during the previous three years. The

[290] From 45 EUR to 1.5 million EUR
[291] From 45 EUR to 6 million EUR

requirement of effectiveness, proportionality and deterrence applies also for fines.

Recent case law in Hungary with respect to or relevant for the GPSD/the national implementation legislation.

The Hungarian authorities did not report recent relevant case law.

The few court cases concerning general product safety challenge the decision of the market surveillance authorities, in some cases successfully. It seems that the business entities are not always aware of the mandatory nature of national standards by virtue of the market surveillance legislation implementing Directive 2001/95/EC, which refers to such standards among the criteria to be considered when assessing product safety. The business entities are confused by the domestic legislation on standards that qualifies the standards as voluntary standards, these being not published as legal texts in the Hungarian Official Journal. These business entities are subsequently faced with a court decision establishing that they are expected as circumspect market players to be aware of the standards applicable to their field of activity available at the sectoral authorities and that such standards are indeed mandatory under the legislation on general product safety.

Two highest court decisions were issued on the law currently in force:

1) Decision of the Kúria, Kfv. II. 37.050/2017/6 of December 13, 2017. (interpretation of standards)

1. The case concerned whether the business entity is bound by the standard applicable to the product to attach separate instructions on use to the product's accessory, which contain safety information on the time of use and degrees of speed. The business entity challenged the delimitation and definition by the market surveillance authority of the accessory as distinct from the product, a main question for establishing its obligation to attach separate instructions to the accessory. Upon request by the first instance court, the International Technical Committee, which established the standard, delivered its opinion and found that those accessories attached to the product, and thus delivered together with the product (as in the case before the court), do not need separate instructions. Based on this opinion, the Kúria established that the international expert opinion was equivalent to an official interpretation of the standard in question and found that the business entity was not infringing the safety requirements.

2) Decision of the Kúria, Kfv. II. 37.020./2016/7 of November 9, 2017. (interpretation of the concept of producer)

   The case concerned products originating from China, inspected through mystery shopping, which only indicated the EU importer and not the producer from China. The market surveillance authority fined the business entity for not complying with the requirement of Article 2 (11) of Law LXXXVIII of 2012 to indicate on the product both the distributor and the producer. The business entity challenged in court both the obligation and the decision of the market surveillance authority by invoking Article 5 (1) of Directive 2001/95/EC.

   The Kúria found that Article 2 (11) of Law LXXXVIII did not correctly transpose Article 2 (e) of Directive 2001/95/EC into Hungarian law and since in such cases the EU law prevails over the conflicting implementing rules by virtue of the principle of supremacy of EU law, the private entities may invoke the directly applicable EU law (Directive 2001/95/EC) before the domestic courts. The Kúria established that based on Article 2 (e) of Directive 2001/95/EC, the lower courts should have first clarified who qualifies as the producer of the product, whether the producer has a representative in the EU with a company seat registered within the EU, and whether in the absence of such a representative the importer of the product into the EU qualifies as a producer in the meaning of the Directive. In the absence of such an assessment it cannot be established whether the business entity infringed its obligation under Article 2 (e) of Directive 2001/95/EC. The Kúria referred the case back to the court of first instance.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Hungary concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The Hungarian authorities did not indicate practical difficulties concerning the traceability of products or definition of safety. Nevertheless, toys, electrical appliances and products falling under the Low Voltage Directive and other harmonised products which use artificial intelligence (AI) were mentioned as presenting emerging safety issues.

Possible improvements to make the implementation of the GPSD in Hungary more effective

The Hungarian authorities are satisfied with the current legal framework on general product safety and did not indicate specific regulatory needs.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Hungary.

Hungary changed its legislation on general product safety and market surveillance in 2012 and on the institutional framework for consumer protection at end of 2016.

1. *Law LXXXVIII of 2012 on market surveillance* provides the implementing rules of Articles 1., 2., 3., 5., 8., 9., 11., 12., 13., and 18 of Directive 2001/95/EC on general product safety.
2. *Government Decree No. 6/2013,* the implementing act of Law LXXXVIII and 2012, provides detailed rules on market surveillance activities. The government decree entrusts the market surveillance authorities with general competence and with sectoral competence and establishes the general requirements on safety and conformity, the tasks of market surveillance authorities, rules on consumer information and data protection and rules on cooperation among the authorities with market surveillance competence.
3. In Hungary the following authorities have market surveillance competencies: the Chief Medical Officer; Budapest city and county government offices competent in issues of public health and mining supervision; district authorities in charge of transport, consumer protection and labour protection tasks; the National Institute of Pharmacy and Nutrition; the Hungarian Mining and Geology Institute; the Government Office of Budapest City (concerning goods sold for business purposes); the minister in charge of consumer protection; the minister in charge of transport; the minister in charge of employment; the National Authority of Mass Media and Communication, and the police. Customs participates in the inspection of imported products.
4. Specific rules are established on market surveillance in the following fields: toys, children's recreational grounds, non-automatic weighting instruments, electrical goods designed for use with limited voltage, lifts and elevators, instruments designed for use in potential explosive environment, measuring instruments, and pressure holding equipment.
5. *Government Decree No. 387/2016* dissolved the National Authority of Consumer Protection on January 1, 2017, and consumer policy was transferred as a shared competence to the Ministry of National Development on the one hand, and the Government Office of Pest county and the 197 district authorities (local level government offices) on the other hand. This reform aimed at the decentralisation of the enforcement activities in the field of consumer policy-related market surveillance in Hungary.
6. District authorities and county offices of the government function as first instance authorities in consumer protection cases. At the second instance, the Government Office of Pest county is the competent authority to solve consumer protection related complaints, country wide. Territorially, the competent district authority is the one where: a) the person or legal entity has its domicile or residence, or its location; b) the activity of the legal entity is conducted or planned to be conducted, or where the infringement took place.
7. Except where provided otherwise, the consumer protection departments of the district authorities have general competence in the field of consumer protection. For example, in the field of cosmetics, the use of certain dangerous substances in electrical and electronic devices, or commercialisation of detergents, it is not the district authorities but the consumer protection departments of county level government offices which have competence.
8. In situations when the case before the district authority also concerns the infringement of rules prohibiting unfair commercial practices, the district authority will be in charge of conducting the administrative procedure.
9. Subsequently, in 2019, the Ministry of Innovation and Technology (MIT) was set up, and consumer protection policy was attributed to this new ministry, although decentralised enforcement of consumer protection remained in place. According to *Ministerial Order No. 4/2019,* the MIT elaborates the national programmes and action plans on general product safety and collaborates with the capital and county level government offices and district authorities in the fulfilment of their market surveillance activities, under the professional guidance of the minister. Within the MIT, a vice secretary of state is responsible for the

elaboration of laws and regulations on consumer protection and market surveillance and determines the financial and institutional framework of market surveillance. The MIT provides methodological guidance for the local and county level enforcement of consumer policy and is responsible for the professional supervision of the decentralised enforcement. Preventive warning and information provision to the consumers in issues of product safety remained centralised at the MIT. The minister may order inspections covering the territory of multiple counties if large groups of consumers are affected by product safety issues and may require specific actions at the county level. The district authorities and the county level and Budapest government offices report on their market surveillance to the MIT on a yearly basis.

10. The Central Market Surveillance Information System, the European Consumer Centre, the ICSMS and RAPEX function at the MIT. The MIT elaborates Inspection and Assessment Programmes and coordinates the international relations of the county offices and local district authorities in the field of consumer protection. The MIT performs product testing related to its competencies concerning market surveillance and upon request from district authorities in its own laboratories or may assign such tasks to other laboratories. For this purpose, two laboratories function within the MIT: the Food and Chemical Industry Laboratory and the Mechanical and Electrical Laboratory.

Plans/programmes in place which define priorities for market surveillance of consumer products

In Hungary, there are national, regional and local surveillance plans (covering all types of products) as well as sectoral surveillance plans in place. Market surveillance priorities are established on the basis of inspection findings, consumer information and complaints, and RAPEX notifications. News and mass media reports are also used for such purposes.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Hungary with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

In Hungary, market surveillance activities are not reported with respect to the safety of new technologies. Nevertheless, surveillance of e-commerce is a strategic issue for consumer protection in Hungary, which caused a decrease in the number of infringements.

No market surveillance is conducted concerning C2C transactions in Hungary.

The legislation in force does not contain specific provisions covering market surveillance of new technologies.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The IT laboratory of the Ministry of Innovation and Technology is continuously monitoring online businesses, especially focusing on websites offering “miracle products”. If these so-called “miracle products” or other online available products need to be examined for product safety reasons, then the chemical or mechanical laboratory of the MIT shall carry out laboratory testing. Following such testing, the administrative procedure may start, leading to the withdrawal and recall of dangerous products from consumers. Online sampling is performed by the inspectors of the consumer protection authority in accordance with the procedure of sampling taking at business premises. The inspectors make mystery orders on the website of the company concerned. When taking over the products they write an official record and leave a sealed sample at the store. Afterwards, the procedure related to the sampled product is the same as if it were taken from a traditional store. Such sampled products shall be examined by the laboratory in accordance with the applicable standards, followed by the injury scenario and risk assessment made by market surveillance experts, documented with an official opinion. Based on these documents, the authority issues its decision and reports the case to the RAPEX system, if needed. Concerning online sampling, the Hungarian authorities reported that there was some difficulty as sampling applies only for those webstores that have the possibility to get the product at the store’s delivery point.

At the county level, market surveillance for online products is based on fixed control numbers established in the National Surveillance Plan, and the same procedures apply to online and offline purchases. The consumer protection departments of the district authorities buy products sold online by mystery shopping and submit these products to laboratory tests. If the product fails the safety test, the authority will start the administrative procedure against the seller.

Market surveillance on online products made up 11% to 20% of the market surveillance activities conducted at the

central level. At the country level, this was much lower at 1-2%, whereas at the local level, 21-30% was reported.

The market surveillance related to online products takes place by checking retailer websites and online marketplaces.

Concerning the frequency of mystery shopping related to online sales, central data was not provided for the purposes of this study. At the county level, mystery shopping is conducted once a month concerning sellers established in Hungary. Such activities were not reported concerning sellers established outside Hungary (in the EU or in non-EU countries). Such checks take place once every three months in the case of companies established in Hungary and once a year concerning companies located in other EU/EEA countries. The absence of jurisdiction was indicated as the reason beyond the lack of mystery shopping for companies established outside Hungary.

Legislative impediments and lack of human and financial resources were indicated by the authorities as hindering effective market surveillance related to products sold online.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Hungary (except customs) with respect to product safety

Cooperation at the central level with other domestic authorities takes place once a week in various forms: through the regular exchange of information, regular meetings, informal channels, the inclusion of other authorities in the elaboration of market surveillance plans, and through common use of the RAPEX system, the ICSMS and the national market surveillance IT system. At the county level, such cooperation was indicated to take place once a month, whereas at the local level it was reported to take place once every six months.

No information on the frequency of such cooperation with the authorities of other EU/EEA Member States was reported from the central or county level. The local authority reported such cooperation once a year.

Cooperation between the Hungarian central authority and other EU/EEA authorities may take place through RAPEX, ICSMS, the Wiki confluence platform, and mutual assistance requests made and received outside RAPEX, as well as through informal cooperation.

With non-EU/EEA countries, previous bilateral agreements on cooperation in product safety issues are still in place.

Cooperation with customs authorities in Hungary with respect to product safety

Market surveillance activities are carried out in close cooperation with the customs authority in the case of products from non-EU/EEA countries, which fall under the customs clearing procedure. Inspection thus begins at customs. There is no targeted legislation for this; both customs and the consumer protection/market surveillance authority have a sharp field competence. The product safety experts are present at customs and monitoring those products which are intended to be put into the Hungarian market. The products that seem to be unsafe are forwarded to the mechanical or chemical laboratory of the Ministry of Innovation and Technology, where based on tests the risk assessment of such products is conducted. If the product is found to be dangerous, then customs suspends its free circulation. In 2019, around 170,000 products were suspended from free circulation in Hungary.

Cooperation between the central market surveillance authority and customs takes place more than once a week at the level of strategy planning (common strategy setting for product safety enforcement, joint setting of priorities, formal agreements, inclusion of customs in preparing the national plans/programmes) and implementation of market surveillance activities (regular exchange of information, joint processes for dealing with unsafe products, regular meetings, informal cooperation). The same applies on for cooperation between customs and the district authorities in charge of product safety-related market surveillance. At the county level, cooperation with customs is based on formal agreements between customs and market surveillance authorities.

The timely transmission of the required information is safeguarded through designated contact points.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

In the absence of jurisdiction, the Hungarian market surveillance authorities cannot initiate proceedings against business entities registered outside Hungary. In cases where unsafe products are identified which originate from other countries, the Hungarian authorities will notify the market surveillance authority of the country where relevant business entity is located.

However, cooperation with market surveillance authorities located in other EU/EEA Member States takes place on

a regular basis within the framework of the RAPEX System, ICSMS, the Wiki confluence platform, and coordinated actions on product safety organised at the EU level, as well as mutual assistance requests made and received outside the RAPEX system.

Cooperation with the authorities of non-EU/EEA states takes place within the framework of bilateral agreements.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

When unsafe products are found on the Hungarian market, the market surveillance authorities alert the central authority and the information is forwarded by the RAPEX national contact point to the RAPEX system. The Ministry of Innovation and Technology is the authority in charge of the management of the RAPEX system; the consumer protection departments of the district authorities are competent to start the proceedings at first instance against the business entities responsible for the dangerous product. The district authorities and the county level government offices enter the information on the dangerous product in the Hungarian central information system for dangerous products, based on which the Ministry for Innovation and Technology processes the data in RAPEX and informs the concerned countries. Once the alert documents are created, this shall be forwarded to the RAPEX system within two weeks. The average time between the detection of a dangerous product and its notification to the RAPEX System is more than two weeks (around 60 days).

Non-safety risks related to consumer products will be notified to the relevant market surveillance authorities and the competent sectoral authorities.

4. Cooperation with stakeholders and awareness raising for product safety

The Hungarian Ministry of Innovation and Technology in charge of general product safety-related market surveillance cooperates with business entities regularly in order to raise business awareness on product safety requirements. Such cooperation takes place once every three months. Fewer cases of cooperation were reported at the local level (once a year).

From the central level and county level, no cases of cooperation were reported with business associations, informal cooperation with consumer associations happens less than once a year.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Consumer awareness on product safety requirements is raised in Hungary via various channels of communication: national websites on product safety requirements and dangerous products, links to the EU RAPEX website through the official websites of the Hungarian authorities, press releases and information campaigns in traditional media (TV, newspapers). At county level, partnership agreements are also in place with consumer organisations and cooperation takes place once a month. At the local level, such cooperation is less frequent (less than once a year).

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Hungary (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

In Hungary, businesses are required to organise product recalls, to take other corrective actions and to use all their available customer information for recalls and other corrective measures. The online marketplaces are also involved in the recall process.

At the central level, no specific recalls were reported; however, the authority considered it important to note the cooperation with the business entities concerned in all cases of product recalls. In the case of recalls, the business entities are required to provide information to the central authority on the following: measures targeted at consumers, information activities targeted at or undertaken in cooperation with other business entities, the list of other businesses involved in the supply chain, the timeline of the recall and recall effectiveness.

The consumers are informed about product recalls by the Ministry of Innovation and Technology through a public database on product recalls. The only authority competent to communicate with consumers in product safety issues is the Ministry of Innovation and Technology. District authorities and county level government offices have no role in communicating with consumers on general product safety.

The district authorities and the county level government offices do not cooperate with businesses on specific product recalls. The county level government offices may however require from businesses information on information activities targeted at consumers on recalls and other corrective measures and information activities targeted at other businesses or undertaken in cooperation with other businesses.

The Hungarian authorities did not report on codes of good practices in place concerning the process of product recalls.

Monitoring of effectiveness of product recalls by market surveillance authorities

In Hungary, effectiveness of product recalls is monitored at county level and is limited to mandatory recalls. The consumer protection departments of county level government offices may make spot checks in shops.

No central monitoring of product recalls was reported in Hungary.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Hungary that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

In Hungary there are central statistics on dangerous products intercepted at the borders by customs and on dangerous products found on the market. Regional databases on consumer complaints are in place.

From Hungary no systematic data collection can be reported on injuries.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Hungary (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Limited human resources for market surveillance, lack of expertise in new technologies, lack of expertise in online market surveillance, lack of expertise and lack of financial resources for testing consumer products was reported by the Hungarian authorities as impediments affecting effective market surveillance. From the local level, the lack of coordination with customs was also mentioned, and the difficulty when carrying out market surveillance of products originating from outside the EU/EEA which are reaching the consumers directly from non-EU/EEA countries was signalled. Concerning the shortage of human resources, the lack of full-time staff to search for dangerous products on the market was stressed.

Product recalls are considered moderately effective by the Hungarian authorities, which mentioned the need for larger jurisdiction at first instance in the procedure of market surveillance.

RAPEX is considered to be very well-functioning, despite the insufficiency of human and financial resources, the lack of information from businesses and the lack of information for tracing notified products. Difficulties related to data protection legislation were also mentioned as affecting the functioning of the RAPEX system.

Areas to make market surveillance of consumer products in Hungary/the EU more effective

In the opinion of the Hungarian authorities, market surveillance works well; there is no need for legislative changes. Nevertheless, there is need for more human and financial resources to be allocated in relation to product recalls, the need for full-time staff allocated to search for dangerous products on the market, and the need for wider jurisdiction for first instance market surveillance.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Hungary since 2013

The general trend is positive, and the safety level of consumer products has improved.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Hungary whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market

surveillance activities
The Hungarian authorities are in the process of developing tools to address new challenges.
Views of market surveillance authorities whether approaches in Hungary can be considered best practice implementation of the GPSD, which could be of interest to other countries
The Hungarian authorities did not share best practices for the purposes of this study.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authorities at the sub-national level (regional/provincial/local)	*3*	*1*	*4*
Notes:	*The data concerns the district authority (first instance authority) of a very large city in Hungary.*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**103**	**3**	**106**
Total number of consumer products inspected	13	0	13
Total number of consumer products tested in laboratories	34	3	37
Total number of consumer products inspected in cooperation with the customs	56	0	56
Total number of dangerous consumer products found	34	0	34
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	2	0	2
Notes:	*The data concerns the district authority (first instance authority) of a very large city in Hungary.*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*n.a.*	*n.a.*	*n.a.*
Total number of mandatory recalls	*n.a.*	*n.a.*	*n.a.*
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	*n.a.*	*n.a.*	*n.a.*

D. Key sources	
Legislation	Law No. CLV of 1997 on consumer protection Law No. LXXXVIII of 2012 on market surveillance Government Decree No. 6/2013 on detailed rules on market surveillance Government Decree No. 384/2016 on the appointment of the consumer protection authorities
Studies/reports/articles	No relevant domestic literature can be reported from Hungary on general product safety.
Websites	https://birosag.hu/ (website of the Hungarian court system, including the case law database) https://www.kormany.hu/hu/innovacios-es-technologiai-miniszterium (website of the Ministry of Innovation and Technology)
Interviews	The interviews were conducted with three market surveillance authorities in written form via questionnaire.

14. Ireland

COUNTRY REPORT IRELAND

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

European Communities (General Product Safety) Regulations 2004, S.I. No. 199 of 2004.

The 2004 Regulations identified the Director of Consumer Affairs as the market surveillance authority in Ireland. This function has since been transferred and now rests with the Competition and Consumer Protection Commission (CCPC) (Consumer Protection Act 2007, and Competition and Consumer Protection Act 2014).

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Ireland

Article 5(1) of the GPSD is transposed faithfully by the EC (General Product Safety) Regulations 2004, in Regulation 6 which provides:

> 6. (1) A producer shall, in relation to any product which he or she has placed on the market, provide consumers with all relevant information relating to the product to enable them to assess the risks inherent in the product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.
> …
> 6.(3) A producer shall, in relation to any product which he or she has placed on the market, adopt measures commensurate with the characteristics of the product, to enable the producer -
> (a) be informed of the risks which the product might pose, or
> (b) choose to take appropriate action, including, if necessary to avoid such risks, withdrawal of the product in question from the market, adequately and effectively warning consumers, or recall of the product from consumers. Recall shall take place as a last resort where other measures do not suffice to prevent the risks involved.
> 6. (4) The measures referred to in paragraph (3) include, for example:
> (a) an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified, and
> (b) in all cases where appropriate, the carrying out of sample testing of marketed products, investigating and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring.

In practice, traceability is affected by a *general* obligation to indicate the name and contact details of the producer on the product or its packaging, and the product reference or batch of products to which it belongs on the product or the packaging.

There are no *product-specific* requirements in operation in Ireland, nor are there other *specific* requirements in operation, such as bar code or other machine readable identifiers on the product or its packaging.

The CCPC (the market surveillance authority in Ireland) noted that the above Irish Regulations from 2004 do not currently align with the requirements or powers provided for in the more recent harmonised products safety legislation which the CCPC also enforce.

The following requirements were identified by both the CCPC and its parent ministry, the Department of Business, Enterprise and Innovation (DBEI), as “the best approaches to improve traceability”:

- For all consumer products (harmonised and non-harmonised) to indicate name and contact details of the producer on the product/ packaging;
- For all consumer products (harmonised and non-harmonised) to indicate product references or, where applicable, the batch of product to which it belongs on the product/packaging;
- ‘One up, one down’ traceability.

The DBEI also considered that the key to traceability is to have as much information as possible included with the product, whether on the product itself or on the packaging. The following were identified as best practices:

- Requirement to use a bar code on the product or its packaging; and
- Requirement to use other machine readable identification on the product or its packaging, such as RFID.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

No. The definition of safety is faithfully transposed from Article 2(b) GPSD into the EC (General Product Safety) Regulations 2004, in the following terms:

> Regulation 2(1)
> …
> 'safe product' means any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.
> …
> Regulation 4(2)
> Subject to Regulation 5, in determining the safety of a product the following shall be taken into consideration:
> (a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
> (b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;
> (c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; and
> (d) the categories of consumers at risk when using the product, in particular children and the elderly.

However, the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk does not constitute grounds for considering a product to be dangerous.

Therefore, given that this definition of a 'safe product' dates from 2004 in the Regulations (and 2001 in relation to the Directive), there is no specific provision made for the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

No. As noted by the relevant ministry, the DBEI, national legislation transposing the GPSD was introduced in 2004 before a lot of these emerging threats became apparent. This legislation has not been amended since that time. Moreover, the GPSD itself is 18 years old and does not appear to be equipped to deal with emerging threats related to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Where European standards referenced in the EU Official Journal do not exist, other benchmarks for assessing safety of a product are provided for in Regulation 5(3) of the Irish Regulations, as follows:

(a) Voluntary Irish Standards transposing European standards other than those referenced in the EU Official Journal;
(b) Other Irish Standard Specifications;
(c) Commission recommendations setting guidelines on product safety assessment;
(d) Product safety codes of good practice in force in the sector concerned;
(e) The state of the art and technology, and
(f) Reasonable consumer expectations concerning safety.

In practice, according to the CCPC, the benchmarks used for assessing safety are:

- Other European standards (not references in the Official Journal);
- National standards (not based on European standards);
- International standards and/or standards from non-EU/EEA countries;
- Commission recommendations setting guidelines on product safety assessment;
- Codes of good practice in force in the sector concerned; and
- Reasonable consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Ireland in case there are consumer product(s) on the market which are found unsafe under the GPSD

The administrative measures at the disposal of the CCPC are prescribed in Regulation 9 of the EC (General Product Safety) Regulations 2004, which addresses the general functions of the CCPC. Regulation 9 states that for the purpose of ensuring that products placed on the market are safe and that producers and distributors of such products comply with their obligations under the 2004 Regulations and the Directive, the [CCPC] may take all reasonable measures, including such of the following as it decides is appropriate in each case:

(a) for any product, to:
  (i) organise, even after it has been placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption,
  (ii) request all necessary information in relation to the product from any person who, in the opinion of the [CCPC], may be in a position to provide such information, and

(b) for any product that could pose risks in certain conditions, to issue a direction –
  (i) requiring that it be marked with suitable, clearly worded and easily comprehensible warnings, in the English language, on the risks it may present,
  (ii) requiring that, prior to placing the product on the market, such specified steps are taken as are necessary to ensure its safety;

(c) for any product that could pose risks for certain persons, to issue a direction, requiring that persons at risk be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;

(d) for any product that could be dangerous, issue a direction prohibiting the supply, offer to supply or display of the product pending the carrying out of the safety evaluations, checks and controls necessary to establish the safety of the product;

(e) for any dangerous product, issue a direction prohibiting the placing of the product on the market;

(f) for any dangerous product already on the market, take all appropriate steps, including if necessary issuing a direction, to ensure –
  (i) the immediate withdrawal of the product from the marketplace, its recall from consumers and its destruction in suitable conditions, and
  (ii) that consumers are alerted to the risks presented to the product.

Regulation 9 does not make express provision for administrative powers to require businesses to provide information about the ownership of websites; to block websites; or to reclaim the costs from economic operators of any administrative measures. However, it should be noted that Regulation 9 states that the CCPC 'may take all reasonable measures' for the purpose of ensuring that products placed on the market are safe and that producers and distributors of such products comply with their obligations under the 2004 Regulations and the Directive, and the list of measures (a) – (f) above is not an exhaustive list. Therefore, it is arguable that this general power to 'take reasonable measures' includes, for example, requiring information about the ownership of websites. In addition, Regulation 9(f)(1) provides that for any dangerous product already on the market, the CCPC may 'take all appropriate steps, including issuing a direction ....'. Again, based on a literal reading of this provision, issuing a direction is not exhaustive of the CCPC's powers under this provision, it is merely one example, and so it is again arguable that this provision allowing the CCPC to 'take all appropriate steps' could include, for example, powers to require businesses to provide information about the ownership of websites, and to block websites.

Moreover, Regulation 14 provides that the CCPC may appoint 'authorised officers' (with extensive powers set-out in subs(3)) for the purposes of ensuring compliance with the 2004 Regulations and the Directive.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other

relevant provisions (types of penalties, their level/amount)

The CCPC may seek the forfeiture of goods and prosecute various offences under the 2004 Regulations.

Accordingly, the CCPC may apply to the District Court (the lowest court in the hierarchy of courts in Ireland) under Regulation 16 for a "forfeiture order", for the forfeiture to the CCPC of any dangerous products.

Moreover, the 2004 Regulations create various offences. For example, pursuant to Regulation 9(5), a person who fails to comply with a direction by or a request from the CCPC under Regulation 9 is guilty of an offence. Regulation 20 states that an offence under the 2004 Regulations may be prosecuted summarily (i.e. before a single judge, without a jury) by the CCPC. And, pursuant to Regulation 22, a person guilty of an offence under these Regulations is liable on summary conviction to a fine not exceeding EUR 3 000 or to imprisonment for a term not exceeding 3 months or to both. The CCPC can also be compensated for the cost of prosecution under Regulation 21. Accordingly, where a person is convicted of an offence under the 2004 Regulations, the court must, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the CCPC the costs and expenses, measured by the court, incurred in relation to the investigation, detention and prosecution of the offence and, where appropriate, any seizure or detention of the product concerned.

As an alternative, the CCPC may seek an injunction under Regulation 15. Thus, where a person fails to comply with a direction of the CCPC under the 2004 Regulations, the CCPC may, in lieu of any summary proceedings against the person in respect of an offence under the Regulations, institute proceedings in the High Court for an order requiring the person to comply with the terms of the direction.

Prosecutions are rare in practice. For example, in 2015, the CCPC successfully prosecuted a motor vehicle trader in the District Court for contravention of the European Communities (General Product Safety) Regulations 2004.

Recent case law in Ireland with respect to or relevant for the GPSD/the national implementation legislation.

There is no relevant case law on the GPSD or national implementing legislation reported in Ireland.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Ireland concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The CCPC reported that, in relation to traceability, it has encountered practical problems in terms of the non-availability of requirements to indicate name and contact details, as required by the legislation.

The CCPC also noted that currently it does not have the power to access supply chain records and such powers would be very helpful.

In relation to the definition of safety, both the CCPC and the DBEI reported that both had experienced practical problems with the definition of safety. In particular, the common view is that the current definition (from the 2001 Directive and 2004 Regulations) is too wide/too general and therefore lacked clarity, and that this leads to practical problems. The CCPC stated that, in an Irish context, the definition is too general to be enforced within the legislative framework or to be clearly understood by economic operators. Officials from the CCPC expressed a preference that the 2001 Directive and the 2004 Regulations align more closely with the definition, duties and powers under the newer harmonised product safety directives. Furthermore, the CCPC identified a problem that the definition does not explicitly cover safety risks for persons with disabilities.

A representative from the parent ministry noted that the definitions in Regulation 2019/1020 on 'risk', 'product presenting a risk' and 'product presenting a serious risk' may be more useful.

Both the CCPC and the DBEI were unable to identify any emerging safety issues in relation to particular categories of products in Ireland that are not addressed by the current legislation. The CCPC noted that it does not have access to or monitor any national data in relation to emerging safety issues. However, the CCPC does monitor media and EU sources of information, where necessary.

Possible improvements to make the implementation of the GPSD in Ireland more effective

The main problem would seem to relate to the fact that the GPSD and the 2004 Irish Regulation are out of date, especially when compared with the newer harmonised legislation. In this regard, the CCPC considered that the GPSD should be aligned more closely to the objectives, requirements, obligation and duties of the harmonised legislation, and that the requirements of market surveillance in relation to the GPSD should be more integrated

with the harmonised legislation, with improved enforcement powers.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Ireland.

The Competition and Consumer Protection Commission (CCPC) is the sole market surveillance authority and the competent authority in Ireland for safety under the GPSD (and a number of other EU measures). The CCPC is an independent statutory body with a dual mandate to enforce competition and consumer protection law in Ireland. The CCPC is also the Irish contact point for the European Commission's rapid alert system (RAPEX). The CCPC was established on 31 October 2014 following an amalgamation of the former National Consumer Agency and the Competition Authority. The CCPC's parent ministry/department is the Department of Business, Enterprise and Innovation (DBEI).

Within the CCPC, product safety is the responsibility of a newly established Product Safety Division (formerly the Product Safety Unit) which now has 10 full-time members of staff (as at 1st December 2019, at a time when the CCPC has 104 full-time staff in total; at the end of 2018 the Product Safety Unit had 5 full-time members of staff, at a time when the CCPC had 102 full-time staff in total: Annual Report 2018). CCPC resources are limited and so the CCPC does not operate as a field inspectorate in relation to product safety. Currently there are very limited laboratory testing facility in Ireland and so laboratories in the UK or other member states are used for this purpose.

Market surveillance only functions at a national level in Ireland. Thus, there is no sub-national (regional, provincial or local) market surveillance system in operation in Ireland. This reflects, in part, the size of the population (4.7 million in 2016) and a relatively centralised government system.

Plans/programmes in place which define priorities for market surveillance of consumer products

The CCPC submits a sectoral surveillance plan to its parent Department, DBEI, on an annual basis. Most recently, the National Market Surveillance Plan for 2019 was prepared and submitted to DBEI at the beginning of 2019.[292] In setting priorities, the CCPC utilises various sources of information, including:

- Inspection results;
- RAPEX notifications;
- Coordinated actions on the safety of products organised at the EU level;
- Consumer complaints;
- Customs information; and
- News and media reports.

Currently, accident reports/injury data and other information e.g. from consumer organisations and insurers is generally not available in Ireland. The CCPC does not proactively monitor social media at present.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Ireland with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

At present, the CCPC does not proactively or specifically target products with new technologies. However, the CCPC has stated that it will consider products containing new technologies subject to a referral.

In contrast, the CCPC does conduct market surveillance regarding products sold online, and in this regard the CCPC investigates individual complaints and follows up on RAPEX notifications of products sold online where those products have been placed on the Irish market by an economic operator based in Ireland.

The CCPC does not conduct market surveillance regarding C2C products as this is outside its legislative competence.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

[292] Available at: https://dbei.gov.ie/en/Publications/Publication-files/Market-Surveillance-Plan-for-Ireland-2019.pdf

In relation to market surveillance of online products, the CCPC conducts market surveillance infrequently. For example, in relation to products sold online in Ireland, market surveillance was reported by the CCPC to occur once every six months; whereas in relation to products sold online within the EU/EEA, market surveillance was reported by the CCPC to occur once every three months. The CCPC has explained this lack of frequency on the basis that it has very limited resources available to conduct proactive and co-ordinated market surveillance programmes and therefore, at present, it prioritises market surveillance on the basis of a referral or complaint or related information.

In conducting market surveillance of online products, the sales channels which the CCPC focuses on are retailers' websites and online marketplaces.

In terms of the percentage of market surveillance that focuses on products sold online (as a share of the total number of inspections conducted), the CCPC reported that it spends 1-2% of its time on online products. Again, the CCPC has explained this small percentage on the basis that, at present, it has very limited resources available to conduct proactive and co-ordinated market surveillance programmes and therefore the CCPC has had to prioritise reactive market surveillance activities. The CCPC has stated that it intends to focus more on proactive market surveillance in 2020.

The CCPC's market surveillance is organised around individual complaints and RAPEX notifications of products sold online. Officials from the CCPC do not currently conduct ongoing mystery shopping activities. This is largely due to the very limited resources available to conduct such market surveillance programmes. The CCPC did conduct an investigation using mystery shopping in October 2013 when an investigation into the safety of amber teething jewellery was undertaken. The CCPC is considering further mystery shopping in 2020.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Ireland (except customs) with respect to product safety

The CCPC maintains a good working relationship with other relevant authorities with respect to product safety. For example, the CCPC cooperates with the relevant authorities within Ireland once every three months; it also cooperates with other relevant authorities located within the EU/EEA once a week. In relation to relevant authorities located outside the EU/EEA, cooperation is less frequent, reported by the CCPC as being less than once a year. The CCPC reported that it had recently engaged with US authorities on an informal basis.

In particular, the CCPC participates in the National Market Surveillance Forum, chaired by the Department of Business Enterprise and Innovation (DBEI). The Forum facilitates the exchange of information between market surveillance authorities in Ireland and meets 3 - 4 times a year.

The CCPC also acts as the Irish national co-ordinator for the European Commission's rapid alert system (RAPEX) and therefore assists other market surveillance authorities in accessing and using RAPEX.

Cooperation with customs authorities in Ireland with respect to product safety

There is close co-operation between the CCPC and customs in Ireland.

The CCPC and customs have an agreed Memorandum of Understanding (MOU) in place since 2019. Customs and the CCPC's predecessor, the National Consumer Agency, have a Data Exchange Agreement in place since 2011.

The CCPC and customs meet and communicate regularly, typically more than once a week, and sometimes more than once a day. There is further cooperation between both organisations through the National Market Surveillance Forum. The Forum is chaired by the Department of Business Enterprise and Innovation (DBEI) and it facilitates the exchange of information between market surveillance authorities, meeting 3 - 4 times a year.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Where the economic operator is located in the EU/EEA, the CCPC provides the information which it has gathered on the economic operator to the Market Surveillance Authority in the relevant jurisdiction. In general, cooperation takes the form of communications via RAPEX; the Wiki confluence platform; coordinated actions on the safety of products organised at EU level; mutual assistance requests made/received outside RAPEX; the regular exchange of information (outside EU fora); regular meetings; and informal cooperation.

To date, the CCPC has not identified dangerous products placed on the Irish market by economic operators based

outside the EU/EEA and so it was unable to comment further on this issue. However, the CCPC has recently engaged with the US on an informal basis.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The CCPC is the National Co-ordinator for RAPEX, and therefore it is very familiar with the system and processes associated with RAPEX. The CCPC provides assistance and information to other Irish RAPEX users. Therefore, the CCPC gathers all of the relevant information and documentation required in accordance with the RAPEX guidelines and inputs this information, as required.

In relation to the average duration (in days) between the detection of a dangerous product and its notification to RAPEX, the CCPC was unable to provide an estimate because at present the CCPC does not have statistics on this matter and each case is unique.

Once the CCPC has all of the relevant information and supporting documents, it can submit a RAPEX notification in less than one day; however, conducting the investigation and gathering and assessing the information can take a considerable length of time (from days to weeks).

The CCPC can only enforce and take action under the legislation under its remit and currently this does not include environmental or security risks.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

On average, the CCPC interacts with business associations/businesses once a month. In particular, the CCPC provides information to economic operators via its website[293] and in relation to general queries, on a case by case basis, as requested. In the past, the CCPC has also prepared articles for trade magazines, as requested. The CCPC does not have any partnership agreements with business organisations or other formal arrangements for cooperation.

In relation to other consumer organisations in Ireland, the CCPC reported that it has contact 'less than once a year'. The main voluntary consumer organisation in Ireland is the Consumers' Association of Ireland (CAI).[294] The CAI is an independent, non-profit, non-governmental organisation, registered with charitable status and working on behalf of Irish consumers. However, at present, the CCPC has no formal interactions with national consumer organisations. In general, the CCPC has a very detailed website with consumer information and the CCPC regularly runs consumer awareness campaigns.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The CCPC provides information to economic operators and consumers via its website and through other channels. In particular, the CCPC used press releases; a national online information system (via its website) for dangerous products/safety issues; links on its website to the EU RAPEX system; and various information campaigns. For example, the CCPC runs targeted campaigns in conjunction with other stakeholders, such as the upcoming Window Blinds Safety campaign in conjunction with the Health Services Executive (the government organisation responsible for the day-to-day management of the health service in Ireland, including issues of product safety) and a recent Toy Safety Campaign with digital content and radio adverts.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Ireland (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Pursuant to the legislation, businesses may be asked to conduct voluntary recalls (or other corrective measures), or the recall (or other corrective measures) may be mandatory. In either case, businesses are expected to use all their

[293] See: www.ccpc.ie
[294] See: www.thecai.ie

available consumer information for recalls (or other corrective measures).

Usually, if the economic operator is only placing or making the product available on the Irish market, the economic operator is required to contact the CCPC and provide all details of the product, the supply chain (distributors, retailers etc.), the risk, and how the recall will be carried out, and then the CCPC will publish the recall notice on the CCPC website.

If the economic operator is placing or making the product available on the Irish market and other Member State markets, then the economic operator is required to notify the CCPC of the recall using the standard Notification Form, based on the former Business Gateway form.[295] The information provided is assessed by the Product Safety and Market Surveillance Division of the CCPC and used to prepare and validate a RAPEX notification. The supply chain and recall process is checked and the recall notice is also published on the CCPC website.

In general, the CCPC will seek information about information activities targeted at consumers; information activities targeting at and cooperation with other businesses in the supply chain; a list of other businesses in the supply chain; information about the timeline of the recall process; and information about the destruction or disposal of the products collected.

Moreover, the CCPC will assist economic operators in relation to specific recalls by checking and influencing the message given to consumers and the broader recall strategy.

In relation to information to consumers about recalls relevant to the Irish market, recalls are published as web notices on the CCPC website and also publicised through the CCPC social media feeds.

Monitoring of effectiveness of product recalls by market surveillance authorities

Only mandatory recalls are monitored in terms of their effectiveness. In this context, the economic operator recalling the product is asked to provide information on the recall's effectiveness in terms of the number of items placed on the market and the number of items returned by consumers (both in terms of absolute numbers of products collected and as a percentage of recalled products actually collected). Further, the recall is required to remain in place until all the products placed or made available on the market are accounted for.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Ireland that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Available data relevant to market surveillance is limited in Ireland. For example, there is no national database on dangerous products and so there are no statistics on dangerous products, outside the RAPEX system. There is also no systematic collection of injury data in Ireland. Relevant data which does exist comes mainly from customs and consumer complaints.

The CCPC keeps data for the consignments referred by customs and can provide information on the number of products within those consignments found to be non-compliant or not in conformity. However, to determine whether the products are 'dangerous' would require laboratory testing. At present, there are a very limited number of suitably equipped or accredited facilities located in Ireland available to carry out such testing. Therefore, the CCPC does not have available statistics on how many products were considered to be dangerous vis-a-vis non-compliant products.

The CCPC also collects data on consumer complaints in relation to dangerous products. The CCPC operates a Consumer Helpline and product safety complaints from the Helpline are referred to the Product Safety and Market Surveillance Division in the CCPC for assessment. While the CCPC does have data on consumer complaints referred to it, this data is again not broken down by dangerous versus non-compliant products.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Ireland (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

In relation to market surveillance in general, the CCPC identified the following five most relevant problems which it

[295] Available on the CCPC website here: https://www.ccpc.ie/business/product-safety/product-safety

has encountered (in no particular order):

8. Limited staff resources;
9. Lack of expertise in testing products;
10. Lack of suitable product testing laboratories;
11. Lack of awareness among businesses about product safety requirements; and
12. Problems to control products from non-EU/EEA-countries directly reaching consumers.

The CCPC's parent ministry, the DBEI, concurred in relation to points 1, 2, and 3 above, and also identified the following as problems for market surveillance, in general:

1. Lack of expertise in new technologies; and
2. Lack of financial resources for testing of consumer products.

In this regard, the DBEI noted that, as with a lot of state bodies, a lack of resources, including qualified and trained personnel, impacts market surveillance work across most market surveillance authorities in Ireland. There is also the additional problem of a lack of suitable testing laboratories in Ireland, along with the possible loss of access to laboratories in the UK after Brexit.

In relation to online products, the CCPC has encountered both legal impediments and financial/resource impediments to effective surveillance online. In particular, the current legislation transposing the GPSD into Irish legislation dates from 2004 (transposing the 2001 Directive) and does not include the same harmonised duties and obligations for economic operators. It also does not include adequate or effective enforcement powers for the CCPC which would be required to facilitate comprehensive market surveillance activities as with the more modern harmonised legislation. In addition, the CCPC also does not currently have sufficient resources or capacity to facilitate proactive market surveillance online.

The CCPC considered RAPEX to be 'moderately well-functioning'. The following problems were identified:

- Lack of information from authorities in other countries;
- Lack of information from businesses; and
- Lack of sufficient information to trace notified products.

In particular, the CCPC reported that many notifications are not accurately entered on RAPEX and often list Ireland and/or all Member States as countries of destination. As a result, the CCPC has to commit considerable resources into investigating and verifying such notifications.

In relation to product recalls, there is currently no data or metrics o which could be used to assess the effectiveness of recalls in Ireland. As the effectiveness of any recall is subject to many factors, the CCPC is not in a position to detail specifically how the recall process could be improved.

Areas to make market surveillance of consumer products in Ireland/the EU more effective

In terms of possible improvements and the RAPEX system, the CCPC raised a particular issue in relation to motor vehicles in Ireland. Many RAPEX notifications relate to motor vehicles, although motor vehicles do not fall within the scope of product safety legislation under the mandate of the CCPC. However as there is currently no competent or market surveillance authority appointed for motor vehicles in Ireland, the CCPC has historically investigated, verified, publicised and submitted reactions to RAPEX for these notifications, which takes considerable amount of time and resources.

In terms of possible improvements with respect to product recalls and market surveillance more generally, in the CCPC's view, updating the GPSD to align with the obligations and enforcement powers currently detailed in the harmonised market surveillance legislation would enable the CCPC to take more appropriate enforcement actions. In addition, the CCPC identified closer collaboration between market surveillance authorities as being helpful. The DBEI also explained that work is currently underway to plot testing laboratories across the EU and other initiatives coming from the new Regulation 2019/1020 have the potential to be a positive influence on market surveillance, in general.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Ireland since 2013

The CCPC currently does not have sufficient data or information available to assess whether the general level of safety of consumer products has improved or developed. However, the DBEI considered that the general trend in the level of consumer safety is positive. In particular, the powers available to market surveillance authorities under the NLF Directives and under Regulation 2019/1020 help in removing dangerous or unsafe products from the market.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Ireland whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

In relation to existing tools, the CCPC considered that it does not have tools at its disposal to address new challenges. At present, the Irish national legislation is not sufficient for investigating or enforcing product safety legislation in the e-commerce or platform economy environments. The new Market Surveillance Regulations will address some of these issues. However, as previously stated, the GPSD should be aligned to the objectives, requirements, obligations and duties of the harmonised legislation and there should be more integration with the requirements of the market surveillance regulations to provide the CCPC with improved enforcement powers.

However, the CCPC did show interest in developing such tools for market surveillance. For example, the CCPC has participated in a number of the EU E-Enforcement Academy training sessions and is examining the feasibility of developing such tools for use in the Irish market. The Digital Investigations Unit within the CCPC is also assisting in new technologies to use such as assessing whether test reports have been digitally manipulated.

Views of market surveillance authorities whether approaches in Ireland can be considered best practice implementation of the GPSD, which could be of interest to other countries

Neither the CCPC nor the DBEI identified any best practice in Ireland.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*n.a.*	*5*
Total (country)	***n.a.***	***n.a.***	***5***
Notes:	*The above figures relate to 2018 (see Annual Report 2018). Within the CCPC, there were 5 FTE for GPSD, Toys, LVD, PPE (recreational & leisure) and Appliances Burning Gaseous Fuel (domestic) at the end of 2018. As of December 2019, the Number of staff (FTE) in the Division has increased to 10 FTE and the CCPC continue to recruit staff into the Product Safety and Market Surveillance Division.*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)

Total number of inspections	*n.a.*	*n.a.*	**492**
Total number of consumer products tested in laboratories	*n.a.*	*n.a.*	1
Total number of consumer products inspected in cooperation with the customs	*n.a.*	*n.a.*	346 739
Notes:	*The above figures relate to 2018 (see Annual Report 2018), and to investigation totals for GPSD, Toys, LVD, PPE (recreational & leisure) and Appliances Burning Gaseous Fuel (domestic).*		

C. Number of recalls of consumer goods (last available year)

Notes: There were 122 Recall Notices published by the CCPC in 2018 (see Annual Report 2018). This figure relates to total number of Recall Notices posted on the CCPC website in 2018 including voluntary, mandatory and RAPEX for GPSD, Toys , LVD, PPE (recreational & leisure) and Appliances Burning Gaseous Fuel (domestic).

D. Key sources

Legislation	European Communities (General Product Safety) Regulations 2004, S.I. No. 199 of 2004.
Studies/reports/articles	There are no recent (since 2013) published studies/reports/ articles on the topic of consumer product safety in Ireland.
Websites	Competition and Consumer protection Commission at www.ccpc.ie Department of Business, Enterprise and Innovation at www.dbei.ie and in particular: https://dbei.gov.ie/en/What-We-Do/Consumer-Competition/Product-Safety-/ "Customs Control in the Area of Product Safety" (June 2019) at https://www.revenue.ie/en/tax-professionals/tdm/customs/prohibitions-restrictions/customs-control-in-the-area-of-product-safety.pdf
Interviews	Competition and Consumer Protection Commission Department of Business, Enterprise and Innovation

15. Italy

COUNTRY REPORT ITALY

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Legislative decree No. 172 of 2004. The provisions thereof later became part of *Legislative decree No. 206 of 2005 – Italian Consumer Code*,[296] Art. 103 ff.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Italy

National legislation sets out general requirement to indicate name and contact details of the producer, product reference or the batch of products to which it belongs on the product or its packaging. According to the Ministry of Economic Development, no practical problems have been encountered with respect to the application of Art 5(1) GPSD regarding traceability. However, traceability could be improved by adopting requirements for business operators to keep supply chain records.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

No.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The answer provided by relevant authorities is that they do not know whether any of these emerging threats are covered. Apparently, the issue has not yet been dealt with by national authorities. The Ministry of Economic Development has indicated incense sticks as a particular category of consumer products posing safety issues that are not addressed in current national legislation.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

If no European standards in the EU Official Journal exist, national standards, international standards outside EU, Commission recommendations, codes of good practice in the sector concerned and state of the art and technology become relevant.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Italy in case there are consumer product(s) on the market which are found unsafe under the GPSD

In the case of unsafe products, the surveillance authorities may require the business to provide relevant information on the product(s), information on supply chain and the distribution of the product(s). Furthermore, they may require economic operators to recall products and other corrective measures (such as restrictions on the placing of products on the market or bringing products into compliance, stopping products from being placed on the market, withdrawal of products, etc. Chambers of Commerce (Camere di commercio) are entitled to impose administrative fines. The surveillance authority is not entitled to reclaim the costs of administrative activities with respect to the unsafe product(s) (e.g. for testing, storage, destruction etc.). Mystery shopping is not allowed either.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other

[296] *Codice del consumo*

relevant provisions (types of penalties, their level/amount)

Pursuant to Art. 112 Consumer Code, manufactures and distributors are liable to pay a criminal fine of 10 000 up to 50 000 Euro, and may be sentenced to prison for 6 months up to 1 year for violating orders by relevant authorities not to sell or to withdraw unsafe products, unless a more serious criminal offence occurs (para 1); manufactures are liable to pay a criminal fine of 10 000 up to 50 000 Euro, and may be sentenced to prison for up to 1 year for placing unsafe products on the market, unless a more serious criminal offence occurs (para 2); manufactures are liable to pay a criminal fine of 10 000 up to 40 000 Euro for non-complying with order by relevant authorities to inform consumers about safety risks, unless a more serious criminal offence occurs (para 3); manufacturers and distributors are liable to pay an administrative fine of 2 500 up to 40 000 Euro for not cooperating with relevant authorities requesting information or doing inspections (para 4); manufactures and distributors are liable to pay an administrative fine of 1 500 up to 30 000 Euro for not complying with information duties under the relevant legislation.

Fines are applied in practice. However, there was no data nor estimates provided regarding the current fining practices and, in particular, the average and/or maximum amount of fines imposed on businesses.

Recent case law in Italy with respect to or relevant for the GPSD/the national implementation legislation.

As to administrative fines and other administrative measures that are available under Art. 112 Consumer Code, no judicial precedents are found in the most used legal databases (Dejure.it and Pluris). This might be due to lack of information rather than lack of cases, given the fact that administrative fines levelled by Chambers of Commerce are quite common.

As to criminal cases under Art. 112 Consumer Code, a limited number of judicial decisions are found in the most used legal databases. The points of law that have been clarified in Italian case law relate to the notions of "producer" (the mere importer does not qualify as producer[297]; a reseller whose activity affects the safety of the product put on sale does qualify as producer[298]), "placing on the market" (the mere storing for the purpose of selling does suffice[299], and the more so the conveying of goods to the courier for delivery to the final consumer[300]), "unsafe" (non-complying with the legal obligation to put the CE marking on the product does not equal to placing on the market an unsafe product[301]; a non child resistant lighter is not per se considered to be unsafe for children, since its unsafety has to be proved by the relevant authority in the specific case at hand[302]; a product intended only for professional use may qualify as unsafe when it is sold directly to final consumers[303]).

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Italy concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Overall, the standardisation process under the GPDS can take too long vis-à-vis technological development. However, this is a critical point that is found in all product-related directives.

Possible improvements to make the implementation of the GPSD in Italy more effective

The standardisation process under the GPDS could be improved by reducing the number of steps and by involving independent safety consultants in the preliminary consultations.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Italy.

[297] Trib. La Spezia, No. 189 of 23/2/2010.
[298] Cass. pen., sez. III, No. 6787 of 4/12/2007; Cass. pen., No. 8679 of 13/11/2013.
[299] Cass. pen., sez. III, No. 15235 of 11/11/2014; Trib. Firenze, No. 2386 of 26/7/2017; Trib. Genova, No. 6284 of 6/12/2016; Trib. Torino, 7/3/2012 in Dejure.it.
[300] Trib. Foggia, 30/10/2017 in Dejure.it.
[301] Trib. La Spezia, No. 300 of 26/3/2009.
[302] Cass. pen., sez. fer., No. 40609 of 9/9/2014.
[303] Trib. Padova, No. 768 of 1/8/2018; Trib. Padova, No. 204 of 14/11/2017.

At the national level: Market surveillance in Italy is entrusted to the following central administrations: Ministry of Economic Development,[304] which is charge of coordinating relevant authorities at national level; Ministry of Health;[305] Ministry of Internal Affairs;[306] Ministry of Finance;[307] Ministry of Environment;[308] Ministry of Infrastructures and Transportation.[309] Each Market Surveillance Authority cooperates with a number of bodies for inspection activities, such as Chambers of Commerce,[310] the Customs Agency[311] and Guardia di Finanza. Administrative sanctions are mostly imposed by the Chambers of Commerce. Violations to criminal laws are reported to the Judiciary.

The Ministry of Economic Development coordinates other authorities' activities by setting up agreements, defining the criteria for the planning of controls, the criteria for selecting the type of business to subject to such controls, the products to be controlled, the requirements of certification bodies and testing labs, the criteria and modalities of inspections.

Each authority relies on its own financial resources. In some instances, product safety related activities are funded with the fines that are imposed by the Italian Competition Authority[312] on businesses.

Each central administration has had to set up a dedicated department, with the task of supervising and coordinating the activities of inspection authorities, defining compliance and recall procedures and, more generally, supervising market surveillance activities falling within its respective competence.

In 2019, human resources equivalent to 40 new staff units were assigned to the Ministry of Economic Development to support its market surveillance activities.

At the sub-national (regional/provincial/local) level: Chambers of Commerce, the Customs Agency and the Guardia di Finanza – Nucleo Anticontraffazione e Sicurezza Prodotti carry out their monitoring activities locally and/or through local units. In addition, Chambers of Commerce check infringements and impose administrative fines on businesses. Criminal sanctions fall directly within the competence of the Judiciary.

The inspection authorities, which includes the Chambers of Commerce, the Guardia di Finanza and the Customs Agency, are entrusted with carrying out inspections, checking infringements, notifying statements of objections and imposing fines.

Controls carried out by inspection authorities can be of three types: i) visual (the inspection authority checks if all due indications required by law are put on the product); ii) documental; iii) testing of samples. Type 2 and 3 controls are made in cooperation with certified labs. Most labs are independent labs. Only recently, the Custom Agency has set up an internal lab for toy testing.

Plans/programmes in place which define priorities for market surveillance of consumer products

The Ministry of Economic Development defines priorities for market surveillance of consumer products by adopting national surveillance programmes, both general (i.e. covering all consumer product sectors) and sectoral. Since the enactment of Regulation (EC) 765/2008, the Ministry of Economic Development has adopted five general plans as well as sectoral plans for eleven kinds of products. The sources of information used for defining priorities are inspection results and RAPEX notifications.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Italy with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Products containing new technologies are checked like any other kind of products if they fall in a product group that will be targeted. There is no special focus on products containing new technologies.

[304] Ministero dello Sviluppo Economico
[305] Ministero della Salute
[306] Ministero dell'Interno
[307] Ministero dell'Economia e delle Finanze
[308] Ministero dell'Ambiente e della Tutela del Territorio e del Mare
[309] Ministero delle Infratrutture e dei Trasporti
[310] Camere di Commercio
[311] Agenzia delle Dogane
[312] Autorità Garante della Concorrenza e del Mercato

None of the authorities use mystery shopping. It is (currently) illegal according to Italian law.

Market surveillance is conducted with respect to C2C sales by the Customs Agency and the Guardia di Finanza. The Customs Agency checks products imported into Italy from non-EU/EEA countries through an automated customs system based on risk analysis.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Moreover, the Guardia di Finanza monitors platforms, retailers' websites and social media offering products for sale. Approximately 41-50% of inspections carried out by the Guardia di Finanza relate to products sold online. The monitoring of online sales relies, among others, on cooperation agreement with e-commerce platforms.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Italy (except customs) with respect to product safety

Relevant authorities meet twice a year under the supervision of the Ministry of Economic Development pursuant to Art 106 of Decree No. 206 of 2005 (Italian Consumer Code), and cooperate in preparing national market surveillance plans/programmes. Besides that, depending on the authorities involved, cooperation at national level may also consist in regular exchange of information, regular meetings, joint training sessions and informal cooperation.

Cooperation with customs authorities in Italy with respect to product safety

Common use of RAPEX, through formal agreements, joint processes for dealing with dangerous products, joint training sessions, regular meetings, and informal cooperation are used for cooperation with customs.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The main vehicles for practical cooperation with authorities in other EU countries are RAPEX, ICSMS and the Wiki confluence platform.

When the economic operator is located outside Italy but within the EU/EEA, and if possible, the Guardia di Finanza activates police forces cooperation channels (Europol). No actions are taken against economic operators located outside the EU/EEA area.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The pre-notification stage is structured as follows: 1) identification of the unsafe product; 2) certification of serious risks for consumers; 3) proposal to the Ministry of Economic Development to enter relevant information into RAPEX. According to the Ministry of Economic Development, the duration between the detection of an unsafe product and its notification to RAPEX can take up to two weeks. The duration varies depending mainly on the risk assessment made by certified organizations.

In the case with non-safety issues, other responsible authorities are informed and may take action.

According to the authorities, the RAPEX system is rather well functioning. Difficulties encountered by relevant authorities in using RAPEX are: insufficient human or financial resources; difficulties with risk assessment; lack of information from other national authorities within Italy; insufficient information about the identity of the economic operator concerned.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The Ministry of Economic Development organizes two general meetings a year (*Conferenza di Servizi*), in which the National Consumer Council[313] and business associations are entitled to participate. The main purpose of such meetings is to prepare national market surveillance plans/programmes.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

As regards businesses, awareness with respect to product safety is pursued through the *Conferenza dei Servizi*, ad-hoc activities by *Unioncamere* (such as regular meetings and informal cooperation with business associations and the issuing of guidelines approved by industry-specific business associations) and a specific business portal for product safety www.prodottisicuri.it.

As regards consumers, the National Consumer Council is entitled to participate in the *Conferenza dei Servizi*. Informal cooperation with consumer association does also play an important role. Awareness on the consumer's side is pursued through press releases, information campaigns, both traditional and via social media, and by referring to EU RAPEX website.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Italy (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls can be either voluntary or mandatory. For this purpose, businesses are required to use all their available customer information. In case of a recall of a consumer product, market surveillance authorities will require from businesses information activities targeted at consumers and other businesses involved in the supply chain, timeline of the recall process, recall effectiveness (i.e. percentage of recalled products actually collected), and destruction/disposal of products collected. However, market surveillance authorities have no role in communicating information to customers.

Monitoring of effectiveness of product recalls by market surveillance authorities

Only in the case with mandatory recall, the relevant authority will require the economic operator to prove that the recall has been made, and collect information about the recall results in terms both of absolute number s and percentage of collected products. Codes of good practice pursuant to Art 5(1) GPDS have not been enacted yet.

According to the Ministry of Economic Development, product recalls are rather effective. Businesses appear to be very active in adopting voluntary recall measure and provide all information required by relevant authorities.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Italy that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The Ministry of Economic Development keeps statistics on dangerous products. These statistics are an outcome of national surveillance programmes but are intended only for internal use.

As to injury data, the Ministry of Economic Development relies on public health related registers, consumer complaints, fire brigade registers as well as occupational safety registers, in order to choose priority areas for surveillance and to identify new risks.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Italy (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The main impediments are the following: limited staff resources; lack of expertise in new technologies; lack of expertise in online market surveillance; unclear distribution of competences for market surveillance at national level; lack of suitable product testing labs.

[313] *Consiglio Nazionale dei Consumatore e degli Utenti*

Areas to make market surveillance of consumer products in Italy/the EU more effective

In general, the impression is that market surveillance in Italy works rather well. According to the relevant authorities, specific elements to be improved at EU level include the information provided through RAPEX regarding the identity of economic operators concerned and the streamlining of standardization procedures. At national level, a particular element to be improved is the testing of products for safety requirements.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Italy since 2013

The general impression is that the safety level has improved thanks to the inspections carried out by the Customs Agency and to national surveillance programmes. The number of confiscated products has constantly increased over the years.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Italy whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Not yet. Webcrawlers are being developed and tested in cooperation with public research institutions and private businesses.

Views of market surveillance authorities whether approaches in Italy can be considered best practice implementation of the GPSD, which could be of interest to other countries

The use of webcrawlers.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

The relevant authorities could not provide any significant data.

B. Number of inspections of consumer products (2018)

The relevant authorities could not provide any significant data

C. Number of recalls of consumer goods (2018)

The relevant authorities could not provide any significant data

D. Key sources

Legislation	*Legislative decree No. 206 of 2005 "Codice del consumo" (Italian Consumer Code)*
Studies/reports/articles	Programma nazionale di vigilanza del mercato 2019 (National Italian Surveillance Programme for the year 2019)
Websites	www.prodottisicuri.it
Interviews	Italian Ministry of Economic Development (Ministero dello Sviluppo Economico) Italian Customs Agency (Agenzia delle Dogane e dei Monopoli) Italian Financial Policy - Guardia di Finanza – Nucleo Anticontraffazione e Sicurezza Prodotti Unioncamere (Italian Association of Chamber of Commerce)

16. Latvia

COUNTRY REPORT LATVIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Law On the Safety of Goods and Services (adopted 07.04.2004, entry into force 01.05.2004, last amendments 16.04.2014), henceforth LSGS;

Cabinet of Ministers Regulations No. 196 Regarding Procedures by which Market Surveillance Institutions Inform the Consumer Rights Protection Centre Regarding the Measures Taken, which Restrict or Prohibit the Placing of Products on the Market, and the Procedures by which the Consumer Rights Protection Centre Sends the Received Information to the European Commission and Handles the Information Received from the European Commission (adopted 6.12.2005, entry in force 09.12.2005);

Cabinet of Ministers Regulations No.482 On Market Supervision Council (03.09.2015, 03.09.2015);

Cabinet of Ministers Regulations No.119 Procedures by which a Producer, Distributor of Goods or a Service Provider Informs the Relevant State Supervisory and Control Institutions Regarding the Goods or Services that Cause a Risk Incompatible with General Safety Requirements (14.02.2006, 18.02.2006);

Cabinet of Ministers Regulations No. 96 Procedures by which Market Supervision Institutions Request and Receive Samples of Goods, and Handle them after a Laboratory or Other Types of Expert Examination (01.02.2005, 09.02.2005);

Cabinet of Ministers Regulations No. 755 Procedures for the Circulation, Supervision and Control of Gas Cylinders (adopted 09.12.2014, in force 31.03.2015;

Cabinet of Ministers Regulations No. 132 Regarding the Safety of Toys (15.02.2011, 20.07.2011);

Cabinet of Ministers Regulations No. 182 Regarding Hygiene Requirements for the Provision of Tattooing and Piercing Services and Special Requirements for the Tattooing Products (14.04.2015, 01.01.2016)

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Latvia

Article 2(1) generally requires that a manufacturer shall indicate (mark) the goods, their packaging, in the technical documentation or the technical registration of the goods his or her name (firm), given name, surname, trademark or other distinctive mark, or the person who has reconditioned the goods in order to put them into circulation. It is recommended list of information.

Article 5 (1) of GPSD (without major changes) is transferred to Article 8 of the LSGS. For example, Article 8(4) of the LSGS provides that the duty of the producer (and service provider) is to take all measures enable the assessment of risks which may be caused by the goods or services. Such measures may include “information regarding the reference number of the producer, product or goods, as well as the identification of the producer on the relevant goods, property or its packing (except in cases where non-provision of such indication is justified)”. There are no requirements to use a barcode or other machine readable identification on the product or its packing.

There are specific rules in the case of serious risk: “the producer, distributor or service provider has a duty to provide at least: 1) information that provides the opportunity to precisely identify the relevant goods, property or production batch of goods or properties; 2) the complete description of the risk caused by the relevant goods or property; 3) all accessible information necessary for tracking the relevant goods or properties; 4) information regarding the measures taken to prevent risk to consumers.”

Article 8(5) of the LSGS provides that also the distributor is under obligation to keep and ensure the necessary documentation for tracing the origin of the goods stating that “the duty of the distributor is to act with due care in order to facilitate conformity of the goods with general safety requirements. The distributor may not sell, supply or otherwise distribute goods if he or she may or should conclude that they fail to comply with safety requirements, as well as goods regarding which he or she lacks sufficient information as to safety thereof. Within the limits of his or her respective activities, the duty of the distributor is to participate in taking safety measures regarding goods,

especially informing of the possible risks, keeping and ensuring the necessary documentation for tracing the origin of the goods, as well as co-operating actively with the producers and State supervision and control bodies in the actions taken to prevent any risks from goods put into circulation."

In practice, it is very difficult to apply such broad and unspecified rules. For example, many products are re-packed and re-labelled thus the original information regarding the product is not retained. It was suggested by the authorities that there is need to harmonise traceability requirements for all consumer products, both harmonised and un-harmonised.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

No.

Article 5(1) of the LSGS states that Safe goods are any goods which, in conformity with the requirements of installation and maintenance, under normal or foreseeable conditions of use, including the intended duration of use, and where applicable, included as part of a service, do not present a risk or only a minimum risk related to the use of the goods, which is considered to be acceptable and consistent with a high level of safety for human life, health and the property of a person, as well as with the level of environmental protection. Theoretically, this broad definition could be applicable also in the area of new technologies; however, there is no yet practical experience.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

No.

However, the CRPC is drafting a new three years strategy that also will cover market surveillance activities regarding new technologies thus most likely the CRPC will develop guidelines for traders in this regard, too.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

It was indicated that competent institutions consult also other international, national and European standards, different recommendations and codes etc. Therefore, too many different benchmarks are used and in practice it might be difficult to oversee all relevant sources as amount of information is too extensive thus there is need for codification.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Latvia in case there are consumer product(s) on the market which are found unsafe under the GPSD

There are various administrative measures available in Latvia. Article 12(2) of LSGS provides that the officials of the market supervision bodies are entitled to, within their competence: 1) Control and supervise conformity with the safety requirements of the goods and services; 2) Require and receive information free of charge necessary for the evaluation of the safety of goods and services or for the implementation of functions of the relevant body; 3) Request and receive free of charge samples of goods, perform control purchases for the acquisition of samples of goods, and organise laboratory or other types of expert examination of the goods or service in order to determine the conformity with the safety requirements of goods or service, if so provided for by the annual supervision and control programme approved by the director (head) of the relevant body, or if there are suspicions regarding the non-conformity with the safety requirements of goods or service, or if a complaint has been received.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The Latvian Administrative Violations Code provides for special penalties for violations of consumer rights protection, including product safety. However, this Code will become void as of 1.07.2020. Article 166.^{9}(3) of this law provides that in the case of offering or selling goods or services that do not comply with the safety requirements specified in regulatory enactments, a fine shall be imposed on natural persons in an amount from 35 to 700 EUR, but for legal persons from 280 to 14 000 EUR, with or without the confiscation of the goods.

As from 1.07.2020 administrative penalties will be provided in the LSGS. The penalty level will be almost the same.

According to stakeholders penalties are imposed; however, there are no official statistics.

Recent case law in Latvia with respect to or relevant for the GPSD/the national implementation legislation.

There are no precise numbers of case law with respect to or relevant for the GPSD but a few cases could be found in public database of judgments.

- Riga city Zemgale parish (first instance) judgment in the case 131032314 dated 14.05.2015.

13.05.2014 The Consumer Rights Protection Centre (henceforth: CRPC) decided to prohibit company A from selling, or distributing unsafe goods (children's helmets) and ordered company A to withdraw the goods from circulation within 2 weeks, to recall the goods from consumers, and to inform CRPC on destruction of the goods. The company did not observe the decision and therefore CRPC imposed a penalty in the amount of 500 EUR pursuant to Article 175.[9] of the Latvian Administrative Violations Code, which provides that in the case of the non-provision of information at the disposal of a person to an advertisement or consumer rights protection supervisory institution after a request therefrom within a specified time period and in the specified amount or in the case of the provision of false information, as well as of the non-fulfilment of the lawful requests or decisions of the supervisory institution, a fine shall be imposed on natural persons in an amount up to 700 EUR, but for legal persons from 700 EUR up to 14 000 EUR

The court based its decision on the LSGS and also the GPSD. The goods were tested and acknowledged to be dangerous. The judge established that the distributor of the goods had an obligation to recall the goods and such conduct would prove responsible behaviour of the company (the company claimed that its reputation would be damaged if goods would be recalled from the consumers). The company's complaint was rejected and the administrative penalty was imposed on the company. The judgment of the court was not appealed and thus entered into force.

- Riga district court (second instance) judgment in the case No. 132054515 dated 19.12.2016:

29.09.2015 CRPC had made a decision for the violation of Article 166.[9](3) of the Latvian Administrative Violations Code against company "A" and imposed a penalty of 280 EUR. Namely, in the company's salt sauna, natural person S. received electric injuries due to a breach of the safety of goods and services. Company A appealed the decision in various instances and the Riga regional court made a final decision. The court determined that there was evidence (expert opinion, witnesses) that the company did not provide safe services and goods in accordance with the LSGS.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Latvia concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Traceability: As there are no clear requirements to provide information on the product itself, when the distributors re-pack the product, original information is removed thus it becomes difficult to trace the origin of product.

Article 5 of the LSGS mirrors the definition of safety included in the GPSD. Opinions regarding the definition of the safety varied. At the administrative enforcement level, the competent authority (the CPRC) was of the opinion that the definition is too broad, but at the governmental level, it was considered to be a well-functioning definition.

Authorities did not indicate emerging safety issues.

Possible improvements to make the implementation of the GPSD in Latvia more effective

It was indicated by the authorities that there is a need for a more harmonised legally binding framework (e.g. with respect to the responsibilities of economic operators for harmonised and non-harmonised goods). Indeed, rules are very fragmented; one sector is regulated very strictly, while the other has no legal framework at all or it is covered by non-binding guidelines.

There is no academic literature in Latvia in this regard.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Latvia.

At the national level*:* the Consumer Rights Protection Centre (henceforth: CRPC) has very broad competencies in market surveillance. Other institutions mentioned below have very limited and specific area of responsibility as regards market surveillance. .

The Customs Administration of the State Revenue Service is also a competent supervision institution under the LSGS (Art. 10(1)).

The State Police is responsible *inter alia* for ensuring that only such explosives and explosive devices are marketed which have a conformity assessment certificate, a CE European conformity marking, and the special mark of the European Union (Article 29 of Law On the Handling of Explosives for Civil Uses (28.10.2010, 01.01.2011)). The Law on the Circulation of Pyrotechnic Articles (23.09.2010, 27.10.2010) provides that the control of the circulation of fireworks and theatrical pyrotechnic articles with respect to the implementation of the requirements provided for in this Law shall be performed by the State Police (Article 21(2)).

The Health Inspectorate acts in accordance with the Cabinet of Ministers Regulations No. 309 On Statutes of the Health Inspectorate in force as of 12.07.2019 (replacing Regulations No. 76 mentioned in National Market Surveillance Programme). In accordance with Article 3 of these regulations, the Health Inspectorate shall *inter alia* monitor the implementation of pharmaceutical legislation concerning the circulation and advertising of medicinal products and active substances for human use, the circulation of narcotic and psychotropic substances and drugs, the circulation of alcohol, and the circulation of precursors; monitor the compliance of high-risk subjects, environmental factors affecting public health, chemicals available on the market, chemical mixtures (including biocides and detergents), cosmetics, tobacco products (including newly introduced tobacco products), herbal smoking products, electronic cigarettes and refill vials with the requirements specified in regulatory enactments; and monitor compliance with requirements stipulated with respect to medical devices.

The competencies of the Assay Office of Latvia are set by the Law on Supervision of Official Fineness (19.01.1995, 16.02.1995). Article 15.[1](6) of this Law provides *inter alia* that the Assay Office of Latvia shall assess the composition of alloys of precious metal and precious stone articles for conformity with the harmlessness requirements for goods.

The State Technical Supervision Agency acts in accordance with by-laws adopted by the Cabinet of Ministers Regulations No. 937 (18.12.2012, 01.01.2013). Article 4.12 of the Regulations provides that the agency safeguards consumer rights protection if non-conforming tractors and their trailers are offered in the market.

The tasks of the State Plant Protection Service are set out in the by-laws adopted by the Cabinet of Ministers Regulations No. 962 (23.11.2004, 01.01.2005). One of those tasks is to provide supervision and control on issues concerning radiation safety and nuclear safety, as well as to carry out the state control of environmental protection and the use of natural resources in the territory of Latvia, its continental shelf, economic zones of the Baltic Sea and Rīga Gulf, its territorial waters and inland waters.

All organisations of market surveillance act at the national level.

Plans/programmes in place which define priorities for market surveillance of consumer products

The Ministry of Economy coordinates market surveillance activities. It accumulates plans of all market surveillance bodies, thus making one national plan. At the administrative level, for example, the CRPC draws up an operational strategy once every three years, highlighting the CRPC's fundamental values, surveillance policy, lines of actions and priorities. Every year, a public report on activities undertaken in the previous year, their results, and statistics are published on the website of the CRPC. Other responsible bodies also work in the same way.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Latvia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

The Ministry of Economy as the responsible authority for the Market Surveillance Council's work has initiated several discussions and sharing of best practices among enforcement authorities regarding products sold online. There are plans to increase the powers of market surveillance authorities regarding restricting access to websites that are not compliant.

However, at the executive level, there are no actions on market surveillance regarding new technologies. There

have been no discussions to introduce market surveillance regarding C2C products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance of products sold online is conducted very often, but due to capacity only concerning products sold online by domestic sellers on their websites or on comparison websites. Market surveillance concerning products sold online is organised and conducted in different ways. The CRPC takes into account information published in RAPEX and monitors information on products published online, including social media. There are special internal guidelines on how to detect dangerous and non-compliant products as well as how to withdraw and test the products. These guidelines also provide for rules on how to secure and possess evidence and what actions shall be taken. The CRPC has developed an e-laboratory and it is available for all departments of the CRPC, thus surveillance is managed in cooperation with other staff as well.

Mystery shopping is also conducted frequently, at least once per week. Employees of the CRPC perform "mystery shopping", obtaining samples either as private persons or using fake identities. However, once employees arrive at the premises of the e-shop, the identity is disclosed.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Latvia (except customs) with respect to product safety

The Ministry of Economy coordinates the Market Surveillance Council, a consultative body composed of, *inter alia,* representatives of the relevant market supervision bodies. The objective of the Council is to ensure the exchange of information and opinions between market supervision bodies. The Council provides recommendations and consultations for the preparation of a working plan for market supervision and evaluates the implementation of the market supervision strategy. The Council meets twice a year.

The CRPC has broad competencies regarding market surveillance; the supervision is more or less centralised, therefore there is not such extensive cooperation with other authorities. The closest cooperation is with the Health Inspectorate.

Cooperation with customs authorities in Latvia with respect to product safety

The CRPC cooperates with customs daily on the basis of an inter-institutional agreement. Every year, the CRPC prepares information for the Customs Administration based on each year's priorities. This includes the designation of specific groups of products, volumes of freight and other specific criteria, in accordance with which checks on imported products are performed. In addition, checklists for the Customs Administration staff are drawn up, setting out the requirements (standards and product labelling requirements) in accordance with which a desk review of imported products is conducted by customs inspectors. In the event of non-compliance (one or more of the criteria defined in the checklist are not fulfilled), the Customs Administration requests that the CRPC give its opinion on whether or not the products conform to regulatory requirements (see also: para 1.3. of National Market Surveillance Programme, 2019).

Joint training is also organised; there is a regular exchange of information between both institutions.

However, authorities considered that the cooperation could be more effective and that custom authorities could develop their own plans and strategies and improve cooperation with neighbouring countries' customs. Moreover, information on dangerous products is not transmitted to customs because the Customs Administration cannot identify those products (they use different code system). The CRPC itself ensures that the dangerous goods are not re-imported into the country.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The CRPC cooperates with relevant authorities located in other EU/EEA countries on a regular basis through RAPEX, ICSMS and Wiki confluence platform.

The CRPC regularly takes part in joint market surveillance projects and events organised by the Commission and ADCO.

Cooperation with non-EU/EEA countries are more at the formal level and it should be improved.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous

products, non-safety risks notified through RAPEX etc)

The CRPC uses the RAPEX system actively in accordance with the developed internal procedures providing for step-by-step guidelines on how to evaluate and submit information. The CRPC notifies about a dangerous product when all information has been assessed and the case has been investigated; in many cases the economic operators do not cooperate, therefore the procedure is rather time consuming and it takes approximately 2 weeks between the detection of a dangerous product and the notification to RAPEX.

The CRPC have not had any emergency cases.

The CRPC deals also with non-safety risks, including environmental risks (ROHS); it is within the CRPC's competence therefore it does not notify other authorities.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Cooperation with businesses and business associations is not intense; mostly the CRPC is contacted by traders in case of possible or existing difficulties.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The CRPC has developed guidelines for businesses, and it trains and consults the representatives of businesses.

The CRPC cooperates more with consumer organisations in other aspects of consumer law. Indeed, joint projects and research would possible but, unfortunately, there is a lack of capacity and financial resources.

The CRPC has a plan to develop a special webpage with respect to dangerous products and product safety in the future (currently information is published on webpage of CRPC, which is not very elaborated). Meanwhile, consumers are informed about dangerous products on the CRPC webpage, through social media and by issuing press releases.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Latvia (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Initially, the CRPC market surveillance activities are aimed at promoting voluntary recalls. The CRPC accepts voluntary recalls, re-publishes them, and helps businesses to distribute relevant information.

In the case of a recall of a consumer product, the CRPC can require different types of information, including information activities targeted at consumers, list of other businesses involved in the supply chain, timeline of the recall process, effectiveness of recalls, information on destruction of products collected.

When businesses are required to conduct mandatory recalls, the CRPC suggests different information channels, i.e., the businesses are asked to use different customer information for recalls. In practice it is difficult to evaluate whether businesses comply and can comply with such request due to data protection rules for natural persons, anonymous loyalty cards, etc. The CRPC carefully reviews all information and the recall strategies, as businesses do not always correctly reflect the necessary data. For example, businesses may misconstrue the difference between the conformity of the goods and the safety of the products.

The CRPC has developed and translated different guidelines for businesses and businesses consult them. However, they are non-binding, therefore businesses may not follow them.

However, the stakeholders indicated that it is crucial to develop a separate portal for such market surveillance activities where all information is located together in one place, so that it is more transparent and structured.

Consumers are informed via social media about recalls and all information is published on the website of the CRPC; however, it is questionable how many consumers are following this information and how it impacts their behaviour.

Monitoring of effectiveness of product recalls by market surveillance authorities

In order to close a case, the CRPC shall monitor both voluntary and mandatory recalls of products and their

respective execution. The CRPC collects different information regarding recalls, but in reality it is difficult to determine the effectiveness of product recalls. In certain cases, the CRPC receives exact number of recalls. For example, one particular product – a saw – was recalled from the market. The CRPC investigated that at least 79 such products were sold and 26 items were returned (The CRPC Official Report of 2018).

6. Availability of statistics relevant for market surveillance

Availability of statistics in Latvia that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

The CRPC collects consumer complaints and statistics on dangerous goods. The latter is published on the webpage of the CRPC.

There is an internal CRPC database of injuries. It is very basic and incomplete as in the most of the cases it is difficult to establish the casual link between the product and injury, i.e. whether the injury was due to a dangerous product or due to other circumstances, which particular product caused the injury, etc. The CRPC is willing to cooperate more with doctors; however, they have limited capacities for this.

Within the meetings of the Market Surveillance Council, this has been discussed with a representative of the Ministry of Health, but it is unclear how the doctors should collect such data in practice.

Recently, there were quite a few complaints regarding public children's playgrounds, including injuries occurring on these playgrounds. Even though the CRPC developed non-binding guidelines regarding safety rules in the playgrounds, it was necessary to adopt binding legislation, therefore the Ministry of Economy along with all stakeholders has drafted new Cabinet of Ministers Regulations on safety of the children's playgrounds.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Latvia (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

It was considered by all interviewed institutions that due to limited capacities and financial resources of market supervision bodies, it is currently impossible to cover each and every sector of the market, therefore the competent institutions set priorities, but ideally it could be improved. Cooperation with local customs could be upgraded as well. Setting the same priorities with the neighbouring countries' customs would also facilitate more efficient market surveillance. There are also not many consumer associations to be involved; businesses are more active to cooperate in cases where they face a problem, but this cooperation should be done before problems arise.

The lack of a clear legal framework and lack of explicitly and legally expressed powers for the CRPC also create problems and impediments. For example, the CRPC cannot currently block websites, and already at the stage of developing the relevant rules, there are legal and practical obstacles to introducing this function.

In general, all stakeholders agreed that RAPEX functions well. However, at the execution level there were comments how it should be improved, e.g. there is need for more advanced statistics tools and there is a lack of information regarding supply chains and measures taken by other Member States. There is an urgent need for WebCrawler tools, as employees of the CRPC currently collect information manually and this is time consuming. The CRPC is also faced with subjective assessments of the risks and with delays of notifications.

The CRPC considered that recalls are not effective in Latvia because they are costly and they take a lot of time. In many cases, consumers are not interested in returning the products.

Areas to make market surveillance of consumer products in Latvia/the EU more effective

The CRPC indicated that it would be advantageous for Member States to get more detailed statistics, for instance on supply chains, how effective the recall of a particular product was, or how many products were returned in other Member States. There is also a need for more detailed databases (for example, currently the inspector takes a photo of the product, but this picture may not reflect exactly the same image as published online on the retailer website).

In general, there is a need for better and clearer legal rules, including with respect to compensation systems, i.e. whether a consumer is entitled to compensation, and if so, who is responsible for providing this compensation (distributor, manufacturer, etc.). While the biggest businesses may care about their reputation and develop their own system for recalls, there are many smaller businesses that may not pay any attention to such issues.

There is a need for more resources to develop better cooperation with business and consumer associations.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Latvia since 2013

Every year the CRPC sets areas of priorities, i.e., which groups of goods and services are especially monitored. For example, in 2018 one of the priorities was special surveillance for electric appliances etc. Thus the best developments can be observed in those prioritized areas. No particular statistics are available.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Latvia whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Surveillance authorities have basic tools; there is an urgent need for more advanced ones. A lot of work is done manually and using very basic databases (for example, developed in Excel), thus authorities are not in line with modern developments. It was also considered that there is a lack of special knowledge and expertise in using new tools. Unfortunately, due to the limited resources, the CRPC does not develop any new technological approaches or tools.

Views of market surveillance authorities whether approaches in Latvia can be considered best practice implementation of the GPSD, which could be of interest to other countries

There are at least three positive features.

Firstly, the CRPC has developed various guidelines for the safety of specific goods, for example, guidelines for safety of children's clothes. Guidelines are very practical and are therefore often used by businesses.

Secondly, all stakeholders considered that it is also a success that the law covers not only the safety of goods but also of services. As indicated in only book regarding consumer rights protection: "as compared with the GPSD, the legislator of Latvia has broadened the scope of the LSGS, covering also services [...] For example, the LSGS shall be applicable also to different entertainment services – paintball amusements parks, ski runs".[314]

Thirdly, the establishment of the Market Supervision Council ensures the exchange of information and opinions between market supervision institutions.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*n.a.*	*n.a.*	*27*
Total (country)	***n.a.***	***n.a.***	***27***
Notes:	*These numbers reflect only staff working at the CRPC. It does not include information from the Health Inspectorate and the Assay Office.*		

[314] See Vītoliņa B. Patērētāju tiesību aizsardzības pamati (Bases of the Consumer Protection Rights). Zvaigzne ABC, 2015, p. 314

B. Number of inspections of consumer products (last available year)			
	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**324**	**75**	**399**
Total number of consumer products inspected	1081	63	1144
Total number of consumer products tested in laboratories	150	12	162
Total number of consumer products inspected in cooperation with the customs	2083	n.a.	2083
Total number of dangerous consumer products found	58	6	64
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	15	2	17
Notes:	*Numbers are accurate for 2018 but do not include the number of inspections conducted by the Customs Administration because there is no harmonised methodology as to how customs should collect such numbers.*		

C. Number of recalls of consumer goods (last available year)			
	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	9	2	11
Total number of mandatory recalls	14	2	16
Notes:	*Numbers reflect the year 2018.*		

D. Key sources	
Legislation	Law On the Safety of Goods and Services (adopted 07 April 2004, entry into force 01 May 2004, last amendments 16 April 2014) Cabinet of Ministers Regulations No. 196 Regarding Procedures by which Market Surveillance Institutions Inform the Consumer Rights Protection Centre Regarding the Measures Taken, which Restrict or Prohibit the Placing of Products on the Market, and the Procedures by which the Consumer Rights Protection Centre Sends the Received Information to the European Commission and Handles the Information Received from the European Commission (adopted 6 December 2005, entry in force 09 December 2005, last amendments 06 November 2014); Cabinet of Ministers Regulations No.482 On Market Supervision Council (03.09.2015, 03.09.2015) Cabinet of Ministers Regulations No.119 Procedures by which a Producer, Distributor of Goods or a Service Provider Informs the Relevant State Supervisory and Control Institutions Regarding the Goods or Services that Cause a Risk Incompatible with General Safety Requirements (14.02.2006, 18.02.2006) Cabinet of Ministers Regulations No. 96 Procedures by which Market Supervision Institutions Request and Receive Samples of Goods, and Handle them after a Laboratory or Other Types of Expert-Examination (01.02.2005, 09.02.2005) Cabinet of Ministers Regulations No. 755 Procedures for the Circulation, Supervision and Control of Gas Cylinders (adopted 09.12.2014, in force 31.03.2015) Cabinet of Ministers Regulations No. 132 Regarding the Safety of Toys (15.02.2011, 20.07.2011)

	Cabinet of Ministers Regulations No. 182 Regarding Hygiene Requirements for the Provision of Tattooing and Piercing Services and Special Requirements for the Tattooing Products (14.04.2015, 01.01.2016) Latvian Administrative Violations Code (07.12.1984, 01.07.1985, invalid as of 01.01.2020) Cabinet of Ministers Regulations No. 911 By-law of the Market Supervision Council (09.11.2004,13.11.2004)
Studies/reports/articles	Strategy of Consumer Rights Protection Centre 2017-2019, Retrieved 05.12.2019 from http://www.ptac.gov.lv/lv/content/ptac-strategija Report of Consumer Rights Protection Centre 2018, Retrieved 05.12.2019 from http://www.ptac.gov.lv/lv/content/publiskie-parskati-un-statistika Consumer Rights Protection Centre's Data base of dangerous goods, Retrieved 05.12.2019 from http://www.ptac.gov.lv/lv/table/latvij-atkl-t-s-b-stam-s-preces Consumer Rights Protection Centre's guidelines, Retrieved 05.12.2019 from http://www.ptac.gov.lv/lv/content/vadlanijas-godigas-komercprakses-stenosanai-un-taisnigu-ligumu-sastadisanai Book: Vītoliņa B. Patērētāju tiesību aizsardzības pamati (Basis of Consumer Protection Rights). Zvaigzne ABC, 2015, p. 314
Websites	Consumer Rights Protection Centre: http://www.ptac.gov.lv/lv Customs Administration of the State Revenue Service: https://www.vid.gov.lv/lv/muita The State Police: http://www.vp.gov.lv/ Health Inspectorate: http://www.vi.gov.lv/ The Assay Office of Latvia: http://www.prove.lv/ The State Technical Supervision Agency: https://www.vtua.gov.lv/#jump The State Plant Protection Service: http://www.vaad.gov.lv/ Ministry of Economics: https://www.em.gov.lv
Interviews	Consumer Rights Protection Centre and RAPEX Ministry of Economy

17. Lithuania

COUNTRY REPORT LITHUANIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The GPSD was implemented into the Lithuanian legal system by the Law on Product Safety of the Republic of Lithuania (01-06-1999 No VIII-1206, as last amended on 15-11-2018) which is specified in the resolutions of the Government of the Republic of Lithuania, orders of the market surveillance authorities and other substatutory acts.

These include:

- Terms of Reference for the Use of the Consumer Rights Information System (15-06-2016, No. 17241, as last amended on 30-01-2019);
- Regulations of the State Consumer Rights Protection Agency (23-12-2015, No. 20360, as last amended on 30-01-2019);
- Rules for the Notification of Dangerous Products and Services by Manufacturers, Distributors and Service Providers (25-11-2009, No. 143-6325);
- Procedures for Hearing Infringement Cases under the Law on Product Safety (13-05-2019, No. 7636)

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Lithuania

Under the Art 7 of the Law on Product Safety, the producer of goods is obliged to properly mark manufactured goods and to provide consumers with the relevant information before supplying them with manufactured goods, in order to enable them to assess the risks inherent in the manufactured goods throughout the entire specified, normal or reasonably foreseeable period of the use thereof, where such risks are not immediately obvious without adequate warnings.

1. The requirements for marking manufactured goods are specified in the order of the Minister of Economy of Lithuania on the rules of labelling and price indication of items (goods) sold in the Republic of Lithuania (15-05-2002 No 50-1927, as last amended on 31-01-2017). According to the mentioned regulation, the following information must be provided on product labels: Product name;
2. Manufacturer's name or trade mark and the address at which the manufacturer can be contacted;
3. The country of origin;
4. Shelf life, - if the characteristics of the goods change over time and, when the time limit expires, they are considered to be wholly or partially unsuitable for their intended use;
5. Date of manufacture;
6. Purpose of the product;
7. Particulars of use (storage), - where this information is necessary for the safe and proper use of the product.
8. Other information for specific products (indicated in the regulation).

These requirements are stated explicitly and as such are binding. However, no barcode or electronic identification requirements can be found in the national legislation.

The producer is also obliged, having discovered the manufactured goods are dangerous, to warn consumers, consumer organisations, the State Consumer Rights Protection Authority and the product safety control bodies of the relevant field about this, to specify what actions consumers should take if they had purchased a dangerous product, to withdraw those goods from the market and to recall them when necessary and on specified occasions to destroy the product and to ensure that it would not be exported. The producer is obliged to do so within 3 calendar days of becoming aware of this circumstance.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

The law on Product Safety does not provide any specific definition of safety concerning the area of new technologies.

However, Art 4(4) of the Law indicates that whenever the conformity of a product to the general safety requirements is assessed, a particular regard should be given, *inter alia*, to the state of the art and technology. The Law on Consumer Protection specifically covers emerging threats related to new technologies, such as cyber security or software-related threats (see the next section).

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Under Art 13(1), the State Consumer Rights Protection Authority has the power to restrict access to websites selling unsafe products. This is further expanded upon in the Art. 49/1 (prim) of the Republic of Lithuania Law on Consumer Protection (10-11-1994, No 94-1833, as last amended on 01-09-2019), where it is stated that the State Consumer Rights Protection Authority has the right to give binding instructions to internet service providers to disable access to information by blocking an Internet domain name.

The State Consumer Rights Protection Authority indicated that such actions are taken if the threats include:[315]

1. Poor cyber security of consumer products that may expose a network to potential attacks;
2. Malfunctioning of software (embedded or non-embedded in a product) that can affect safety of consumers; and
3. Products with AI/machine learning capabilities that affect the safety of consumers.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Under Art 4(4) of the Law on Product Safety, the conformity of a product to the general safety requirements is assessed with regard, in particular, to voluntary national standards other than those specified in the EU Official Journal, to other national standards, to recommendations of the European Commission laying down the guidelines for product safety assessment, to codes of good practice in the sector concerned, to the state of the art and technology and to the safety which consumers may reasonably expect.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Lithuania in case there are consumer product(s) on the market which are found unsafe under the GPSD

These include: (i) fining (Art 19 of the Law on Product Safety); (ii) issuing a warning (Art 19 of the Law on Product Safety); (iii) issuing community service (Art 23 of the Code of Administrative Offenses of the Republic of Lithuania, 25-06-2015, No. XII-1869, as amended on 01-11-2019).

Under Art 13 of the Law on Product Safety, market surveillance authorities may also (i) require businesses to provide relevant information on the product(s), their distribution, ownership of websites where such products are sold; (ii) carry out unannounced inspections; (iii) acquire product samples; (iv) block websites; (v) require the recalls of products and request businesses to pay the costs of administrative activities with respect to the unsafe products.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Art 19 of the Law on Product Safety states that:

A fine of between EUR 150 and EUR 2 500 is imposed on the manufacturer, importer, authorised representative or distributor, which places dangerous products on the market (or to the service provider which has or is providing dangerous services to the market).

[315] The Consumer Rights Protection Authority has not yet applied these measures in specific cases.

A fine of between EUR 2 500 and EUR 6 500 is imposed on the manufacturer, importer, authorised representative or distributor, which places dangerous products on the market (or to the service provider which has or is providing dangerous services to the market) if the State Consumer Rights Protection Authority or another market surveillance authority decides to prohibit the provision of dangerous products or the provision of dangerous services to the market.

A fine between EUR 2 500 and EUR 15 000 is imposed on economic operators which place or have placed dangerous products on the market, if the products have harmed the health of the consumer.

A fine between EUR 6 500 and EUR 25 000 is imposed on economic operators which place or have placed dangerous products on the market, if they have led to the death of a consumer.

Recent case law in Lithuania with respect to or relevant for the GPSD/the national implementation legislation.

The following rules have been set out by the Lithuanian courts when expanding upon the regulation of product safety:

- The requirement to provide relevant instructions on the use of the product should only be considered fulfilled when the buyer of the product receives the instructions in a fashion they can understand, for example the instructions should be in the national language (judgment of the Vilnius Regional Court, civil case No. e2A-302-262/2019).
- In determining the risk of a dangerous product, market surveillance authorities need only to examine the given instructions. It is presumed that the composition of a product matches that which is indicated in the instructions given with the product. The duty of rebutting the presumption lies with the plaintiff (judgment of the Supreme Administrative Court of Lithuania, case No. A492-14/2012).
- Consequences of placing a dangerous product on the market do not need to be determined for the application of liability. It is enough to determine that a dangerous product was placed on the market or that the subject did not act in accordance with the orders of the market surveillance authorities. In the case that appropriate consequences are also identified (damage to the health of the consumer, death of the consumer), it entails a more severe sanction (judgment of the Supreme Administrative Court of Lithuania, case No. A^{146}-778/2010).
- In the event of an accident (in the specific case – the plaintiff failed to notice the glass table, stumbled upon it and collapsed, severely injuring her right arm), civil liability arises not only from the provision of an improper service but also from the general duty to act with due care and attention (Article 2.246 (1) of the Civil Code) (judgment of the Lithuanian Court of Appeal, civil case No. 2A-198/2007).
- The concept of a safe product should be understood differently when regarding the regulation set out in the Law of the Product Safety and the Civil Code. The Court has emphasised that the concept provided in the Law on Product Safety does not in itself include the aspect of the possible threat of damaging the property of a consumer (19-11-2010 Supreme Court of Lithuania case review).

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Lithuania concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

There are no emerging safety or traceability issues or other practical problems. No relevant problems can be identified from the scientific (legal literature) level.

Possible improvements to make the implementation of the GPSD in Lithuania more effective

Lithuanian market surveillance authorities expressed a need to be able to run safety tests on products where safety infringements are visible or can be detected using minimal set of tools.

Under the current legislation, market surveillance authorities may only perform tests when they are scheduled according to the programmes prepared by category of product. Tests may also take place *ad hoc* upon receipt of individual complaints by consumers (tests cannot be initiated independently).

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Lithuania.

Market surveillance is organised by the State Consumer Rights Protection Authority. It is a single authority with general competence and national jurisdiction. All non-food related products (cosmetics, toys, personal protective equipment, appliances burning gaseous fuels, electrical appliances and equipment under LVD, etc.) fall under its jurisdiction.

There are a few exceptions to this, as markets of the following products fall under the jurisdiction of other institutions:

- Pyrotechnics (Police Department under the Ministry of the Interior)
- Explosives for civil uses (Weaponry Fund of Lithuania)
- Measuring instruments, non-automatic weighing instruments and pre-packaged products (Lithuanian Metrology Inspectorate)
- Electrical equipment under EMC, radio equipment under RED (Communications Regulation Authority)
- Electrical and electronic equipment under RoHS and WEEE and batteries, chemical substances under REACH and Classification and Labelling Regulations, other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.) (Environmental Protection Agency);
- Recreational crafts, marine equipment, motor vehicles, non-road mobile machinery (Lithuanian transport safety administration).

Plans/programmes in place which define priorities for market surveillance of consumer products

Nationally there is the State consumer development programme 2019-2027 (10-07-2019, No. 728).

The State Consumer Rights Protection Authority also makes early plans for consumer protection (such as the 2019 Operational plan of the State Consumer Rights Protection Authority (05-03-2019, No. 1R-99).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Lithuania with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

The State Consumer Rights Protection Authority analyses the market with respect to the emergence of new technologies and examines consumer complaints related to it. The Authority analyses other information sources, such as mass media, RAPEX and ICSMS.

Also, as mentioned before, the State Consumer Rights Protection Authority has the power to restrict access to websites selling unsafe products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance for products sold online from sellers established in Lithuania is conducted more than once a week, while market surveillance for products from sellers established outside of Lithuania is conducted once a month.

Regarding mystery shopping, surveillance of Lithuanian sellers is done once every three months, while sellers in other EU/EEA countries are surveilled once every six months (no surveillance is done outside the EU/EEA). However, it should be noted that the State Consumer Rights Protection Authority was authorised to conduct mystery shopping only from September 2019, and so the given data may change.

Online sales channels include retailer websites, online marketplaces and social networks (mystery shopping is conducted in the retailer websites and in online marketplaces).

Almost a third of all the market surveillance done by the State Consumer Rights Protection Authority is conducted for products sold online. These are done periodically or when a complaint is filed with the Authority.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Lithuania (except customs) with respect to product safety

The State Consumer Rights Protection Authority uses a common national market surveillance IT system with other authorities, as well as RAPEX and ICSMS. The Authority also concludes formal agreements with other authorities, includes them in preparing national market surveillance plans, has joint processes for dealing with dangerous products and joint training sessions. It also regularly exchanges information with other authorities.

Cooperation with customs authorities in Lithuania with respect to product safety

The State Consumer Rights Protection Authority uses a common national market surveillance IT system (also RAPEX and ICSMS), concludes formal agreements and includes customs in preparing national market surveillance plans. It also has joint processes for dealing with dangerous products, joint training sessions, a common strategy for product safety enforcement, joint priorities in the market surveillance and joint risk assessment. It also regularly exchanges information and has regular meetings with customs.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The State Consumer Rights Protection Authority cooperates with other authorities in the EU/EEA through RAPEX, ICSMS and the Wiki confluence platform. The Authority also makes and receives mutual assistance requests outside of RAPEX and has regular meetings with other authorities. Actions on the safety of products organised at the EU level are generally coordinated among all the authorities.

Meanwhile, the authorities located outside EU/EEA countries cooperate only through assistance requests, formal cooperation agreements on consumer rights, product safety and market surveillance activities, and through joint training sessions.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The State Consumer Rights Protection Authority acts according to the EU RAPEX Guidelines. It usually notifies RAPEX about a dangerous product two weeks after detection.

When the State Consumer Rights Protection Authority is notified about products with non-safety risks (i.e. compliance issues), it usually informs other responsible authorities to take actions where needed.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Cooperation is done through partnership agreements, regular exchange of information, regular (formal and informal) meetings and requests for advice when needed. Consumer organisations are also included in the process of preparing the national market surveillance plan.

The State Consumer Rights Protection Authority cooperates with consumer organisations once a week on average, while business associations are reached out to only once a month.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The State Consumer Rights Protection Authority makes press releases, updates the website containing information on dangerous products[316], translates RAPEX notifications and provides links to them on their website. The Authority also does information campaigns on social media and/or through the press.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Lithuania (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Under Art 7-11 of the Law on Product Safety, the business operator of the products must inform consumers, consumer organisations, the State Consumer Rights Protection Authority and other relevant market surveillance

[316] http://www.vvtat.lt/pavojingi-produktai/481

authorities of the dangerous nature of the product within three calendar days (within a day when they are a distributor) of becoming aware of the nature of the product. They must also inform consumers of the actions that should be taken by those who have purchased a dangerous product, withdraw it from the market and, where necessary, recover it, and, where appropriate, even destroy the product and take measures to ensure that it is not exported.

In the cases mentioned above, the business operator is required to provide the State Consumer Rights Protection Authority with (i) information from the activities targeted at consumers and/or other businesses involved in the supply chain; (ii) a list of other businesses involved in the supply chain; (iii) a timeline of the recall process; and (iv) information on recall effectiveness and on the destruction/disposal of products collected (as indicated in the rules for the notification of dangerous products and services by manufacturers, distributors and service providers (25-11-2009, No. 143-6325)).

If no responsible business operator can be found, surveillance authorities might recall the product themselves. The market surveillance authorities also have input on the content of the messaging by the business operator related to product safety. Once a recall strategy is concluded, the authorities can check the compliance of the subjects involved and alter the strategy if needed.

Monitoring of effectiveness of product recalls by market surveillance authorities

The State Consumer Rights Protection Authority monitors all product recalls (including voluntary recalls) and collects information on recall results in terms of the absolute number of products collected. It also collects information on consumer awareness with respect to the recall and may perform spot checks in shops (regarding withdrawal of product) (as specified in Art 13 of the Law on Product Safety).

6. Availability of statistics relevant for market surveillance

Availability of statistics in Lithuania that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Market surveillance authorities conduct interviews with consumers and collect data regarding customer complaints. The State Consumer Rights Protection Authority also collects statistics on dangerous products and dangerous products intercepted by customs at the borders.

According to publicly available information, last year, the State Consumer Rights Protection Authority conducted 7 861 product and service inspections on the Lithuanian market, including consumer complaints, of which 2 282 did not meet safety and quality requirements. In 2017, the service carried out 7 366 inspections of various product groups and 1 697 inspections (23%) revealed irregularities.

However, the State Consumer Rights Protection Authority does not collect systematic data on injuries related to safety products.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Lithuania (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Market surveillance authorities indicate that the following issues have an effect on market surveillance:

- Limited staff resources and lack of financing for laboratory tests;
- Lack of expertise in new technologies;
- Lack of expertise in online market surveillance;
- Lack of financial resources for testing of consumer products;
- Lack of suitable product testing laboratories;
- Problems in taking effective action when the responsible economic operator is in another EU/EEA country;
- Problem in taking effective action when the responsible economic operator is outside the EU/EEA;
- Problems controlling products from non-EU/EEA-countries that reach consumers directly.

The authorities also indicated that while using RAPEX, they encounter a lack of sufficient information to trace notified products.

There is also a problem in advocating awareness of the business operators with respect to voluntary recalls of unsafe products, as the number of mandatory recalls outweighs these 10 to 1.

Areas to make market surveillance of consumer products in Lithuania/the EU more effective

The State Consumer Rights Protection Authority suggests establishing a national business information system that would relay all the needed information on product safety.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Lithuania since 2013

No information was available.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Lithuania whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

The market surveillance authorities do not feel that they have the tools needed to address the new challenges mentioned above. No changes to the current situation are currently planned.

Views of market surveillance authorities whether approaches in Lithuania can be considered best practice implementation of the GPSD, which could be of interest to other countries

No information was provided.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*10*	*5*	*15*
Responsible authorities at the sub-national level (regional/provincial/local)	*20*	*5*	*25*
Total (country)	***30***	***10***	***40***
Of which staff allocated to market surveillance activities regarding products sold online	*2*	*1*	*3*
Notes:	*The same staff might be working in different areas and so the statistics might overlap (2019 data)*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**1700**	**800**	**2500**
Total number of consumer products inspected	1500	500	2000
Total number of consumer products tested in laboratories	700	0	700
Total number of consumer products inspected in cooperation with the customs	500	0	500
Total number of dangerous consumer products found	59	0	59
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	16	0	16
Notes:	*2019 data*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	5	0	5
Total number of mandatory recalls	59	0	59
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	80%	0%	80%
Notes:	*2019 data*		

D. Key sources	
Legislation	The Law on Product Safety of the Republic of Lithuania (*register of legal acts, 01-06-1999 No VIII-1206, as last amended on 15-11-2018*) Terms of Reference for the Use of the Consumer Rights Information System (*register of legal acts, 15-06-2016, No. 17241, as last amended on 30-01-2019. Issued by the Government of Lithuania*); Regulations of the State Consumer Rights Protection Agency (*register of legal acts, 23-12-2015, No. 20360, as last amended on 30-01-2019. Issued by the Government of Lithuania*) Rules for the Notification of Dangerous Products and Services by Manufacturers, Distributors and Service Providers (*register of legal acts, 25-11-2009, No. 143-6325. Issued by the director of the State Consumer Rights Protection Agency*) Procedures for Hearing Infringement Cases under the Law on Product Safety (*register of legal acts, 13-05-2019, No. 7636. Issued by the director of the State Consumer Rights Protection Agency*) State consumer development program 2019-2027 (*register of legal acts, 10-07-2019, No. 728. Issued by the Government of Lithuania*). 2019 Operational plan of the State Consumer Rights Protection Authority (*register of legal acts, 05-03-2019, No. 1R-99. Issued by the minister of Justice*). Order of the Minister of Economy of Lithuania on the rules of labelling and price indication of items (goods) sold in the Republic of Lithuania (15-05-2002 No 50-1927, as last amended on 31-01-2017)
Studies/reports/articles	There is no relevant literature.
Websites	*http://www.vvtat.lt/pavojingi-produktai*
Interviews	The State Consumer Rights Protection Authority

18. Luxembourg

COUNTRY REPORT LUXEMBOURG

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The General Product Safety Directive (GPSD) was implemented in the national legislation of Luxembourg by the law of July 31st, 2006 concerning general product safety (hereafter: 'implementation law of 2006').[317]

Additionally, the law of May 20th, 2008[318] established a new market surveillance authority in Luxembourg, competent for the enforcement of the implementation law of 2006 (hereafter: 'ILNAS').[319] This surveillance law of 2008 only remained in force until July 27th, 2014, as it was repealed by the law of July 4th, 2014 (hereafter: 'surveillance law of 2014'),[320] which reorganised ILNAS. According to this new law, ILNAS houses a Market Surveillance Department responsible for the supervision and enforcement of the product safety requirements pertaining to non-harmonised 'GPSD' products and most harmonised products. The surveillance law of 2014 thus implements the market supervision and enforcement requirements from the EU legislation in the field of product safety, including those of the GPSD.[321]

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Luxembourg

The traceability requirements are implemented in Article 4(1) of the implementation law of 2006, which repeats the requirements of Article 5(1) GPSD. This provision therefore contains the general requirement to indicate the name and contact details of the producer on the packaging of the product as well as the general requirement to indicate product reference or, where applicable, the batch of products to which it belongs, on the product or its packaging. These general provisions can be specified by more specific rules ('*règlement grand-ducal*'), but to date this power has not yet been exercised. The traceability measures mentioned in Article 5(1), fourth paragraph GPSD are formulated as examples, while in the Luxembourg implementation legislation, these traceability measures are formulated as mandatory.

Article 4(2) of the implementation law of 2006 also implemented Article 5(2) GPSD by simply repeating the phrasing of the directive.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

The implementation law of 2006 does not contain a specific definition of safety (nor 'safe product'). See Article 3 of the implementation law of 2006 in this respect, which simply replicates the definition of a safe product from the GPSD.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The national implementation law of 2006 does not specifically cover emerging threats related to new technologies, such as cyber security or software-related threats. It confines itself to replicating the definitions of the GPSD, as the Market Surveillance Department of ILNAS pointed out. The department further stated that it is unclear whether any of these threats fall within the scope of the definition of a 'safe product'.

[317] '*Loi du 31 juillet 2006 relative à la sécurité générale des produits*'; see http://legilux.public.lu/eli/etat/leg/loi/2006/07/31/n3/jo
[318] See http://legilux.public.lu/eli/etat/leg/loi/2008/05/20/n1/jo
[319] '*l'Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits*'.
[320] See http://legilux.public.lu/eli/etat/leg/loi/2014/07/04/n2/jo
[321] Other market surveillance requirements imposed at the EU level can for example be found in Regulation 765/2008, *Official Journal L 218, 13/8/2008*, P. 30 – 47.

However, it is also possible that the very broad safety concept of Article 2 (b) GPSD can be interpreted with a certain flexibility so that it covers some of the emerging threats related to new technologies, such as connected devices.[322] Following this interpretation of the GPSD, the Luxembourg national implementation legislation would then also apply to these threats, as the safety definition is an almost identical implementation of the GPSD. However, even in that case, the problem remains that the GPSD of 2002 does not explicitly address the new technologies and their specific characteristics.[323] This lacuna creates uncertainties in the national context.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Article 3(3) of the implementation law of 2006 copies the content of Article 3(3) GPSD. The following benchmarks are used according to the Market Surveillance Department of ILNAS:

- Other European standards (not referenced in the EU Official Journal)
- National standards
- International standards and/or standards from non-EU/EEA countries
- Commission recommendations setting guidelines on product safety assessment
- Codes of good practice applied by the sector concerned
- State of the art and technology
- Reasonable consumer expectations concerning safety

Additionally, the Market Surveillance Department of ILNAS reports that in some cases the principle of precaution was applied to assess the safety of a product (see Article 8(2) GPSD and Article 191 TFEU).[324] In application of this principle, the burden of proof shifts to the economic operator to demonstrate that a certain product can be considered 'safe' and that there is an absence of danger.

The Luxembourg surveillance law of 2014 contains a provision that allows the surveillance authority to take provisional measures during this procedure. Article 13(2), 2° states that in the event of precise and converging indications that a product exhibits a non-conformity, the surveillance authority may temporarily prohibit the supply, offering of supply or exhibition of this product or the batch of this product. A similar temporary measure is also included in Article 6 of the implementation law of 2006.

The principle of precaution was applied by ILNAS in a case where a baby mattress exhibited a bad smell. According to ILNAS this corresponded to 'precise and converging indications that a product exhibits a non-conformity'. It therefore decided to temporary withdraw this product from the market until the producer brought forth proof that this smell was not related to a safety risk for young children. The example also shows that ILNAS acted in line with Article 2(b)(iv) GPSD by taking into account the vulnerability of infants.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Luxembourg in case there are consumer product(s) on the market which are found unsafe under the GPSD

According to the Market Surveillance Department of ILNAS, the following measures are at the disposal of the market surveillance authorities:

- Require businesses to provide relevant information on the product(s)
- Require businesses to provide relevant information on the supply chain and the distribution of the product(s)
- Require businesses to provide relevant information to ascertain the ownership of websites, where relevant
- Carry out unannounced on-site inspections and physical checks of shops
- Require product recalls from economic operators and other corrective measures
- Reclaim from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s)

[322] European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, P. 10. Article 2(b)(ii) GPSD states that the safety assessment of a product will take into account 'the effect on other products, where it is reasonably foreseeable that it will be used with other products'. It follows that software problems of connected devices can be interpreted as a safety issue.
[323] See on existing gaps in safety regulations, European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, P. 16.
[324] See more extensively: European Commission (2000), Communication from the Commission on the precautionary principle.

The legislation provides more details concerning the available administrative measures. Article 5 of the implementation law of 2006 states that the competent market surveillance authorities have the possibility to check the characteristics of a product relevant to its safety, request all the necessary product information from the relevant parties involved, take product samples with the purpose of submitting them for safety analysis, and to interrogate all parties involved and other persons capable of furnishing useful information.

Furthermore, at the request of the competent minister, the competent authority (i.e. ILNAS) can apply the following decisions of the minister (see Article 6):

- Order that persons likely to be exposed to the risk arising from a product be informed of this risk in good time and in an appropriate form, including by the publication of special warnings;
- Temporarily prohibit the economic operator, for any product likely to be dangerous, for the period necessary for the various checks, verifications and safety assessments, from supplying it, offering to supply it or exhibiting it;
- Prohibit the placing on the market of a product or a batch of products which has been shown to be dangerous;
- Order or organise the withdrawal of a dangerous product already on the market and warn consumers of the risks it presents;
- Order or coordinate or, where appropriate, organise with producers and distributors the recall of a product from consumers and its destruction under appropriate conditions.

The reclaiming of costs from the relevant economic operator can only take place when the administrative activities reveal that the economic operator infringed the product safety obligations specified in the implementation law of 2006.

Article 13 of the surveillance law of 2014 contains similar competences which are characterised as administrative competences. This law of 2014 also applies to the harmonised products, whereas the competences listed above in the implementation law of 2006 only applied to GPSD products. Moreover, the competences of the surveillance law of 2014 are granted not only to ILNAS, but also to the customs authority. Both authorities can:

- Require the publication of warnings concerning dangerous products;
- Temporarily prohibit the economic operator, during the period necessary for the various controls, from supplying, offering to supply or exhibiting a product or a batch of products when there are precise and converging indications concerning their non-compliance;
- Prohibit or restrict the making available on the market of a product or a batch of products which does not comply with the legal provisions referred to in paragraph 1 and take the accompanying measures required to ensure compliance with this prohibition;
- Order, coordinate or, where appropriate, organise with economic operators, the recall, withdrawal or modification of a product presenting a serious risk, including a serious risk whose effects are not immediate, from the market or with consumers and its destruction under the appropriate conditions;
- Prohibit the display of a product for sale in a manner which induces or risks misleading its actual characteristics.

These measures are targeted at the producer, importer, distributor or other particular persons of interest. An appeal is possible against these measures within a three-month period starting from the date of reception of the notification of the decision.

The GPSD does not contain any express requirement for Member States concerning temporary measures in national legislation. Yet, the above shows that the Luxembourg legislator provides temporary trading restrictions which, for example, by application of the principle of precaution as mentioned above, may adequately respond to safety risks.

According to Articles 14 and 15 of the surveillance law of 2014, certain qualified civil servants of ILNAS and the ranking officers of the customs authority, and in the context of these two legal provisions also police officers, have the following investigative competences for the purpose of determining an infringement of the provisions of the product safety legislation and regulations, including the GPSD implementation law of 2006. In short, they may check and verify the legal and regulatory conformity of any product, even after it has been made available on the market, request all documents and any information they deem necessary, apply the temporary prohibition mentioned in Article 13 of the surveillance law by their own motion, and apply the other administrative measures mentioned in Article 13 by request of the competent market surveillance authority. Furthermore, they may search locations, sites and means of transport to find evidence of an infringement and, in accordance with additional

procedural conditions and safeguards, they may also access inhabited premises. Furthermore, Article 15 provides the competence to carry out tests on apparatus or devices, request the communication of books, registers and files relating to a product, take samples of a certain product or seize products.

Police officers and also the civil servants and officers mentioned in the above paragraph are not required to disclose their official identity when performing verifications and checks in publicly accessible premises, during which they may search for non-compliant products, check the markings on products or their packaging, without unpacking them, or check other easily visible compliance criteria without alteration, destruction or dismantling of the product. In the event of an irregularity which may constitute an infringement, the officers or civil servants draft a report.

When these administrative controls are exercised by the qualified civil servants of ILNAS or the ranking officers of the customs authority, they may appeal for the assistance of police officers when they encounter difficulties, such as resistance by an economic operator. In the event that an infringement is discovered, the producer, importer or retailer can be charged with refunding the surveillance costs.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

A distinction must be drawn between sanctions of an administrative nature, imposed by the administrative authorities, and criminal sanctions, imposed after completion of a criminal procedure before a criminal court. It is submitted that the sanctions provided in the implementation law of 2006 can only be applied to violations related to GPSD products, whereas the sanctions provided in the surveillance law of 2014 also apply to the harmonised products mentioned in Article 8 of this law of 2014.

The implementation law of 2006 contains two criminal sanctions in Articles 8 and 9. In the event that producers place a product on the market of which they knew or should have known that this product was not safe, they risk a fine ranging from 251 to 25 000 Euros. The same fine can be applied when producers or distributors violate the information obligations related to traceability of Article 4 as well as the decisions from the competent minister taken on the basis of Article 6, such as the obligation to warn consumers or organise a product recall. Disregarding these ministerial decisions mentioned in Article 6 is also sanctioned by imprisonment of the producers or distributors ranging from 8 days up to one year if they fail to comply with these decisions.

Article 17 of the surveillance law of 2014 contains sanctions of an administrative nature. The competent authorities may impose administrative fines ranging from 250 to 10 000 Euros when they establish infringements on the marking and labelling requirements or when there is an absence of a declaration of conformity. When an economic operator refuses to provide documentation and information requested by competent authorities or their staff, or obstructs the exercise of market surveillance, administrative fines may be imposed ranging from 250 to 15 000 Euros. An administrative appeal is possible within three months upon receiving the notification of the decision.

Article 19 of the surveillance law of 2014 provides for criminal sanctions for anyone who has placed a product on the market violating conformity requirements, such as a fine ranging from 250 to 500 000 Euros or an imprisonment sentence between 8 days and three years. Violation of the enforcement decisions specified in Article 13 are sanctioned by the same sentences, but the fine can in this case amount to up to 1 000 000 Euros. Furthermore, the courts may order the confiscation and destruction of the property used for the offense as well as order the confiscation of the unlawful profits.

Criminal sanctions require prosecution by the public prosecutor before a criminal court. However, as is often the case in criminal sanctioning of economic law provisions, the lengthy procedures and existing procedural burden of criminal prosecution causes such cases often to be dismissed in practice.[325] It therefore seems unlikely that these

[325] An OECD study of 2006 stated that 'reliance on the criminal or civil justice processes for the imposition of penalties may result in insufficient deterrence for traders. This is a consequence of the fact that, the costs of these processes typically being high, not many cases reach this stage (own emphasis)'. Furthermore, it was observed that 'the criminal law may not always be an appropriate mechanism to respond to breaches of consumer protection law. This might be because resources within the criminal prosecution service become too stretched, with consumer protection being accorded insufficient priority. Or it might be because officers within the criminal prosecution service tend to adopt a perspective on the goals of consumer protection enforcement different from those of the enforcement agency, and this is considered inappropriate except for the minority who constitute "rogue traders" (own emphasis)'. See OECD (2006), Report on the Effectiveness of the Enforcement Regime, P. 6 and P. 53 respectively. These conclusions of the 2006 OECD report were later voiced in the comparative implementation study of the Consumer Protection and Cooperation Regulation study as a concern for Member States relying too strongly on either criminal or civil procedures for consumer law

sanctions are applied in practice, which is supported by the absence of published case law in Luxembourg of cases relating to product safety before a criminal court.

Recent case law in Luxembourg with respect to or relevant for the GPSD/the national implementation legislation.

There is no published case law relating to the GPSD, the implementation law of 2006 or the surveillance law of 2014 included in the national database of jurisprudence, nor does ILNAS report to have knowledge about any published case law.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Luxembourg concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

With regard to traceability, the Market Surveillance Department of ILNAS reports that in one particular case, the lack of cooperation from an economic operator located in a different Member State raised some problems relating to the enforcement of the traceability requirements. ILNAS was dependent upon the informal assistance of the market surveillance authority in the Member State where the economic operator concerned was established.

According to ILNAS, the definition of safety is problematic since it does not explicitly cover cybersecurity risks. Furthermore, ILNAS considers the open character of the definition to be lacking in clarity, making it difficult to assess whether or not a particular product or risk falls under the GPSD; connected devices are a common example.

Lastly, ILNAS indicates that products targeted at children (childcare articles, jewellery for children and toys) and electrical appliances and equipment under the Low Voltage Directive can be considered emerging safety risks.

Possible improvements to make the implementation of the GPSD in Luxembourg more effective

The Luxembourg surveillance authority considers that new provisions specifically tailored to emerging issues related to new technologies such as artificial intelligence (AI) and Internet of Things (IoT) and to cybersecurity must be introduced. The list of products that fall under the GPSD should also be updated in that respect.

Cases with cross-border elements, which are likely to increase in the future as the EU market continues to integrate,[326] indicate that additional formal cooperation procedures between national authorities may prove useful. This would especially contribute to enforcement in smaller Member States where producers or distributors are often located in neighbouring Member States and the Member State authority has to rely on the foreign market surveillance authority to, for instance, enforce traceability requirements.

Lastly, academic literature and other scientific research additionally point to some areas where some room for improvement of the current legislative framework might exist. As regards the scope of application of the GPSD, it has been argued that this should be aligned with the Product Liability Directive.[327] For instance, the GPSD and the implementation law of 2006 exclude some second-hand products from the safety concept and do not explicitly exclude immovable goods from the scope of application due to the definition of a product. The exclusion of second-hand products from the GPSD should be removed and the Product Liability Directive should also include immovable products, which improves legal certainty and avoids the case where some products are regarded to be safe under one set of safety regulation but unsafe under the other.

Moreover, products which do not fulfil the requirements of a safe product under the GPSD are defined as a 'dangerous product'. To avoid confusion with products that are dangerous by nature (e.g. knifes), this aspect of the safety concept should be amended by defining these products as 'unsafe'.[328]

II. Functioning of market surveillance of consumer products

enforcement, see European Commission (2014), Study on enforcement authorities' powers in the application of Regulation 2006/2004/EC on Consumer Protection Cooperation, P. 13.

[326] See 'Intra-EU trade in goods – main features'. Retrieved on March 17, 2020, from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Intra-EU_trade_in_goods_-_main_features.

[327] See Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia, P. 89-90. *See* also on this point: Straetmans G. and Verhoeven D. (2016), Other EU laws concerning similar issues (in: Machnikowski, P. (ed), European Product Liability: An analysis of the state of the art in the era of new technologies, Antwerp – Cambridge, Intersentia), P. 97-103.

[328] See European Economic and Social Committee (2013), Opinion on the 'Proposal for a regulation of the European Parliament and of the Council on Consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC', recital 4.4.4.

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Luxembourg.

In Luxembourg, several ministerial departments of the national government are involved in market surveillance of product safety as there are no sub-national authorities assigned with this task. As the National Market Surveillance Programme of 2020 indicates, these authorities are:

- The Environmental Department
- The Department for Agricultural Technical Services
- ILNAS – the Luxembourg Institute of Standardisation, Accreditation, Safety and Quality of Products and Services
- The Ministry of Economic Affairs
- The Ministry of Health – Health Department
- The Ministry of Health – Pharmacy and Medicines Division.

Apart from the customs authority,[329] six government authorities are responsible for product safety. Be that as it may, in practice the Market Surveillance Department within ILNAS is the competent authority for enforcing the GPSD (implemented by the law of 2006) and 30 other European legislative acts regarding product safety.[330] This department thus holds supervisory and enforcement competence in Luxembourg for non-harmonised products and most harmonised products. The national coordination also falls within the remit of this department, which includes informing the European Commission of the National Market Surveillance Programme, acting as the point of contact between the other national authorities and the European Commission, acting as the point of contact for Safety Gate and ICSMS and serving as the national product safety contact point.[331] Viewed in that perspective, the Market Surveillance Department of ILNAS is the central and most important supervisory authority within the field of product safety and the protection of the health and safety of consumers in Luxembourg.

The Market Surveillance Department of ILNAS consists in both a surveillance unit as well as a laboratory unit. While the activities of the surveillance unit are related to the 31 legislative acts as mentioned above, the activities of the laboratories are limited to toys, low voltage tests, electromagnetic compatibility tests and radio equipment tests. These laboratories do not offer services to the private sector.[332] However, ILNAS also cooperates with external laboratories, such as the National Health Laboratory,[333], to check the legal conformity of products.[334] Information between the Market Surveillance Department and the laboratories is exchanged through an electronic database.[335]

Plans/programmes in place which define priorities for market surveillance of consumer products

ILNAS constructs a national market surveillance plan at the beginning of the year containing the surveillance priorities. It bases the priorities for market surveillance of consumer products on many sources of information. These priorities may change if a new trend emerges during the year, for example when a new product appears on the market which poses risks to the health and safety of consumers. There are also sectoral market surveillance plans for certain products or groups of products.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Luxembourg with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

ILNAS confirms that new technologies like the Internet of Things and connected devices are placed under its surveillance, but also admits that this is confronted in this respect with new challenges relating among other to the usage and processing of information and surveillance activities. It follows that supervision is exercised by the national data protection agency (CNPD). ILNAS itself also supervises products sold online through visual inspections.

With respect to online activities, it must be submitted that the definition of a 'safe product' in the GPSD as in the

[329] *l'Administration des Douanes et des Accises*
[330] See Article 8 (4) of the surveillance law of 2014.
[331] *Point de Contact Produit*
[332] ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 12 – 13.
[333] *Laboratoire National de Santé*; ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 17.
[334] ILNAS (2019), Stratégie du département de la surveillance du marché de l'ILNAS, P. 21.
[335] ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 25.

implementation law of 2006 refers to *commercial* activities. As a result, the European Commission stated in its 'Notice on the market surveillance of products sold online' that, in principle, 'C2C products' fall outside the scope of the GPSD.[336] In the same vein, ILNAS does not conduct market surveillance activities on C2C products, stating that legislation would not allow it to do so. It can be submitted that this should not necessarily be the case since the European Commission emphasised in its notice that whether a C2C product is being supplied as part of a commercial activity must be assessed on a case-by-case basis, taking into account all the relevant criteria such as regularity of supplies and the intention of the supplier etc.[337]

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

In terms of organisation, a distinction must be made between market surveillance conducted by ILNAS and by private online marketplaces. As concerns the first type of surveillance, ILNAS reports that it both conducts own surveillance activities online and participates in European campaigns. On average, surveillance activities take place once a month and these are focused on both retailers' websites as well as online marketplaces. ILNAS estimates that 3 to 5% of annual surveillance activities pertain to the online context and, in general, online inspections only represent a small proportion of the total inspections. Regarding commercial activities taking place on the internet, the national procedure seems not well adapted to online market surveillance as there are some legal impediments, such as the absence of a mystery shopping competence. This lacuna will be filled in as the Market Surveillance Department of ILNAS indicates that legislation allowing for mystery shopping in the online context is currently under preparation.

As concerns the second type of surveillance, ILNAS ppoints to its good cooperation with Amazon.eu, one of the signatories of the Product Safety Pledge. Amazon.eu checks the latest notifications on Safety Gate RAPEX on a weekly basis and, in the event that a product has been notified as presenting a high/serious risk, Amazon.eu provides the sales numbers as well as the destination countries to the Market Surveillance Department of ILNAS.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Luxembourg (except customs) with respect to product safety

In general it can be submitted that a smooth cooperation exists between the different market surveillance authorities in Luxembourg. Bilateral contacts between the Market Surveillance Department of ILNAS and the other surveillance authorities take place on at least a weekly basis and national meetings are organised twice a year.

Cooperation between most of the other market surveillance authorities is further enhanced by the common use of a national market surveillance IT system (see the ECSDM explained below), as well as the common use of RAPEX and ICSMS by all the authorities. All authorities contribute to the national surveillance plan and join ILNAS in setting the priorities at the beginning of the year. There are joint processes in place for dealing with dangerous products as well as joint training sessions. Furthermore, cooperation occurs both through formal agreements, such as a cooperation agreement[338] between ILNAS and the Environmental Department,[339] as well as through informal contacts. There is a regular exchange of information as well as regular meetings between these authorities.

Cooperation with customs authorities in Luxembourg with respect to product safety

ILNAS also cooperates intensely and regularly (at least on a weekly basis) with the customs authority for the purpose of the effective control of imported goods from non-EU/EEA-countries that are to be placed on the

[336] See European Commission (2017), Commission notice on the market surveillance of products sold online (2017/C 250/01), P. 4.
[337] In this respect, see the criteria set forth by the Court of Justice of the European Union (CJEU) in case C-105/17, 4 October 2018, *Komisia za zashtita na potrebitelite v Evelina Kamenova*). Although the Court concluded in that case that the activities of a consumer on an online platform did not constitute a commercial activity (within the meaning of the Unfair Commercial Practices Directive), it could in other circumstances be otherwise. There seems no reason to deviate from this fundamental concept of 'commercial activities' in case of the GPSD.
[338] See 'Une collaboration pour la protection de la santé, de la sécurité, de l'environnement et des consommateurs'. Retrieved on March 10, 2020, from: https://www.infogreen.lu/Une-collaboration-pour-la-protection-de-la-sante-de-la-securite-de-l.html.
[339] *l'Administration de l'Environnement*

market. Cooperation activities (meetings, joint training sessions, priority setting, etc.) take place in execution of a formal agreement, which was first signed in 1998 with the latest revision in 2012.[340] Joint inspection initiatives of imported products are also based on a signed convention.

In the daily practice, there is a common use of a national market surveillance IT system called ECSDM, which was briefly mentioned above. This database was introduced in 2013 with the purpose of improving and optimising the information exchange between the Market Surveillance Department of ILNAS and the customs authority.[341] The officers of the customs authority will contact the Market Surveillance Department of ILNAS when they have doubts concerning the legal conformity of a product or the product is not accompanied by the required administrative documents, and when the product does not have the necessary legal markings and labels or the CE marking has been affixed falsely or in a misleading manner. The national customs authority can upload pictures in the ECSDM database, after which the inspectors at ILNAS can quickly make the necessary verifications and give a decision or advice within 3 working days, and are therefore able to act in line with Article 28 of Regulation 765/2008. These decisions or measures taken in the context of product inspections at the border range from an extension of the three-day period to a destruction of the product.[342,343]

As soon as ILNAS becomes aware of information on a dangerous product, acting as the national contact point for the RAPEX Safety Gate and as a member of the Consumer Safety Network, it disseminates all relevant information on the dangerous products to the customs authority, which then in turn is entitled to forward this information to customs authorities in other countries.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

When a safety risk is discovered, ILNAS will first contact the economic operator directly, whether established in the EU or not, in order to inform them of the safety risk and to request measures for its elimination. If the economic operator is established in the EU and ILNAS does not get any reply, the assistance is requested of the competent market surveillance authority of the country where the economic operator is established.

Cooperation with the other authorities in the EU/EEA takes place through the use of RAPEX, ICSMS and the Wiki confluence platform. Cooperation with the authorities in other countries also occurs within the framework of coordinated actions organised at the EU level. Contacts are further based on mutual assistance requests made or received outside of RAPEX and the regular meetings in order to exchange information (e.g. in the Benelux context). Moreover, ILNAS emphasises the importance it attaches to good informal contacts with the staff members of the foreign authorities. In general, those contacts allow for swift assistance or advice through a direct phone call in case an economic operator located in the contacted country does not cooperate with ILNAS. These informal contacts are not only established during the organised European meetings, but also within the framework of the CASP VisitUs Exchanges (formerly known as the exchange of officials).

As a member of the Consumer Safety Network, ILNAS has the opportunity to meet authorities from non-EU/EEA countries in several workshops organised by the European Commission (e.g. during the International Product Safety Week and, more recently, during the EU Workshop on the Efficiency of Product Recalls). Recently, in the context of the CETA Treaty, an Administrative Arrangement was concluded between the EU and Canada for the reciprocal use of their rapid alert systems.[344] As a market surveillance authority of the EU, ILNAS reports that it has access to the information in the reporting system of Canada ('RADAR'), which further enables it to check whether products available on the Luxembourg national market might present a risk to the health and safety of consumers.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The Market Surveillance Department of ILNAS also houses the RAPEX contact point. The bundling of surveillance of most of the harmonised products and the non-harmonised 'GPSD' products in this department safeguards the timely and proper notification through RAPEX. As regards other types of products (e.g. cosmetics, medical devices

[340] ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 17.
[341] See ILNAS (2019), Rapport d'activité 2018, P. 30.
[342] As mentioned in Article 19 of Regulation 765/2008.
[343] ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 26 – 27.
[344] See 'Administrative Agreement (AA) on the exchange of information on the safety of non-food consumer products'. Retrieved on March 10, 2020, from: https://ec.europa.eu/info/sites/info/files/aa_final_en-eu_version.pdf.

or biocides) for which the department itself is not competent, the information is transferred as soon as possible to the competent national authority abroad through the appropriate procedure.[345]

After dispatching the notification, the national RAPEX contact point makes the follow-up and sends a friendly reminder in case the notification cannot be validated rapidly. Validation means that the RAPEX contact point checks and ensures that the notification contains correctly filled-in entry fields and adequately clear pictures. If needed, the RAPEX contact point also provides assistance within GRAS RAPEX.

ILNAS reports an average duration between detection of a safety risk and notification through RAPEX of more than two weeks. According to ILNAS, Article 21 of Regulation 765/2008 lengthens the notification period as ILNAS must grant 10 working days to the economic operator for their observations in response to the information about the non-compliant product (this period may even extend beyond two weeks if the economic operator requests counter-expertise). Even though provisional measures can be adopted to guarantee the safety of consumers in the form of e.g. a temporary sales ban, the regulation nevertheless creates an obligatory administrative burden for surveillance authorities.

When ILNAS discovers that a product poses a non-safety risk (e.g. environmental or security), then the relevant market surveillance authorities and other responsible authorities are informed and will take the necessary actions.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

ILNAS cooperates closely with businesses and business associations. This cooperation takes place through the regular exchange of information and regular meetings with business organisations. Cooperative measures entail creating awareness for product safety among businesses and providing guidance. It also allows businesses to inform ILNAS about market trends and, for certain products, to give additional input for the drafting of the national surveillance plan. ILNAS serves as the national Product Contact Point and provides in that capacity adequate responses to businesses and business associations in response to their requests within an average timespan of 15 working days (see Article 10 of Regulation 764/2008).[346] Furthermore, ILNAS informs economic operators about dangerous products on the market by periodically transferring the weekly RAPEX notification list to them and, vice versa, as soon as these economic operators detect a notified product in their sales channels, they are supposed to inform the Market Surveillance Department of ILNAS.[347]

ILNAS informs consumer organisations once a week by forwarding the Safety Gate Report to the national consumer organisation ULC.[348] Furthermore, all public warnings on dangerous products issued by the Market Surveillance Department of ILNAS are forwarded also to the ULC for publication.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The Market Surveillance Department of ILNAS issues press releases and organises information campaigns in traditional media to raise the awareness of consumers and businesses. For example, in 2019, ILNAS staff members published extensive press articles[349] in the national newspaper and gave radio interviews with the specific purpose of raising awareness about product safety and the activities of the Market Surveillance Department of ILNAS.

Furthermore, ILNAS has an online portal[350] which contains several publicity and awareness measures, such as the possibility to subscribe to a newsletter or to consult recent reports. The portal serves as the national information website on dangerous products and product safety information and also contains RAPEX notifications (with a

[345] See European Commission (2010), Commission Decision laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive).
[346] See ILNAS (2019), Rapport d'activité 2018, P. 39.
[347] ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS, P. 18.
[348] *Union Luxembourgeoise des Consommateurs*
[349] See e.g. 'Die EU hat die Verbraucherrechte gerade im Bereich Spielzeug in den letzten Jahren verschärft – enge Zusammenarbeit der Länder'. Retrieved on February 20, 2020, from: https://www.journal.lu/article/enorme-entwicklung/
[350] https://portail-qualite.public.lu/fr.html. in an evaluation performed within the European project BRIDGE-Health (November 2016). Retrieved on, March 23, 2020, from: https://www.lih.lu/blog/our-news-1/post/luxembourgs-injury-surveillance-system-rated-excellent-and-sustainable-102#blog_content

weblink to the EU RAPEX website) translated in the national languages. Lastly, in an effort to raise awareness about the product safety legislation businesses have to comply with, a small proportion of the checks on location are performed with the exclusive intent of educating businesses.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Luxembourg (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and other corrective measures are organised in Luxembourg on a voluntary or mandatory basis. In both cases, the economic operator remains responsible for the organisation, but only after mutual agreement has been reached between the businesses concerned and the Market Surveillance Department of ILNAS about, for example, the exact recall information and the information channels through which consumers will be informed. As concerns the latter, the economic operator will normally have to put up a recall poster when organising a product recall or, if they have the contact details of the consumers (e.g. customer database), will have to contact them directly.

In order to successfully supervise, organise and realise such a product recall process, the Market Surveillance Department of ILNAS requires the concerned businesses to provide it with the list of all businesses involved in the supply chain, a timeline for the recall process, and information about the destruction or withdrawal of the collected products if that would be imposed. In the near future, the Market Surveillance Department will draft and publish a guideline document for economic operators so that the processes of product recalls and corrective measures may be further facilitated (see the optional implementation of Article 5 GPSD).

The Market Surveillance Department of ILNAS also takes on a communication role in the case of product recalls and engages traditional media channels in the process to inform consumers as well as in the organisation and supervision of recalls for almost all non-food consumer products.

Only if no responsible economic operator (producer, importer, distributor or seller) can be found, it will be incumbent on the competent authorities themselves to organise the recall. In cases where businesses refuse to cooperate, the Market Surveillance Department of ILNAS will also make its own recall poster and send it to the relevant retailers for publishing.

Monitoring of effectiveness of product recalls by market surveillance authorities

All the recalls, including those of a voluntary nature, are monitored by the Market Surveillance Department of ILNAS. The department organises spot checks in shops to see whether recalled products are still available and to verify whether the recall information is published in a clear, visible manner. It is also in contact with the retailers to verify whether they returned the products to the responsible business(es).

The economic operator organising the recall is not asked to provide feedback or results on the recall effectiveness. Only for some specific products are recall results collected in terms of the absolute number of products gathered during the process. Recall results in terms of percentages are not available. However, ILNAS referred to the planned guideline document mentioned above, which intends to include additional instructions for economic operators as to support monitoring recall effectiveness (e.g. detailed feedback and return results).

6. Availability of statistics relevant for market surveillance

Availability of statistics in Luxembourg that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

ILNAS has an electronic database which includes all the checks performed at the economic operators with, on the one hand, information concerning the product and type of inspection and, on the other, information concerning the product itself, such as the manufacturer, distributor, imported quantity, brand, model, non-compliance, pictures, etc. ILNAS states that it has no knowledge of statistics concerning dangerous products intercepted by customs at the border, nor concerning dangerous products, other than RAPEX statistics.

ILNAS collects consumer complaints concerning dangerous products and always provides for a follow-up of those complaints in accordance with Article 7 of the implementation law of 2006. The complaint and non-conformity form is accessible through the internet portal of ILNAS.

In response to a complaint, the product is investigated by checking, for example, customer evaluations on the web and the possibly high return rate in shops. When appropriate, a provisional sales ban is imposed, during which the product can be analysed in a laboratory. When the product fails to comply with the requirements of the relevant

legislation, a risk assessment is made. In the event that the product presents a serious risk for the health of consumers, ILNAS notifies the product risk via Safety Gate RAPEX.

Luxembourg has a strongly developed collection of systemic injury data with verified excellent international reputation. The Luxembourg Institute of Health (LIH) collects injury data from accidents in cooperation with the Emergency Departments of several hospitals in Luxembourg. Hospital staff (doctors and nursery staff) are requested to fill in a specific form when a patient has suffered injuries from an accident. All data collected are then forwarded to the LIH where they analyse the data for the statistics in the RETRACE project.[351] The retrieved information is treated with due care for anonymity in order to be in compliance with the General Data Protection Regulation (GDPR).

Data concerning physical injury caused by a product are collected by the public health registers/reports from hospitals and also following consumer complaints.[352] Based on these statistics, the market surveillance authorities of Luxembourg are able to select the priority areas for surveillance and identify new risks. Injury data also provide information for risk assessments, e.g. the frequency of specific types of injuries related to specific categories of products.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Luxembourg (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

As regards market surveillance in general, ILNAS points out that many economic operators are not aware of the existence of ILNAS and/or do not know the safety legislation applicable to the products they are placing on the market. The first issue can be explained by the relatively young age of the national supervising authority. Both problems can be addressed by national information and awareness campaigns through traditional media, which is already taking place as mentioned above, as well as through social media. Furthermore, a lack of expertise and legal impediments in online market surveillance has been mentioned in this respect. Furthermore and notwithstanding an excellent injury data collection system, there remains a lack of other relevant data. Finally, ILNAS points out that there are problems to take effective action when the responsible economic operator is established in another EU/EEA country or outside the EU/EEA. While the first problem could be remedied by introducing more strict cooperation procedures at the EU legislative level, the second problem requires intervention by the European Commission. However, as regards the first type of cooperation problems within the EU, the GPSD is not included in the scope of two recent regulations on market surveillance and consumer protection, namely the revised Consumer Protection and Cooperation Regulation 2017/2394 (entered into force on January 17, 2020) and the Regulation on market surveillance and compliance of products No 2019/1020 (full entry into force on July 16, 2021). This results in a lacuna in formal cooperation procedures between national market surveillance authorities in the field of non-harmonised products.

As concerns RAPEX, ILNAS considers RAPEX to function rather well. Nevertheless, the visibility for other Member States concerning the follow-up and newly gathered information of a notification by a specific Member State responding to a RAPEX alert could be improved. Apart from this lack of information from national authorities in other countries, ILNAS also indicated both a lack of information from other national authorities in Luxembourg and businesses as well as a lack of sufficient information regarding the traceability of notified products. Lastly, difficulties with the risk assessment and also related to delays of notifications were pointed out.

Finally, ILNAS considered the product recalls conducted at national level to be rather effective. However, ILNAS states that it cannot confirm the same in cross-border contexts.

Areas to make market surveillance of consumer products in Luxembourg/the EU more effective

While ILNAS reported a lack of awareness of product safety requirements and market supervision activities, responsive measures are already taking place through traditional media channels. Yet, information campaigns through social media channels could be strengthened further so as to remedy this problem. In the same vein, the basic information about a recall is channelled to consumers through a poster, whereas a more resolute emphasis

[351] See for more information on the RETRACE project: https://sante.public.lu/fr/publications/r/retrace-traumatismes-accidents-luxembourg-fr-de-pt-en/index.html

[352] For more information, see: https://sante.public.lu/fr/publications/r/rapport-retrace-2014/rapport-retrace-2014.pdf.

on online channels, such as social media, retailers' websites and online market places, may also appear to be adequate and effective measures to foster recall effectiveness.[353]

The EU has recently committed to enhancing the protection of consumers in the EU through the introduction of legislation dealing with the enforcement of infringements of a cross-border nature, with strong emphasis on the cooperation between national government agencies. This follows from the revised CPC Regulation 2017/2394 in the field of general consumer protection legislation, which recently entered into force, and the promulgation of the Regulation on market surveillance and compliance of products No 2019/1020. Yet, as was pointed out, the GPSD is not included in the scope of these regulations and cross-border enforcement of non-harmonised products remains, to a large extent, subject to the more informal cooperation between national market surveillance authorities, while ILNAS confirms the necessity for more formal cooperation requirements. The absence of the GPSD in these regulations extends also to the mystery shopping competence in an online context, which was reported to be a legal impediment. Its absence could also be problematic for the performance of several market surveillance activities, as it is believed that a mystery shopping competence increases enforcement possibilities in the context of online sales channels, as is further explained in the Belgian country report for this study. Finally, a formalisation of cross-border cooperation through EU legislation and procedures could also contribute to the reported problem of a lack of visibility regarding the follow-up of a RAPEX notification in another Member State.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Luxembourg since 2013

ILNAS estimated that the general trend of the level of safety is positive and that the safety of products has therefore improved. It stated that since 2013, awareness among consumers and economic operators has been raised through the communication campaigns made by the Market Surveillance Department of ILNAS. The Safety Gate RAPEX system has been developed further, and together with the Product Safety Business Gateway (developed for voluntary notifications made by economic operators), these two systems constitute efficient tools to guarantee a high level of safety of non-food consumer products. As mentioned above, ILNAS has good cooperation with national retailers who inform it when a product listed in the SAFETY GATE is found in their shop. Further, ILNAS has performed significantly more safety checks since 2013 and has consequently gained more experience which in its view also results in an increased awareness among economic operators. To that aim, ILNAS reported that safety checks are not only aimed at checking whether a product shows a non-conformity but are also performed with the explicit purpose of educating economic operators about the existence and scope of product safety requirements.[354]

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Luxembourg whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Regarding the new challenges related to e-commerce and the platform economy, ILNAS stated that it does not have specific tools at its disposal. Yet, it must be said that some new tools are in preparation (e.g. mystery shopping) and that ILNAS is already using a web crawling tool.

Views of market surveillance authorities whether approaches in Luxembourg can be considered best practice implementation of the GPSD, which could be of interest to other countries

In Luxembourg, there is a common database (ECSDM) on product safety used by several market surveillance

[353] See also U.S. Consumer Product Safety Commission (2013), The Regulated Products Handbook, P. 30.

[354] The activity report draws an explicit distinction between surveillance inspections conducted to check legal conformity as opposed to inspections conducted with an educational purpose. See ILNAS (2019), Rapport d'activité 2018, P. 33. Retrieved on February 19, 2020, from: https://portail-qualite.public.lu/fr/publications/accreditation-notification/rapport-annuel/rapport-annuel-2018-ilnas.html.

authorities. The database was initially developed for cooperation between customs authorities and the Market Surveillance Department of ILNAS in 2013, but in 2016, a cooperation agreement[355] between ILNAS and the Environmental Department was signed, granting an additional government agency access to ECSDM. In the near future, other authorities will also join, such as the Ministry of Health, so that the idea of one national database can be further accomplished. This brings about several practical advantages, such as swift information exchange between responsible authorities, so that it can be seen as best practice, especially since ILNAS indicates that this idea of a uniform database is in place (or under development) in only a few other EU Member States.

Lastly, there is an increasing consensus in academic literature that market surveillance strategies should not focus exclusively on deterring regulatees by imposing sanctions and stringent inspections to achieve compliance with regulation.[356] These strands in academic literature, which have also been reflected in recent international studies,[357] connect several advantages to a so-called 'cooperative approach' in market surveillance, such as a more durable degree of compliance from market participants and reduction of administrative costs.[358] Moreover, establishing trust and cooperation between these regulatees and public administration is fundamental to ease voluntary compliance,[359] which is also important in the context of stimulating voluntary product recalls. Cooperative enforcement strategies can complement the existing deterrence strategies when appropriate, for example when a business committed an infringement unwillingly because it was unaware of its legal obligations.[360] Enforcement tools of market surveillance authorities should therefore not only entail sanctioning and stringent inspections, but also focus on educational measures (i.e. 'awareness raising'), supportive and constructive dialogue and persuasion (i.e. negotiation) with the regulatees.[361]

These perspectives on more effective regulation and enforcement show that certain practices in Luxembourg can potentially be seen as 'best practices', as these alternative, more 'soft' approaches are not yet systematically used at European or national level.[362] The enforcement activities by the Market Surveillance Department of ILNAS show elements of such a cooperative approach. For instance, the close informal cooperation between the Market Surveillance Department and businesses, namely Amazon.eu and retail sellers, can be seen as a plus. ILNAS confirms that this works well in practice and that this does not occur in all of the Member States. Also the abovementioned practice of visiting economic operators with the exclusive intent of raising awareness through educational dialogue (and not a stringent infringement-detection inspection), may be classified among best practices.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	12	1	13

[355] 'Une collaboration pour la protection de la santé, de la sécurité, de l'environnement et des consommateurs'. Retrieved on March 10, 2020, from: https://www.infogreen.lu/Une-collaboration-pour-la-protection-de-la-sante-de-la-securite-de-l.html.
[356] 'The deterrence approach has been challenged that it is ineffective, costly and non-sustainable for public authorities and regulatees.' See Rangone, N. (2018), Making Law Effective: Behavioural Insights into Compliance (European Journal of Risk Regulation, vol. 9:3), P. 490 and the references made there. In the same vein, the seminal academic contribution of Ayres and Braithwaite contends that enforcement tools should range from persuasion and educational measures to licence revocation and even criminal penalties. See Ayres, I and Braithwaite, J. (1992), Responsive Regulation: Transcending the Deregulation Debate, Oxford, Oxford University Press, P. 35.
[357] See e.g. OECD (2014), Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections, 68 pages; European Commission (2014), Study on enforcement authorities' powers in the application of Regulation 2006/2004/EC on Consumer Protection Cooperation, P. 9.
[358] See Faure, M.G., Ogus, A. and Philipsen, N. (2009), Curbing Consumer Financial Losses: The Economics of Regulatory Enforcement (*Law & Policy*, vol. 31:2), P. 170-171.
[359] Rangone, N. (2018), Making Law Effective: Behavioural Insights into Compliance (European Journal of Risk Regulation, vol. 9:3), P. 501.
[360] See Scott, C. (2018), Enforcing Consumer Protection Laws (in Howells, G. and Ramsey, I., Handbook of Research on International Consumer Protection Law, Second Edition, Cheltenham (UK), Edward Elgar Publishing), P. 481 – 482.
[361] OECD (2014), Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections, P. 66.
[362] See Rangone, N. (2018), Making Law Effective: Behavioural Insights into Compliance (European Journal of Risk Regulation, vol. 9:3), P. 489 (fn. 28).

Total (country)	**12**	**1**	**12**
Notes:	This information is related to ILNAS, which declares that every collaborator also does visual online inspections if necessary. These numbers therefore relate to the GPSD products and harmonised products that fall within the surveillance competences of ILNAS.		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**707**	**160**	**867**
Total number of consumer products inspected	707	160	867
Total number of consumer products tested in laboratories	140	46	186
Total number of consumer products inspected in cooperation with the customs	123	40	163
Total number of dangerous consumer products found	15	0	15
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	134	16	150
Notes:	This information is also related to ILNAS, as explained above.		

C. Number of recalls of consumer goods (last available year)

ILNAS monitors the recalls. However, the national database does not allow this Market Surveillance Authority to generate these statistics.

D. Key sources

Legislation	Regulation 764/2008, *Official Journal L 218, 13/8/2008, P. 21 – 29.* Regulation 765/2008, *Official Journal L 218, 13/8/2008, P. 30 – 47.* Regulation 2019/1020, *Official Journal L 169, 25/06/2019, P. 1 – 44.* Regulation 2017/2394, *Official Journal L 345, 27/12/2017, P. 1 – 26.* Directive 2001/95/EC, *Official Journal L 11, 15/01/2001, P. 4 – 17.* Loi du 31 juillet 2006 relative à la sécurité générale des produits, *Journal Officiel du Grand-Duché de Luxembourg 162, 08/09/2006, P. 2977 – 2981.* Loi du 4 juillet 2014, *Journal Officiel du Grand-Duché de Luxembourg 135, 28/07/2014, P. 2143 – 2157.* Loi du 20 mai 2008, *Journal Officiel du Grand-Duché de Luxembourg 74, 28/05/2008, P. 1065 – 1080.*
Studies/reports/articles	Ayres, I. and Braithwaite, J. (1992), Responsive Regulation: Transcending the Deregulation Debate, Oxford, Oxford University Press, 216 pages. European Commission (2017), Commission notice on the market surveillance of products sold online (2017/C 250/01). Retrieved on March 10, 2020, from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XC0801(01). European Commission (2000), Communication from the commission on the precautionary principle. Retrieved on March 10, 2020, from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l32042. European Commission (2020), Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics. Retrieved on February 28, 2020, from: https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-

	internet-things-and-robotics-0_en. European Commission (2014), Study on enforcement authorities' powers in the application of Regulation 2006/2004/EC on Consumer Protection Cooperation. Retrieved on March 20, 2020, from:https://ec.europa.eu/info/sites/info/files/study_on_enforcement_powers_2016_en.pdf. European Commission (2020), White Paper on Artificial Intelligence. Retrieved on February 22, 2020, from: https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf. European Economic and Social Committee (2013), Opinion on the 'Proposal for a regulation of the European Parliament and of the Council on Consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC', COM(2013) 78 final – 2013/0049(COD). Faure, M.G., Ogus, A. and Philipsen, N. (2009), Curbing Consumer Financial Losses: The Economics of Regulatory Enforcement (Law & Policy, vol. 31:2), pages 161 – 191. ILNAS (2019), Rapport d'activité 2018. Retrieved on February 19, 2020, from: https://portail-qualite.public.lu/fr/publications/accreditation-notification/rapport-annuel/rapport-annuel-2018-ilnas.html. ILNAS (2019), Stratégie du département de la surveillance du marché de l'ILNAS. Retrieved on February 20, 2020, from: https://portail-qualite.public.lu/fr/publications/surveillance-marche/documentations/strategie.html. ILNAS (2019), Fonctionnement du département de la surveillance du marché de l'ILNAS. Retrieved on February 20, 2020, from: https://portail-qualite.public.lu/fr/publications/surveillance-marche/documentations/fonctionnement.html. ILNAS (2019), Autorités compétentes de surveillance du marché et organismes notifiés au Grand-Duché de Luxembourg. Retrieved on February 2020, from:https://portail-qualite.public.lu/content/dam/qualite/fr/publications/surveillance-marche/organisation/directives-autorites-nationales/ILNAS-DSM-A005-Autorites-competentes-et-organismes-notifies-au-GDL.pdf. OECD (2006), Report on the Effectiveness of the Enforcement Regime. Retrieved on March 20, 2020, from: http://www.oecd.org/dataoecd/56/7/37863861.doc. OECD (2014), Best Practice Principles for Regulatory Policy: Regulatory Enforcement and Inspections. Retrieved on March 23, 2020, from: http://www.oecd.org/gov/regulatory-enforcement-and-inspections-9789264208117-en.htm. Rangone, N. (2018), Making Law Effective: Behavioural Insights into Compliance (European Journal of Risk Regulation, vol. 9:3). Scott, C. (2018), Enforcing Consumer Protection Laws (in : Howells, G. and Ramsey, I., Handbook of Research on International Consumer Protection Law, Second Edition, Cheltenham (UK), Edward Elgar Publishing), pages 466 – 490. Straetmans, G. and Verhoeven, D. (2016), Other EU laws concerning similar issues (in Machnikowski, P. (ed), European Product Liability: An analysis of the state of the art in the era of new technologies, Antwerp – Cambridge, Intersentia), pages 97 – 108. Verhoeven, D. (2018), Productaansprakelijkheid en Productveiligheid, Antwerp, Intersentia
Websites	https://www.infogreen.lu/Une-collaboration-pour-la-protection-de-la-sante-de-la-securite-de-l.html https://www.journal.lu/article/enorme-entwicklung/ https://ec.europa.eu/info/sites/info/files/aa_final_en-eu_version.pdf https://portail-qualite.public.lu/fr.html https://portail-qualite.public.lu/content/dam/qualite/fr/publications/surveillance-marche/organisation/directives-autorites-nationales/ILNAS-DSM-A005-Autorites-competentes-et-organismes-notifies-au-GDL.pdf https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Intra EU_trade_in_goods_-_main_features https://www.lih.lu/blog/our-news-1/post/luxembourgs-injury-surveillance-system-rated-excellent-and-sustainable-102#blog_content https://sante.public.lu/fr/publications/r/retrace-traumatismes-accidents-luxembourg-fr-de-pt-en/index.html
Interviews	Three interviews conducted with ILNAS, Department of Market Surveillance

19. Malta

COUNTRY REPORT MALTA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The General Product Safety Directive ('GSPD') was implemented as the Product Safety Act[363] (Chapter 427 of the Laws of Malta) ('PSA') in 2001, three years before Malta's accession to the European Union. As such, the PSA was modelled on the draft form of the GPSD and in view of the changes that were implemented in the final GPSD draft, the PSA was not an identical transposition of the GPSD.

The provisions related to RAPEX were transposed through the Further Provisions for Product Withdrawal and Recall Regulations 2004[364] ('the Recall Regulations') issued under the PSA by way of Legal Notice 32 of 2004.

The PSA was subsequently amended in December 2007[365], and responsibility for the management and implementation of the PSA was given fully to the Malta Standards Authority ('MSA'), with the Head of the Market Surveillance Directorate of the MSA being responsible for its enforcement. These amendments also included the substitution of the definition of 'safe product' so as to align it to the definition in the GPSD.

The PSA was amended again in April 2011 as per Act VI of 2011[366], the Malta Competition and Consumer Affairs Act. This Act provided for the setting up of the Malta Competition and Consumer Affairs Authority ('MCCAA') and the Technical Regulations Division ('TRD') within the MCCAA absorbed a large part of the responsibilities previously covered under the remit of the MSA, including responsibility for the implementation, management and enforcement of all legislation issued by virtue of the PSA. The responsibility for the carrying out of market surveillance for non-food and non-medicinal products lies with one entity, the Market Surveillance Directorate ('MSD-TRD') within the TRD. As such, all national market surveillance efforts are centralised in one entity – the MSD-TRD.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Malta

Article 6 (2) of the PSA, which transposes Article 5(1) of the GPSD, provides that producers and importers are to include *'…whenever appropriate, marking of the products or product batches in such a way that they can be identified….'.*

Under the abovementioned Article, in the case of non-harmonised consumer products and for those harmonised products for which legislation does not provide specific traceability requirements, producers are therefore required to include some form of identification as a link between themselves and the product in question. The form that this identification may take is left up to the producer/importer.

MSD-TRD has indicated that in their interaction with producers and importers they emphasise the importance of traceability details and advocate the inclusion of the name and contact details on the product or its packaging. In terms of enforceability however, in view of the discretionary language of the PSA in this respect, MSD-TRD accepts various forms of traceability information e.g. even just model numbers as long as the link between the product and the producer/importer can be established through reference to the documentation presented, such as the declaration of conformity or the so-called 'technical file'.

In terms of traceability, distributors are required to provide MSD-TRD with clear identification details as to where they procured the product, i.e. one step up in the distribution chain of the product. This so that MSD-TRD can accurately map out the profusion of the product on the market. In view of the fact that distributors do not affect the packaging of the product, their obligations under the PSA extend solely to adherence to the general safety

[363] As per Act V of 2001, http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=16335&l=1
[364] http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10791&l=1
[365] As per Act XXIV of 2007, http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=18453&l=1
[366] http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=22036&l=1

requirements, monitoring the safety of the products they distributed and passing on any relevant information to their suppliers and their customers.

While MSD-TRD is open to the application of new approaches in relation to traceability, such as barcodes or electronic identification, as stated above no form of identification is mandatory under the PSA.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

MSD-TRD confirmed that there is not any specific definition of safety used for the application of the PSA in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

No it does not. This has at times raised issues with regards to whether the PSA can be relied upon by MSD-TRD in order to look into and ultimately take enforcement action in relation to products that incorporate new technologies such as 'connected toys' as elaborated in more detail later in this report. This is mainly due to the rather restrictive interpretation to the concept of 'safety', as not including perceived or alleged threats to the privacy and security of consumers.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

MSD-TRD explained that in assessing the safety of a product, it refers to other European standards applicable in the case of harmonised products and to Commission recommendations setting guidelines on product safety assessment. When these exist, MSD-TRD also refers to codes of good practice in force in the sector concerned. Thus, for example, in assessing the safety of gas regulators, reference was made to guidelines issued by the Malta Resources Authority.

Moreover, in gauging the safety or otherwise of particular products, MSD-TRD always keeps to the reasonable consumer expectations in terms of the general benchmark for determining the safety thereof.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Malta in case there are consumer product(s) on the market which are found unsafe under the GPSD

The enforcement of the PSA and its subsidiary legislation falls on the personnel within the MSD-TRD acting under a Director General ('DG-TRD') who has the statutory power to issue enforcement notices to producers and distributors of products.

Under the PSA[367], the DG-TRD may, when they believe that an operator has failed to comply with the PSA or any regulation made under it, issue notices requiring the application of remedial measures within a specific period of time.

The DG-TRD is also empowered under the PSA to prohibit the placement on the market of product or product batches which are unsafe or non-compliant[368] and to impose conditions on product marketing, advertising, labelling and marking[369]. Article 15 (c) of the PSA provides that the DG-TRD is empowered to require *'the immediate withdrawal of unsafe products from the market and, whenever he deems it necessary, to order the destruction of such products under such conditions as he may deem appropriate.'* As per this provision, DG-TRD is empowered to require the withdrawal and destruction of products which have been assessed as being unsafe. The power to order the recall of products is not specifically mentioned in the PSA but is included in the Recall Regulations[370], in the context of the procedure to be followed in the case of exchanges of information and rapid intervention in the case

[367] Article 26
[368] Article 15 (a) and (b)
[369] Article 15 (e)
[370] Regulation 5

of serious risks. The DG-TRD is required to first seek to achieve voluntary compliance by the producers or distributors involved[371].

The PSA[372] empowers the MSD-TRD acting under the DG-TRD to require businesses to provide relevant information or documentation on the product in question or on the supply chain and the distribution of a particular product. In the case of serious risks, the Recall Regulations[373] specify the minimum information that a producer or distributor is obliged to provide MSD-TRD in relation to that product. MSD-TRD is also empowered to carry out unannounced on-site inspections and physical checks of products. It can also seize and detain, against the issuance of a receipt, any goods, documents or records in the exercise of its powers under the PSA[374].

The MSD-TRD indicated that it is not legally empowered to conduct mystery shopping. In this regard, Article 20 (a) of the PSA, which sets out the powers of authorised officers, states that such officer may, in the course of carrying out their functions *'purchase a sample of any product or any material capable of being used in the preparation, manufacture or assembly or such product.'*

While no provision has been included in the PSA that specifically empowers MSD-TRD to carry out mystery shopping, in the absence of the stated requirement that authorised officials identify themselves as such with the business, it would appear to be possible that the abovementioned Article 20(a) could be relied on by MSD-TRD to carry out mystery shopping.

The DG-TRD may not impose administrative fines or penalties. Offences under the PSA are prosecuted before the Court of Magistrates sitting as a court of criminal judicature which may, as illustrated in more detail below, order fines, imprisonment, the suspension of licence/s and the destruction of the product in question.

The DG-TRD may, however, with respect to any violation of the PSA or any regulations made thereunder, instead of initiating proceedings before the Courts, choose to instead obtain undertakings from producers and distributors confirming that the latter will refrain from such conduct and take any remedial action specified by the DG-TRD[375].

Under Article 28 of the PSA, the DG may also issue public statements identifying both the products which are or may be unsafe and also identifying the producers and distributors of the such products.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Under the PSA, the MSD-TRD is not empowered to issue administrative fines or penalties. The penalties indicated in the PSA can only by imposed by the Court in the case of a conviction of an offence under the PSA, after proceedings are instituted at the instance of the DG-TRD.

In this regard, under Article 32 (1) of the PSA, any person found to be guilty by the Court of having obstructed, resisted, threatened or given misleading or false information to the DG-TRD shall be liable to a fine not less than EUR 465.87 and not exceeding EUR 2 329.37, or to imprisonment for a term not exceeding 6 months, or both such a fine and imprisonment.

In the case of a conviction of any other offence under the PSA, the Court may impose a fine of between EUR 1 164.69 and EUR 11 646.87 and/or imprisonment for a term not exceeding three years[376]. Conviction for a second or subsequent offence carries a fine of not less than EUR 1 747.03 but not exceeding EUR 23 293.73 and/or imprisonment not exceeding four years or both such fines[377].

The Court may, upon conviction of an offence under the PSA, also order the suspension of a licence/s issued in favour of the person charged or the premises involved in the proceedings[378].

MSD-TRD is not empowered under the PSA to reclaim from the economic operator the administrative costs incurred in the process of ascertaining that a particular product is unsafe – i.e. seizure, testing and analysis. Said costs may only be reimbursed to TRD upon a conviction of an offence under the PSA by the Courts upon

[371] Article 10 (3)
[372] Article 20
[373] Regulation 4(2)
[374] Article 20
[375] Article 29
[376] Article 32(2)
[377] Article 32 (3)
[378] Article 32(4)

proceedings instituted by the Director General (TRD).

As explained in more detail below, these penalties are in practice not being applied and this is due to the reluctance of the DG-TRD to initiate proceedings for potential infringements of the PSA before the courts.

Recent case law in Malta with respect to or relevant for the GPSD/the national implementation legislation.

There are currently no pending court proceedings in relation to infringements of the PSA and the regulations thereunder. This was confirmed by MSD-TRD which indicated that it tends to initiate proceedings in Court only in the case of repeat offenders. At this point in time, the only pending cases initiated by DG-TRD relate to offences under the Pesticides Control Act[379], which also falls under its responsibility.

MSD-TRD justified the lack of court proceedings under the PSA on the basis that it favours recourse to voluntary agreements in its interaction with economic operators. Court proceedings take time, sometimes years, to conclude, and the MSD-TRD's priority is to make sure that the unsafe or non-compliant products are removed from the market. This aim is more often than not achieved through voluntary agreements.

While from the data available, one can conclude that recourse to voluntary agreements with the operators has indeed been a successful tool, particularly in the case of recalls, DG-TRD's reluctance to initiate court proceedings in practice means that TRD is failing to make proper use of all the powers available to it. The initiation of court proceedings, in the most serious cases, could at the very least serve as a powerful deterrent not only to the operator being prosecuted but also to other players in the market. The lack of recourse to the courts also means that as things stand, MSD-TRD can never recoup the expenses it incurred in carrying out testing and analysis of products since as indicated above, only the Court can order that a person convicted of an offence under the PSA reimburse the DG-TRD for any costs incurred in connection with the proceedings instituted against them[380].

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Malta concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

MSD-TRD referred to the fact that there are quite a large number of importers who tend to favour products sourced from non-EU/EEA suppliers, particularly suppliers located in East Asia. This is predominantly due to the fact that these sources are cheaper than suppliers in other regions. The majority of these products sourced from these suppliers however are not branded and do not have the information required in terms of traceability. MSD-TRD expressed the belief that this lack of information is done purposefully so that the supplier divests itself of any responsibility. In practical terms, this state of affairs translates into a number of cases where the importer finds itself without any support in terms of the information and documentation required for the product to be allowed to enter the Maltese market.

While no data is available to quantify the exact number of products impacted, both MSD-TRD and the Customs Department confirmed that there is a sizeable portion of imports that are impeded from entering the Maltese market by customs due to the lack of the appropriate traceability information and non-compliant documentation. In most cases, the importer would be given the option of either re-exporting the products, or, if this is not a possibility or they decide not to opt for it, the products are destroyed under the supervision of the Customs Department.

MSD-TRD referred to the fact that where the issue is solely a question of non-compliance in terms of the traceability obligations, there are cases when the Maltese importer would indicate that it intends to label the product itself and this is permitted once it presents the necessary documentation to MSD-TRD including the so-called 'technical file'. If MSD-TRD is satisfied with the documentation provided, the products are released upon condition that they are appropriately labelled by the Maltese importer, at which point the responsibility under the PSA shifts on to the importer.

Apart from the obvious attraction of buying from cheaper sources, this trend is also clear evidence of the lack of familiarity of importers with the applicable legislation and the possible repercussions of importing such products.

MSD-TRD believes that the definition of 'safety' is too wide and too generic. In the past, the narrow interpretation

[379] Chapter 430 of the Laws of Malta
[380] Article 32 of the PSA

given to the current definition of 'safety' in the GPSD gave rise to doubts as to whether it could be interpreted so as to cover emerging issues related to so-called 'connected toys' or 'electronic devices' such as smart watches which are susceptible to hacking. When faced with these cases, the MSD-TRD has held, the risk presented relates more to 'security' or 'privacy' rather than to 'safety'. Notwithstanding this interpretation, notifications relating to these products, such as in the case of the ENOX Safe-Kid One smartwatch, were followed up as per the procedure applicable in the case of other products, with the result that no such products were present in the Maltese market. This interpretation however would prove problematic if similar products are found in the Maltese market, since it raises doubts as to what action, if any, the MSD-TRD would be willing to take.

Possible improvements to make the implementation of the GPSD in Malta more effective

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Malta.

As already pointed out in this report, the responsibility for the carrying out of market surveillance for non-food and non-medicinal products lies with one entity, the MSD-TRD within the Technical Regulations Division in the MCCAA. As such, all national market surveillance efforts are centralised in one entity – the MSD-TRD. Currently MSD-TRD is made up eight (8) full-time officials with varying technical expertise. Each officer is responsible for a particular product sector.

As from this year, MSD-TRD is participating in a government-driven project aimed at coordinating the inspections of various entities including those carried out by MSD-TRD. The objective is to minimise the burden of inspections on businesses and sole traders and to ensure that the inspections carried out are transparent and as effective as possible. In practice, when carrying out inspections on businesses, the participating entities do not focus solely on checks falling exclusively within their remit but carry out other checks that would generally require inspections by one or more other entities. The initiative is entrusted to the Inspections Coordination Office within the Office of the Prime Minister, which was set up in 2017 as per the Coordination of Government Inspections Act, Chapter 568 of the Laws of Malta[381]. MSD-TRD indicated that while it believes that the initiative is a positive one, it is too early to determine the benefits derived from participating in it.

Plans/programmes in place which define priorities for market surveillance of consumer products

As required under the PSA[382], MSD-TRD publishes the national market surveillance programme on an annual basis.

The programme, which is available on the website of the MCCAA[383], is a simple one, and consists of a list of market surveillance responsibilities that fall within the MSD-TRD's remit under the GPSD and under the specific sectoral legislation and an indication of the timing of and the officer who will be conducting the routine inspections, amongst other things.

From a quick reference to the programme, it becomes apparent that taking action as a response to notifications and complaints received from consumers and economic operators remains the priority for the Directorate. MSD-TRD confirmed that while care is taken to keep with the annual national programme, on a day-to-day basis, priorities for market surveillance of consumer products are very much conditioned by the inspection results, RAPEX notifications, EU coordinated actions on the safety of products, consumer complaints and information received from the Customs Department.

MSD-TRD also relies on 'notifications' received from the Public Relations unit of the same Authority in terms of relevant news/media reports and social media posts. In terms of consumer complaints, in the majority of cases, consumers make contact directly with MSD-TRD. However, there are instances where the complaints are lodged with the consumer complaints division (the Complaints and Conciliation Directorate) within the same Authority and it is the latter which passes on the complaint to MSD-TRD. Similarly, in the case of vehicles, information generally reaches MSD-TRD through the Type Approval Authority, which is also part of the MCCAA.

MSD-TRD referred to the lack of consistency of accident and injury data available to it. In the majority of cases, the

[381] http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=12619&l=1
[382] Article 27
[383] https://www.mccaa.org.mt/Section/Content?contentId=1163.

information collected, and the data recorded by the responsible emergency services, often does not include a reference to the cause of the accident and/or injury so it cannot be relied upon by MSD-TRD.

MSD-TRD stated that while it strives to be proactive in some areas falling within its remit, in view of the very limited resources it has at its disposal, its actions are more often than not driven by the complaints and notifications that it receives from the abovementioned sources.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Malta with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

MSD-TRD commented that while it strives to carry out market surveillance in the case of products containing new technologies, its expertise in this regard is limited. In practice, market surveillance activities in regard to these products are confined to the conducting of administrative checks confirming that the products have the required information and documentation to be placed on the market. MSD-TRD indicated that as things stand, it is not in a position to conduct in-depth market surveillance on these products, which also includes testing. As a result, there is no formal market surveillance program targeting these products, and action on the part of MSD-TRD is primarily reactive and triggered by notifications received from customs or as a secondary response during the carrying out of inspections on other products.

MSD-TRD also confirmed that it does not actively conduct market surveillance with respect to C2C products, primarily due to the challenges that these products present in terms of enforcement.

The MSD-TRD has itself labelled its online market surveillance as rudimentary. In reality, its market surveillance efforts in this area consist of inspectors going on social media and checking for products being sold on these platforms. In the case of Malta, as opposed to the situation in other Member States, online shops are yet to gain popularity and the majority of business is done on social media platforms. These platforms present particular challenges to MSD-TRD, since it is at times very difficult for it to take concrete action due to the lack of proper identification of the seller and/or relevant contact details. This is a trend which has proved problematic, particularly due to the ease with which sellers can deactivate or switch accounts.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

MSD-TRD has indicated that it carries out market surveillance regarding products sold online from sellers established in Malta once a month. It does not however carry out market surveillance with regards to products sold online by sellers established outside Malta (in EU/EEA countries and non-EU/EEA countries).

MSD-TRD pointed out that online inspections are still a novelty in Malta, and it recognises that a formal system needs to be set up. As things stand, the process followed is simple. The responsible MSD-TRD inspector goes online and browses the sites. As already pointed out above, MSD-TRD's efforts in this regard are primarily focused on social media platforms. Information as to any relevant product, including the contact details of the economic operator in question, are passed on to the officer responsible of the enforcement of the particular sectoral legislation for further analysis. As indicated previously in this report, MSD-TRD does not conduct mystery shopping.

According to the data provided by MSD-TRD, the online inspections account for only 3% to 5% of the total of market surveillance activities undertaken by the Directorate.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Malta (except customs) with respect to product safety

In light of the fact that market surveillance responsibilities are centralised within MSD-TRD, there is little scope for cooperation or coordination with other entities apart from the Customs Department. Contact is however maintained through exchanges of information and joint training sessions primarily with the Malta Communications Authority (MCA), which is responsible for the regulation of wireless spectrum in Malta, and the Department of Health, which is the entity responsible for food safety.

Cooperation with customs authorities in Malta with respect to product safety

MSD-TRD and the Customs Department both confirmed that the two entities maintain close relations and that the

cooperation arrangements they have in place have yielded good results.

Formally, the relationship between the two entities is governed by a Memorandum of Understanding, signed in 2014, which lays down a high-level agreement for the sharing of information and cooperation in enforcement between the two entities. In practice, the cooperation between the two entities relies for the most part on informal cooperation channels and frequent contact is made between MSD-TRD and customs officers, mostly through electronic and voice communication media.

Customs are regularly notified by MSD-TRD of either potentially unsafe or non-compliant products, so that the former might identify said products during the checks that the customs officials carry out at the border.

Customs also regularly contacts MSD-TRD with queries or requests for advice in relation to products that it would have seized or stopped at the border. In 2018, there were 140 recorded instances when customs requested technical assistance from MSD-TRD[384]. In these instances, pictures and/or a sample of the said product are sent to MSD-TRD, and after conducting the necessary checks and analysis, MSD-TRD issues its advice. While customs is not obliged to heed the advice received, and the ultimate decision and the taking of enforcement action rests exclusively with customs, in the majority of cases the decision would reflect the advice given by MSD-TRD.

Both entities confirmed that the established system of exchange of information and samples between customs and MSD-TRD has shown to be very efficient and effective, with decisions taken in a short period of time, thus proving to be a very reliable mode of operation.

In recent years, customs officers have also received periodical training by MSD-TRD. These training sessions have proven to be beneficial for both entities since they not only serve to establish a certain common understanding of the requirements applicable in the case of the different product types falling under the responsibility of MSD-TRD, but have also helped to establish personal contact between the officers of the two entities.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

MSD-TRD indicated that cooperation with other relevant authorities located in EU/EEA countries occurs primarily through RAPEX, ICSMS and the Wiki confluence platform. In 2018, MSD-TRD, as the RAPEX point of contact for Malta, made 22 new notifications of products found on the local market and reacted to 22 notifications received from other Member States through RAPEX. The products in question ranged from vehicles, toys, hair care products, electrical products and socket adaptors. In the same year, a total of 1 032 RAPEX notifications were followed up by MSD-TRD[385].

In 2018, the MSD-TRD also took part in various Joint Actions which were organised by PROSAFE and which focused on a number of consumer products - professional and domestic refrigerators, impact drills, personal protective equipment, electrical toys, and cots and baby carriers. In MSD-TRD's opinion, these Joint Actions represent the preferred form of coordination in order to get insight into best practices and for the MSD-TRD officials to hone the skill set and knowledge necessary to carry out their duties effectively.

MSD-TRD also indicated that in 2018, there were a total of 135 notifications/recall campaigns instigated by other sources such as ICSMS, manufacturers and other consumer safety networks outside the EU that were also followed up. No breakdown of this data per source is available.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

As already mentioned above, MSD-TRD is the RAPEX contact point for Malta. As market surveillance responsibilities are centralised under MSD-TRD, all RAPEX notifications are initiated, submitted and notified by the same directorate.

MSD-TRD has indicated that it takes it on average one week from detection for it to notify a dangerous product to RAPEX. This notification period varies predominantly due to the availability of officers to conduct the necessary assessment. However, notification is carried out as soon as MSD-TRD determines that the product is likely to pose serious risk.

[384] https://mccaa.org.mt/media/4159/2018-annual-report.pdf, Pg. 25
[385] Ibid., Pg. 26

Environmental risks are also handled by MSD-TRD and the same processes are also applied in these cases.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

In its role as the national contact point, as a minimum on a weekly basis, MSD-TRD forwards the relevant information it receives through RAPEX to importers and distributors according to the product types.

Seminars and training sessions are organised on a regular basis by the Regulatory Affairs Directorate within TRD, particularly when (or before) new legislation comes into force. These sessions are aimed at informing the stakeholders of the legislative changes and the effects thereof. MSD-TRD also confirmed that communication occurs regularly both with the economic operators themselves and with business organisations, such as the Chamber of Commerce.

MSD-TRD has indicated that it cooperates with consumer organisations on average on a monthly basis so as to create awareness for product safety among consumers. This cooperation is an informal one.

In this regard, according to the MCCAA Annual Report for 2018, there were a total of fifty-four (54) meetings held with consumers, economic operators, other authorities and other stakeholders[386].

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

As indicated above, TRD organises a number of meetings with business and consumer organisations. It also seeks to raise the awareness of the relevant stakeholders through the publication of press releases and through information campaigns in traditional media and through social media.

The warnings and recall notices issued by MSD-TRD-TRD are also posted on the Authority's website.[387]

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Malta (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

As soon as a notification or a report is received by MSD-TRD through one of the channels indicated above in relation to a potentially dangerous product, MSD-TRD would move immediately to assess the actual risk posed by said product. Provisional risk assessments of the safety of products alerts are based on alerts received and field inspection. When the possible unsafe products are located and procured, this is followed by an examination of the documentation made out by the producer and the evaluation of tests carried out by the producer. MSD-TRD may then, according to the circumstances, proceed to carry out more testing on the product sample.

Once the serious risk posed by a product is confirmed, MSD-TRD contacts the relevant economic operators and the withdrawal and/or recall process is initiated. The operators in question would be asked to provide information as to the number of products that have already been distributed and in the case of a recall, they will be asked to indicate whether they have any means of contacting the consumers directly through the retention of their contact details upon purchase or through an existing loyalty scheme.

In those cases where the operator has appropriate tools to communicate directly with the consumers who had purchased the product in question, they are asked to communicate the recall to the impacted consumers. In these cases, MSD-TRD would monitor how the message is communicated to the consumers and also indicate the most appropriate information channels through which such communication needs to be made.

In those cases where it is apparent that not all the consumers can be reached individually, or in those cases where the economic operator is not cooperating willingly and is taking too long to take the required action, the Authority would itself proceed with the issuance of press releases. Press releases are published on all the national

[386] Ibid.
[387] https://mccaa.org.mt/Section/Content?contentId=4407

newspapers, communicated through participation in popular radio and television programmes and are posted on the MCCAA's social media account and its website[388].

MSD-TRD monitors the effectiveness of the recall process from its inception by determining how the recall and the reasons behind the recall are communicated to the consumers, by making sure that the best information channel is used in order to make sure that the largest number of consumers affected by the recall are reached, and by laying out the applicable timeline after discussions with the operator/s. At the end of the process, the success or otherwise of the recall exercise is determined through the carrying out of a simple comparative exercise. The number of recalled products is compared to the number of products which had been previously indicated by the economic operator/s as being the number of distributed products.

Businesses are asked to conduct recalls and other corrective measures, if needed, on a voluntary basis. This occurs as per Article 10(3) of the PSA, which provides that the DG-TRD should, *'whenever he considers it possible and reasonable to do so, first seek to achieve voluntary compliance by the producer or distributors involved.'* MSD-TRD confirmed that this approach has been shown to work, and in those situations where the business appears to drag its feet, the intervention of the Directorate in issuing public notices and warnings is generally enough to instigate increased cooperation from the economic operator/s and to inform the public of the risk posed by the products.

There are no established codes of good practice or other formal information documentation that could serve as guidelines in the case of recalls.

As already mentioned in this report and as evidenced the lack of case law, there is a clear reluctance on the part of DG-TRD to initiate judicial proceedings against operators. MSD-TRD has indicated that it is of the opinion that current process of voluntary withdrawals/recalls functions well. In situations where operators appear to be unwilling to cooperate fully, the issuance of public statements are generally enough of an incentive to convince them to cooperate with the process.

In the absence of the power to issue dissuasive sanctions without recourse to the Courts, MSD-TRD has indicated that it does perceive the institution of lengthy court proceedings as an effective tool particularly in the case of withdrawals or recalls of unsafe products from the market, in cases where time is of essence.

Monitoring of effectiveness of product recalls by market surveillance authorities

As stated above, MSD-TRD monitors the effectiveness of product recalls through a simple comparative exercise. MSD-TRD would have asked the operator/s for a clear indication of the number of products sold or otherwise disseminated on the market at the very start of the recall process. The effectiveness or the recall exercise would be determined by comparing the number of products collected as a result of the recall with the total number of products that had been disseminated on the market.

MSD-TRD has reported an average success rate of 70% in terms of the recalled consumer products that were actually collected[389].

6. Availability of statistics relevant for market surveillance

Availability of statistics in Malta that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

While the MSD-TRD does keep a general record of the complaints received and products investigated, in the absence of proper IT tools, no specific data is kept as to the results of investigations. As a result, there is no data in terms of products determined to be non-compliant, compliant or unsafe.

Consumer complaints generally reach MSD-TRD directly or are otherwise referred to the Directorate by the consumer complaints handling division (The Complaints and Conciliation Directorate) within the same Authority. Once a complaint reaches the MSD-TRD, the complaint is assigned to an officer and once the necessary information is gathered, inspections or communication with the relevant economic operator are initiated. All the information is

[388] https://mccaa.org.mt/Section/Content?contentId=4407
[389] Section C, Data Annex, Questionnaire for National Market Surveillance Authorities, pg. 21

gathered and analysed, and a decision is taken by the officer and discussed at a directorate level. The final decision or outcome of the investigation is always communicated to the consumer who lodged the complaint. In 2018[390], MSD-TRD reported sixty-three (63) reactions triggered by consumer complaints.

No systematic injury data is collected in Malta. This could potentially be a good source of information for the MSD-TRD, but at this point in time, there do not appear to be any plans to introduce the necessary changes as to how this data is collected, recorded and disseminated to the relevant authorities. In truth, the Injury Data Base, which was launched in 2004 and which falls under the Directorate for Health Information and Research within the Ministry for Health, does not appear to be operative[391].

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Malta (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The overall lack of human resources and the shortage of expertise in MSD-TRD are the most evident operational shortcomings. MSD-TRD has indicated that keeping up with its obligations as the national centralised surveillance authority for all non-food and non-medicinal products is demanding and its already limited resources are stretched to the full, with the Directorate having to constantly choose where and how to best deploy its officers.

While the Directorate relies on other entities within the same Authority, primarily the Complaints and Conciliation Directorate in terms of consumer complaints and the Public Relations Unit, this assistance is circumscribed and does not extend to the market surveillance responsibilities, which fall squarely on MSD-TRD. In this regard, MSD-TRD relies almost exclusively on its eight (8) full-time officers to carry out all the duties falling within the Directorate's remit.

As indicated earlier in this report, as from this year, MSD-TRD is participating in a government-driven project aimed at coordinating the inspections of various entities, including those carried out by MSD-TRD.

While, as pointed out by MSD-TRD, it is too early to assess the success or otherwise of the scheme, if implemented properly, it could help alleviate, at least in part, the workload on MSD-TRD in terms of the on-site inspections it carries out

MSD-TRD's 'struggles' are even more apparent in the case of the carrying out of online market surveillance. While MSD-TRD does attempt to conduct this surveillance, this surveillance is at the MSD-TRD's own admission very limited in scope. MSD-TRD has indicated that online market surveillance account for only 3 to 5% of its total market surveillance operations. As pointed out by MSD-TRD, the carrying out of online market surveillance can be labour and time intensive unless one has the necessary knowledge and tools in terms of carrying out surveillance but also in terms of data gathering and reporting. MSD-TRD's deficiencies in this sector are particularly worrying when one considers the ever-increasing popularity of online shopping.

All the interviewees agreed that there is a clear general lack of awareness of the applicable legal and regulatory product safety framework among the different stakeholders. This lack of awareness takes various forms and is evidenced through different means.

MSD-TRD referred to the fact that in the process of carrying out its duties, it has at times encountered issues related to the lack of knowledge as to the distribution of competences for market surveillance amongst national authorities and other entities. This is particularly true in the case of vehicles and food.

MSD-TRD emphasised that this shortcoming is however even more apparent in the case of businesses and consumers.

The majority of businesses that MSD-TRD deals with fall within the SME category. While there is an overall lack of awareness of economic operators as to product safety requirements, this is even more evident in the case of small businesses, which more often than not do not carry out the necessary research prior to investing in particular products and which do not have the necessary support in terms of the legal and technical aspects of their business. These economic operators are driven solely by the perceived profit margins and have little or no awareness of the applicable requirements and the repercussions of non-compliance when choosing suppliers. MSD-TRD also referred to the fact that there have been instances where it encountered difficulties in getting the required information

[390] https://mccaa.org.mt/media/4159/2018-annual-report.pdf, Pg. 26
[391] https://deputyprimeminister.gov.mt/en/dhir/Pages/Registries/injuries.aspx

from business and believes that this is in part due to the lack of prior knowledge by the operators of their obligations and of the MSD-TRD's role.

Similarly, MSD-TRD reported that a general lack of awareness is also evident amongst consumers. While the reasons behind this state of affairs are multiple, it is evident that the channels that have been used by the MCCAA to communicate information to the public are at times not the best suited to reach all consumer segments. As previously mentioned in this report, MCCAA has in the past relied almost exclusively on traditional media to disseminate information to consumers and it is known that these channels are largely ineffective in terms of reaching certain consumer demographics. The last few years has seen the MCCAA shift from utilising exclusively more traditional media in favour of more modern communication channels. In this regard, the MCCAA has in recent years built up its social media presence and even issued a mobile application, named "*Konsumaturi*", targeted specifically at consumers. This app is predominantly an information tool for consumers but is also a means for the latter to lodge complaints[392]. The app was made available as from March 2018, so it is too early to assess whether the app and more generally the new social platforms being utilised by the MCCAA have been effective.

MSD-TRD have however also reported that even when the communication reaches consumers, the latter have at times exhibited a worrying lack of understanding of the importance of product safety. In some cases, notwithstanding having the right to return a product and be given an adequate remedy in terms of redress, consumers have chosen to ignore the instructions given by the Authority and have instead opted to retain the non-compliant or unsafe product. This was particularly evident in the case of vehicle recalls, with the consumer choosing to retain the vehicle in question on the basis of other considerations e.g. aesthetics and/or vehicle engine power.

MSD-TRD has indicated that in its opinion, RAPEX is functioning well, and it referred to the fact that this is one area where having just one centralised point of contact has proved to be beneficial. The disadvantage of having MSD-TRD as the RAPEX contact point is, as in other areas, the lack of human resources. MSD-TRD at this point in time can only dedicate an average of sixteen (16) hours a week to RAPEX. This limitation impedes MSD-TRD and indeed more generally all the relevant stakeholders from deriving further benefits from the system.

MSD-TRD referred to the fact that at times it faced difficulties in relation to risk assessments carried out as a result of RAPEX notifications. It pointed out that not only do risk assessments vary considerably from one Member State to another, but even within the MSD-TRD, there is a divergence in the way risk assessments are carried out or the results thereof. While MSD-TRD recognises that ideally there would be more than one officer involved in carrying out a risk assessment so as to reduce the chance of subjectivity, due to restricted human resources, it is generally difficult to have more officers involved.

One major deficiency that appears to be common at all levels and in the majority of entities involved is the lack of data being collected and recorded. There is an issue both in terms of the volume of information being recorded and in terms of the categorisation of the information collected. This in in turn raises concerns as to the accuracy of the data available. As already mentioned in this report, the absence of a functioning injury data collection systematically means that a valuable source of information is not being made use of. Having accurate injury data could be extremely beneficial in guiding the MSD-TRD's market surveillance efforts in the case of potentially unsafe products.

Areas to make market surveillance of consumer products in Malta/the EU more effective

With regards to RAPEX, MSD-TRD has itself indicated that there is a dire need for a dedicated set-up within the MCCAA to deal with RAPEX notifications. As mentioned earlier, MSD-TRD can only commit to having two (2) employees who dedicate roughly sixteen (16) hours a week to handle the RAPEX notifications. This is yet another example of a valuable tool available to the MSD-TRD which is not being utilised to its optimal level.

With regards to recalls, rather than changing the process itself, MSD-TRD believes that general and targeted information campaigns aimed both at consumers and businesses would go a long way in improving the process in the long-term. MSD-TRD referred to the fact there have been a number of cases where it was apparent that the impacted consumers had no prior knowledge of the possibility that a product could be recalled and the repercussions that such a recall would have on them.

MSD-TRD also indicated that there is scope for better use of and implementation of online inspections. MSD-TRD

[392] https://mccaa.org.mt/Section/Content?contentId=3005

suggested that apart from the introduction of changes within the same Directorate in terms of the introduction of specific processes and reporting templates and having a dedicated team of officers responsible for conducting online surveillance, there could be increased benefits if online market surveillance is targeted at an EU level. MSD-TRD is of the opinion that this could be done through a joint action or through a central forum responsible for online inspections for the whole EU market.

Under said proposal, inspections would be carried out on online sites that market products across the EU, such as non-EU/EEA e-commerce online markets like Alibaba. In MSD-TRD's opinion, this could be done through a concerted effort in the collection of data from specified online marketing sites or conversely with each Member State given particular products to focus on. If the processes to be adopted and the reporting formats are adequately predetermined, the work done by each Member State would then easily feed into the general and overarching inspection exercise.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Malta since 2013

MSD-TRD is of the opinion that there was a considerable improvement in terms of awareness both from the importers and the consumers and that this has translated into more compliant and safer products entering the Maltese market. MSD-TRD believes that while most of the economic operators are not aware of the GPSD and the obligations which stem from it, as a result of the interaction that they have had with customs or with the MCCAA, they are now more aware of what they need to do in terms of compliance. This heightened level of awareness is evidenced from the number of queries that the MSD-TRD and the other relevant entities within the MCCAA have received from economic operators prior to importation in the last few years. MSD-TRD views this as a very positive development which stems predominantly from the fear of economic operators of incurring potential losses or delays resulting from non-compliance with the GPSD and the relative national legislation.

The feedback received from the Standardisation Directorate within the MCCAA reflected to a large extent the opinion expressed by MSD-TRD. The Directorate stated that the general trend is a positive one and referred specifically to the more common reference to standards in the issuance of tenders by the Government and the private sector. This is evidence of an increased awareness of the applicable standards that need to be adhered to.

The Customs Department appeared to agree with MSD-TRD that there appears to be more awareness on the part of the major importers in terms of the product safety requirements. This awareness has not, however, in the Customs Department's opinion, translated to improvements in the level of safety of consumer products. The Customs Department is of the belief that particularly in the case of smaller importers and of the majority of consumers, their choices in terms of products imported and purchased are often driven by other considerations, primarily price and delivery efficiency.

The statistics available, for the reasons already referred to above, cannot be relied upon in terms of accuracy. Moreover, the data available does not evidence any emerging trends in terms of the level of safety of consumer products.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Malta whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

As already indicated in this report, MSD-TRD does not have the resources and tools to address the new challenges that it is facing as the national surveillance authority for all non-food and non-medicinal products. The Directorate is cognisant and very much aware of its deficiencies in these areas.

Nevertheless, the results achieved by MSD-TRD since 2013 take on a different significance when one considers the limited manpower available to the Directorate – 8 full-time employees – and the limited tools and resources available to it. If MSD-TRD is to evolve as a market surveillance entity capable of taking on new challenges in an ever-evolving market, it needs to be better equipped both in the terms of personnel and of the technological tools available to it.

Views of market surveillance authorities whether approaches in Malta can be considered best practice implementation of the GPSD, which could be of interest to other countries

There are no market surveillance approaches in Malta which could be considered as best practices in the implementation of the GPSD. It appears clear, for reasons already elaborated upon, that there is ample scope for growth in terms of the market surveillance efforts currently in place in Malta.

This belief is also shared by the MSD-TRD itself, which does not consider any of its market surveillance approaches to be best practices. MSD-TRD did however refer to the fact that while having all the responsibilities attributed to it in terms of market surveillance is a challenge, the fact that all the resources and actions taken are centralised has its positives. One such advantage is that communication between officers responsible under the different legislation is facilitated and therefore effective. Moreover, each officer has full sight and knowledge of the different responsibilities and actions taken within the directorate. This *modus operandi*, which to a very large extent is the result of the circumstances MSD-TRD finds itself operating in, can in certain cases translate into positive outcomes such as increased efficiency.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total (country)	***n.a.***	***n.a.***	**8**
Of which staff allocated to market surveillance activities regarding products sold online	*n.a.*	*n.a.*	**0.5**
Notes:	Figures for 2019		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*n.a.*	*n.a.*	**319**
Total number of consumer products inspected	*n.a.*	*n.a.*	**1313**
Total number of consumer products tested in laboratories	*n.a.*	*n.a.*	**69**
Total number of consumer products inspected in cooperation with the customs	*n.a.*	*n.a.*	**140**
Total number of dangerous consumer products found	*n.a.*	*n.a.*	**22**
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	*n.a.*	*n.a.*	**22**
Notes:	Figures for 2018		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)

Total number of voluntary recalls	*n.a.*	*n.a.*	**44**
Total number of mandatory recalls	*n.a.*	*n.a.*	**0**
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	*n.a.*	*n.a.*	**70%**
Notes:	Figures for 2018		

D. Key sources	
Legislation	Product Safety Act, Chapter 427 of the Laws of Malta Directive 2001/95/EC, Official Journal L 11, 15/1/2002, p21-34 Further Provisions for Product Withdrawal and Recall Regulations 2004 Coordination of Government Inspections Act, Chapter 568 of the Laws of Malta The Malta Competition and Consumer Affairs Act, Chapter 510 of the Laws of Malta
Studies/reports/articles	Malta Competition and Consumer Affairs Authority, Annual Report 2018, Retrieved on the 30th of October 2019, from https://mccaa.org.mt/media/4159/2018-annual-report.pdf Malta Competition and Consumer Affairs Authority, Annual Report 2017, Retrieved on the 30th of October 2019, from https://mccaa.org.mt/media/3457/2017-annual-report.pdf Customs Department, Annual Report, Retrieved on the 1st of November 2019, from https://customs.gov.mt/docs/default-source/Annual-Reports/annual-report-nbsp-2018-nbsp-(rapport-annwali-2018).pdf?sfvrsn=0 Consumers' Association submission, Response to the draft bill amending Chapters 379, 378 and other laws (April 2019), Retrieved on the 1st November 2019, from http://camalta.org.mt/wp-content/uploads/2019/04/GhK-Comp-Cons-Rpt-0818.pdf
Websites	http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1 http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10791&l=1 https://www.gov.mt/en/Government/DOI/Press%20Releases/Pages/2017/June/26/pr171536.aspx http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=22036&l=1 https://ec.europa.eu/commission/news/eu-rapid-alert-system-used-remove-dangerous-products-2017-mar-16_en https://mccaa.org.mt/Section/Content?contentId=4407 https://customs.gov.mt/docs/default-source/Annual-Reports/annual-report-nbsp-2018-nbsp-(rapport-annwali-2018).pdf?sfvrsn=0 https://www.mccaa.org.mt/Section/Content?contentId=1163. https://publicservicecms.gov.mt/en/Documents/Imporving_Business_Inspections.pdf https://deputyprimeminister.gov.mt/en/dhir/Pages/Registries/injuries.aspx https://www.maltachamber.org.mt/en/reform-in-government-entity-inspections-for-businesses https://apps.apple.com/mt/app/konsumatur/id1179983946 https://timesofmalta.com/articles/view/a-stronger-competition-law-deo-debattista.712332 https://timesofmalta.com/articles/view/landmark-ruling-for-estate-agents-group.565399 https://timesofmalta.com/articles/view/changes-in-competition-law-might-make-things-worse-consumers.714319
Interviews	Malta *Competition* and Consumer Affairs Authority, Market Surveillance Directorate Customs Department Malta Competition and Consumer Affairs Authority, Market Surveillance Directorate (Standardisation Directorate)

20. The Netherlands

COUNTRY REPORT THE NETHERLANDS

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The amendments to the existing Commodities Act[393] and the Decree on General Product Safety (hereafter the Decree on GPS)[394] implement the provisions of the GPSD. The amendments to the Commodities Act were published on 18 October 2005, and entered into force on 1 December 2005. The Decree was published on 27 October 2005 and also entered into force on 1 December 2005. Since the implementation of the GPSD, the substantive articles of both the Commodities Act as well as the Decree have hardly changed. (Legislative changes regarding the appointed authorities, enforcement and sanctions will be addressed under section I, subsection 4.)

The safety requirement under article 2 (b) GPSD as well as the benchmarks from art. 3(3) GPSD are implemented through the already existing and very general article 18, introduction and point a thereof, of the Commodities Act, which holds (unofficial translation): 'Without prejudice to the provisions under or pursuant to the preceding articles, it is prohibited: a. to market goods, other than food and drinks, of which the person who trades them knows or must reasonably suspect that their use may, due to their intended use, pose particular risks to human safety or health, or if concerns technical products, to the safety of objects.'

This article also forms the basis for enforcement in the non-harmonised sectors, as well as for the implementation and enforcement of vertical EU regulations and directives if specific norms regarding certain risks are missing.

The presumption of conformity from article 3 (2) GPSD, which applies when the manufacturer is complying with harmonised standards, is implemented through article 18a of the Commodities Act, which holds (unofficial translation):

'1. Goods that comply with standards designated by regulation of our Minister are, with regard to the risks regulated in those standards, not suspected of presenting any hazards as referred to in Article 18, under a.
2. Our Minister only designates standards that transpose European standards whose references have been published by the Commission of the European Communities in the Official Journal of the European Communities.'

Article 21 (1) Commodities Act enables the Minister to issue a measure to a trader to inform the holders of a product of its dangers (warning). Article 21 (2) Commodities Act enables the Minister to issue measures to order traders to cease trading goods or to take all necessary measures to take goods back (read: withdrawal and recall).

Article 21a Commodities Act holds the obligation for the Minister to make information relating to products and their risks to consumer health and safety available to the public. Article 21b (1) implements article 5 paragraph 3 GPSD and holds the obligation for a person who trades or has traded a product who knows or should know professionally on the basis of the information available to him that a product presents a danger to human safety or health, to inform the Minister thereof and to inform him of the measures which were taken to protect those interests. Article 21b (3) includes the duty for economic operators to cooperate with governmental actions.

The structure of the Dutch implementation differs from the GPSD in a sense that it holds a prohibition rather than an order (art. 3 (1) GPSD: producers shall be obliged to place only safe products on the market), but this does not appear to be an issue in practice.

Moreover, as the previous rapporteurs have mentioned, the Decree contains a drafting error regarding the implementation of article 1 (3) GPSD, by providing: 'this Decision [read: the Decree] does not apply to products if specific provisions of Community law have been adopted for the same purpose as the requirements laid down by this Decision.' The Explanatory Notes, however, do correctly speak of 'in so far as' (see also under 12 of the GPSD). Based on the interviews conducted as well as our own professional opinion, not all actors involved in market surveillance are aware of the exact scope of the GPSD, as explained in article 1(2) and preamble under 12 GPSD.

[393] *Warenwet*
[394] *Warenwetbesluit algemene productveiligheid*

Another implementation issue is the lack of explicit implementation of the criterion and benchmarks as mentioned in article 2(b) (i to iv) and 3(3) GPSD. The Explanatory Notes indicate that it was not considered necessary to explicitly implement the criterion and benchmarks as mentioned in art. 2(b) and 3(3) GPSD in the Decree (Explanatory notes, p. 3, 9 and 10). Therefore, in practice, the open standard that is mentioned under article 18 (and point a thereof)Commodities Act in combination with the European duty of consistent interpretation should warrant correct application of these benchmarks in case vertical EU legislation is absent, incomplete or when national regulations/norms and/or standards are not available. Article 18 (and point a thereof) Commodities Act functions as a safety net or catch-all clause because of its open wording. The lack of explicit implementation is not considered a problem from the perspective of market surveillance authorities (see paragraph II, subsection 7). At the same time, it is unclear to what extent the market surveillance authorities are actually aware of this inconsistency in implementation and the exact wording of the directive with regard to its definition of safety. At the same time, one can see that the factors that follow from article 2(b) (i to iv) and 3 (3) GPSD are taken into account when assessing the risks that are not addressed explicitly by the current legal framework other than article 18 (and point a thereof) Commodities Act. What the open wording of article 18 (point a thereof) Commodities Act further implies in practice for businesses in individual cases would require further investigation. For some findings regarding the absence of norms and the risks thereof from other reports, the interviews and other research, please see hereafter under section I, subsection 3. .

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in the Netherlands

Article 5(1) GPSD is implemented through article 2(1)(b) in conjunction with 2(2)(a) of the Decree on GPS.

Article 2 reads as follows (unofficial translation):

'1. The producer shall within the scope of his activities:

(..) b. take measures adapted to the characteristics of the product provided by him, to:

be informed of the possible safety and health risks of these products;

be able to take appropriate measures to avoid any possible health and safety risks, including:

- the withdrawal of the product concerned;

- the appropriate and effective warning of the consumer;

- the recall of the product concerned.

2. The measures referred to in paragraph 1 under b should be understood to include amongst other:

a. the indication, on the product or on its packaging, of the identity and contact information of the producer and the product reference, or if applicable, the batch of the product to which it belongs, unless omission of that indication is justified;

b. in all cases where applicable:

1˚ the carrying out of sample testing of marketed products;

2˚ investigation of complaints;

3˚ if applicable, keeping a register of complaints;

4˚ if applicable, informing the distributors of the monitoring of products.

The wording of Article 5 (1) (b) GPSD is ambiguous in a sense that it leaves open whether other measures would also suffice as measures within the meaning of art. 1 paragraph 3 GPSD. Although the wording of the Dutch implementation varies slightly from the English and Dutch official translations of the GPSD, the wording of the Dutch implementation holds almost the same ambiguity. In our view, a teleological interpretation of article 5 (1) (b) GPSD – in light of the goals and principles that underlie the directive – would indicate that article 5 (1) (b) GPSD at least holds some minimum requirements. In that case, the indication, on the product or on its packaging, of the identity and contact information of the producer and the product reference or, if applicable, the batch of the product to which it belongs, should be required under the national implementation, unless the omission of this information is justified. Article 2(2)(a) of the Decree on GPS should subsequently be interpreted in conformity with the directive, which would imply that art. 2(2)(a) holds (some) requirements. The Explanatory Notes to the implementation also hold the view that the indication of the identity and contact information of the producer is a

mandatory requirement. At the same time, the product reference or, if applicable, the batch of the product to which it belongs, is not mentioned.[395]

Neither the GPSD nor the national rules specify under what circumstances it may be justified not to apply the 'indication' as a measure. Apart from the example of the prayer card mentioned above, the Dutch legislative proceedings are silent on the issue and there are no decisive court decisions. It is questionable whether the nature and the potential risk of a product – as mentioned in the Explanatory Notes – is a suitable criterion to determine whether omission of 'the indication' is justified, especially since a products actual risk will often show itself after it has been placed on the market. Barcodes or electronic identification are not required under the Dutch implementation legislation but they may certainly constitute 'good practices'.

The traceability obligations of distributors mentioned in Article 5(2) GPSD are implemented by article 2(3) of the Decree on GPS, which reads as follows (unofficial translation):

'3. The distributor shall take part in the monitoring of the safety of the products placed on the market, especially by:

a. passing on information on the product risks;

b. keeping and providing the documentation necessary for the tracing of the origin of the products.'

The general duty of care that is mentioned in the first part of article 5(2) GPSD not explicitly mentioned in the Explanatory Notes but may be assumed to be implemented through article 18 (and part a thereof) Commodities act.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the national legislation of the GPSD in the area of new technologies as far as the Commodities Act and underlying Decrees are concerned. New technologies are however included in market surveillance.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Because of the wide scope of article 18 (and point a thereof) of the Commodities Act, new technologies, cyber security and other software related product threats are covered by the Commodities Act insofar as they result in physical health and safety risks and risks to other things. In practice, however, these risks remain a challenge for market surveillance authorities, not only because specific norms often are missing, but also because it is not always clear which authority is competent with regard to these risks. As explained below, a refrigerator with Wi-Fi falls under the competence of the Radio Communications Agency Netherlands (AT), a fridge without falls under the competence of the Netherlands Food and Consumer Product Safety Authority (NVWA).

It is uncertain whether risks regarding the loss of data, pure economic loss, lack of privacy and damage to honour and good name are covered by the Commodities Act. The latter risks may be covered by other legislation, but these instruments have not been included in this report. At this moment, article 18 (and point a thereof) Commodities Act does not appear to be used actively as a ground for action regarding these risks. More often, as follows from the conversations with authorities, it appears that authorities try to bring these risks under the existing vertical regulations and directives (essential requirements) and use this for a ground of action. Regarding the Internet of Things (IoT) with respect to internet connected devices, the official policy statement is that the Netherlands would like to see new norms under the Radio equipment directive (Roadmap Digitally Safe Hard and Software, p. 25).

[395] 'In Article 5, first and second paragraph, of the GPS directive, the aforementioned derived obligations for the producer and distributor are extended. For example, producers must take measures with regard to their products and operations that, if necessary, they will not only be able to warn the consumer but also to recall the product that is already with the consumer. These measures include the obligation to state the identity and the «contact information» (name and address but also: e-mail address, correspondence address, telephone number) of the producer on the product, «unless omission of that information is justified» (Article 5 (1) (b) (a)). During the negotiations in Brussels, the Commission mentioned a prayer card as an example of a product on which this information may be omitted. It may be clear that the identity of the producer is mandatory unless the nature of the product makes this unnecessary because no unacceptable risks can arise with the product in question.'

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Art. 3(3) GPSD leaves room to use national technical regulations for risks or categories of risks that are not covered by vertical legislation and/or harmonised standards.

In the Netherlands, new initiatives to national rules and regulations regarding the Commodities Act and underlying decrees are discussed in the General Commodities Act Consultation Group.[396] The last published meeting regarding the GPSD was in 2013 when the Product Safety Package was launched. Since then, various meetings have taken place regarding diverse risks and product problems, most outside the ambit of the GPSD. Areas of consumer products that are addressed by national legislation are for example legislation on tattooing inks and the safety of fairground and playground equipment.

The NVWA tries to include new risks to health and to the safety of objects in its market surveillance activities through various means. If no national legislation is created, policy measure may still address new risks. The art. 3 (3) (e) GPSD refers to the state of the art and technology as a benchmark in case any other norm or standard is missing.

The NVWA may use the advice of the Risk Analyses and Research Bureau[397] to identify and analyse new emerging risks. Also, universities and other experts may be consulted with regard to general risk analysis, although the resources of market surveillance authorities in that regard are limited. Furthermore, the NVWA has its own mechanical and chemical labs that are used to identify new risks to be included in market surveillance, but they may also help translate the knowledge gained into new and adjusted testing procedures. For certain risks, the existing harmonised product rules and standards or other technical standards may be used by analogy. Moreover, existing testing protocols may be adjusted to include new technologies that are not covered. Such new benchmarks may result in policy advice and adjusted policy or may form the basis of new market surveillance projects. In the latter case, such new benchmarks are often communicated with the industry involved before a new project is started. After a project is finalised, the research outlines including the standards and benchmarks used are published online with the project surveillance outcomes. Any internal testing procedures that have been applied but that have not been published may be requested from the NVWA. In this way, risk analysis and management based on the state of the art are fully integrated in market surveillance regarding non-harmonised consumer products.

As the analysis of case law regarding other product areas will show, this type of use of the state of the art and risk analysis where norms are absent appears to be accepted by Dutch national courts, as long as the risk analysis is sound (see section I, under 4).

One interviewee indicated that product safety codes of good practice (art. 3 (3) (d)) other than standardisation are also used, but a quick scan did not show any examples thereof. Reasonable consumer expectations concerning safety as a benchmark under art. 3 (3) (f), which is also used as defectiveness-criterion under the product liability directive, do not appear to be benchmark that is used for market surveillance, probably because it is too vague. Reasonably foreseeable use and misuse, however, are taken into account.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in the Netherlands in case there are consumer product(s) on the market which are found unsafe under the GPSD

The market surveillance authorities as administrative bodies have inspection powers as mentioned in article 5:13 t/m 5:20 of the General Administrative Act (Awb),[398] as well as specific powers as mentioned in the Commodities act (articles 26 to 32 a to k Commodities Act) and in the future also the ones mentioned in the Regulation (EU) 2019/1020 on market surveillance.

The authorities may require a business to provide relevant information on the product and on the supply chain and distribution of the product (art. 5:16 Awb). For business, there is a general duty to cooperate (art 5:20 Awb and 21 under b of the Commodities Act). Authorities may carry out unannounced inspections on site (art. 5:15 Awb and 29

[396] *Regulier Overleg Warenwet*
[397] *Bureau Risicobeoordeling & onderzoek BuRo*
[398] *Algemene wet bestuursrecht*

Commodities Act), in transportation vehicles (art. 5:19 Awb), perform physical checks of products (art. 5:18 Awb and art. 27 Commodities Act) and take product (batch) samples that may be tested (art. 5:18 Awb and art. 31 Commodities Act). Compensation has to be awarded if the product/property is damaged (art. 26 Commodities Act). The authorities may require insight into business information, administration and paperwork and are allowed to make copies (art. 5:17 Awb). They may perform mystery shopping and block websites if needed.

Each Market Surveillance Authority acts in accordance with its own specific Market Surveillance Policy. The NVWA's surveillance policy consists of the Market Surveillance Framework NVWA,[399] the General Intervention Policy[400] and the Specific Intervention Policy on Product Safety.[401]

The type of intervention depends on the type of violation. Violations are categorised in classes A to D as indicated in the General Intervention Policy.

A or B violation: A violation that under a realistic scenario may result in serious injury or serious damage to health.

C violation: A violation that under a realistic scenario may result in injury or damage to health.

D violation: A violation that does not concern a risk for injury or damage to health (such as formal non-compliance).

Annex 2 to the Specific Intervention Policy Product Safety holds the policy for enforcement of obligations regarding quality assurance for production.

The intervention policy documents are very extensive and the types of interventions are very diverse. These consist of informal interventions, corrective interventions or sanctioning interventions. Some interventions will be highlighted here.

The NVWA may use informal interventions that are not based on a decision. For example, the NVWA may provide a warning to an economic operator or feedback after inspection or investigation. The NVWA can carry out a re-inspection after feedback, provide compliance assistance by providing information about compliance with rules and issue warnings. The prevention of imminent reputational damage is an important motivation for market participants follow up on warnings. The NVWA may also use corrective interventions, such as an order to warn, recall or withdraw subject to a penalty payment[402] or an order subject to administrative enforcement (art. 32 Commodities Act).[403] The power of the Minister to issue measures to order a recall in case of danger to the safety or health of a human has been implemented through the amendment of article 21(2) of the Commodities Act. In case of an order subject to administrative enforcement, any costs regarding the administrative enforcement may be reclaimed in theory (art. 5:25 Awb). In practice, this option is hardly used. An order subject to a penalty payment, which means that the initiative is on the offender, is used more often.

The minister may issue a prohibition of trade of a product (art. 32k Commodities Act) or confiscation/seizure of goods (art. 32L Commodities Act), or order the destruction of goods (art. 32m Commodities Act). The costs of seizure or destruction may be claimed from the economic operator under art. 32n Commodities Act.

Recently, a new article 13d (1) Commodities Act was introduced that adds a procedure for mutual recognition in line with ECJ 27 April 2017, C.627/15 (Noria). Furthermore, a new art. 21d Commodities Act was added which gives the authorities the power to issue an export declaration for products which are destined to non-EU/EEA-countries and which are not in transit. Moreover, art. 32k Commodities Act, which implements article 8 (1) d GPSD, now allows the order of suspension of trade to be mandated to the market surveillance authorities to save time and make it more effective (in this case to the NVWA). When these changes will take effect has not been determined yet. (Collecting Law on Public health, Welfare and Sport 2018, Verzamelwet VWS 2018).

Individual decisions and decisions of the NVWA are not always disclosed, but as part of the active disclosure policy, more and more data are becoming available on its website, in particular summaries of inspection results. The publication procedure still falls under art. 8 paragraph 1 of the Law on Public Administration (Wob), the General Administrative Code (Awb) and established policy rules. To improve transparency, the Health Act and the Youth Care Act were amended in 2016, which will have major consequences for the NVWA's disclosure policy. It is expected that in the future about 200 000 documents per year will be made public. Publication of company or

[399] *Toezichtkader NVWA*
[400] *Algemeen interventiebeleid*
[401] *Specifiek interventiebeleid productveiligheid*
[402] *Last onder dwangsom*
[403] *Last onder bestuursdwang*

production data is not permitted under the Health Act, just like under the Wob. (Decision on active publication of market surveillance and execution of the Health law and Youth law,[404] and the decision on its entry into force).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Different penalties or sanctions are available, such as the administrative fine mentioned in the Commodities Act Decree on Administrative Fines[405] in connection with Articles 32a and b paragraph 1 of the Commodities Act, and criminal sanctions under the Economic Offences Act.[406]

The administrative fines under the Commodities Act may vary from EUR 525 to EUR 820 000. The Decree on Administrative Fines under the Commodity Act and its Annex[407] hold the categories of fines. The size of the company is relevant. Fines for companies with more than 50 employees are twice as high (Cat. 2) as fines for smaller companies (Cat. 1). Cat. 3 is a turnover-related fine. If an X is mentioned in the Annex under Cat.3, the turnover-related fine is applicable.

Article 18 under A Commodities Act is mentioned under A-1.1 of the Annex. The Decree on General Product Safety is mentioned under B-1 of the Annex.

The following fines may be imposed:

A-1.1 Violation of art. 18 under a Commodities Act: Cat 1. EUR 795, Cat. 2 EUR 1 590, Cat. 3 X

B-1.1 and B-1.2 Violation of art. 2 (1) (a) in conjunction with art. 2a (1) of the Decree on GPS: Cat 1. EUR 795, Cat. 2 EUR 1 590 Cat. 3 X

B.-1.3 Violation of art. 2 (3) in conjunction with art 2a (1) of the Decree on GPS: Cat. 1 EUR 525, Cat. 2. EUR 1 050, Cat. 3 X

B-1.4 Violation of art. 2a (3) of the Decree on GPS: Cat. 1 EUR 525, Cat. 2 EUR 1 050, Cat. 3 X

The turnover related fine was introduced in 2016 and entered into force on 1 July 2018, but is hardly applied in practice in non-food cases. Two additional cumulative requirements must be met to impose a turnover-related fine. Firstly, it must be established that the offence was committed with intent or gross negligence. Secondly, the offender must be a company with an annual turnover of more than 10 million euros per year. The turnover-related fine amounts to one percent of the annual turnover in the financial year prior to the offence if the behaviour referred to in the offence was committed with intent, with a maximum equal to the amount of a fine of the sixth category (Article 23 of the Criminal Code, being per 1 January 2016: EUR 820 000), or half a percent, if the behaviour referred to in the offence was committed with gross negligence. It is striking that the fine had never been imposed until October 2017. Although up until that point there were 55 offences that were eligible in general, the cumulative conditions were not met in any case. The council of state pointed earlier on the ambiguity of the requirements. Furthermore, it is uncertain when a violation of Article 18 of the Commodities Act is punished with a regular fine from the point of view of proportionality and when a turnover-related fine is imposed. This can in practice prevent the imposition of the fine. Although recent numbers were not provided, it was indicated that the turnover-related fine is hardly used in consumer product cases. It is used more often in food cases.

The Directive for the Criminal Procedure for the Commodities Act[408] forms the policy framework for the criminal enforcement of the Commodities Act. Criminal offenses/crimes against the Commodities Act (art. 32a, paragraph 3 of the Commodities Act) are classified as economic offences (art. 1 under 4 and art. 2 (4) of the Economic Offenses Act (WED)). The maximum penalty that can be imposed for this is six months' imprisonment or a fine of the fourth category (Article 6, paragraph 1, subsection 5 of the WED). In the aforementioned advice of the Council of State, it was already pointed out that with the introduction of the turnover-related fine, the administrative sanctioning would go beyond the criminal sanctioning. Up to now, this inconsistency has not been corrected.

Recent case law in the Netherlands with respect to or relevant for the GPSD/the national implementation legislation.

[404] *Besluit openbaarmaking toezicht- en uitvoeringsgegevens Gezondheidswet en Jeugdwet*
[405] *Warenwetbesluit bestuurlijke boete*
[406] *Wet economische delicten*
[407] *Warenwetbesluit bestuurlijke boeten en de bijlage daarbij*
[408] *Richtlijn Strafvordering warenwet*

Not all court cases are being published in the Netherlands. Among the court cases published between 2013 and 2018, three cases of courts in first instance mentioned article 18 (under a) Commodities Act.

Rb. Rotterdam 4 April 2013, ECLI:NL:RBROT:2013:BZ8322 regarded wishing balloons. The court found that a violation of norms which were developed by the NVWA in consultation with stakeholders, may constitute a violation of article 18 (and paragraph a) Commodities Act. Therefore, the decision holding an administrative fine of EUR 525 was upheld. Two other decisions were annulled on the basis of incorrect information in the formal reports.[409]

Rb. Rotterdam 1 May 2018, ECLI:NL:RBROT:2018:3492, regarded candle bags. Based on tests applying the flammability criteria for toys by analogy (NEN-EN 71-2:2011 + A1:2014), the NVWA issued a decision holding an order to recall subject to a penalty payment of EUR 1 000 per week with a maximum of EUR 15 000 (art. 32 Commodities Act). According to the judge, the decision of the NVWA was not manifestly unjust or incorrect.

Rb. Rotterdam 23 October 2014, ECLI:NL:RBROT:2014:8551 regarded nitrosamine in balloons. The court held that a decision of the NVWA in which the trader is informed that no penalties shall be imposed may be classified as a formal decision.

There was only one lower court case that explicitly mentioned the Decree on General Product Safety: Rb. Middelburg 13-04-2005, ECLI:NL:RBMID:2005:AT4286.[410]

The lack of published cases mentioning article 18 (under a) Commodities Act and/or the Decree on GPS is probably due to the fact that a lot of products and decisions fall under vertical EU legislation. Moreover, a lot of the published cases under the Commodities Act regard food and feed.

The legal department of the NVWA has provided a judgement in interim proceedings that has not been published as well as a decision of the Minister of Health, Wellbeing and Sports – under whose responsibility the NVWA formerly operated -after a declaration of objection by an economic operator regarding the Decree on GPS which – like other decisions – has not been published, which will be discussed below.

The court case Rb. Rotterdam 14 August 2013, ROT 13 / 4577 BC WILD (not published) regards a recall of table fireplaces on the basis of article 18 (under a) in conjunction with art. 2a (2) of the Decree on GPS and art. 21 Commodities Act. A total recall was found disproportionate by the judge in interim proceedings because a warning together with an adjustment to the fireplace – a metal ring – to be put in place by the consumer would take away the risk.[411]

The decision by the Minister on a declaration of objection by an economic operator concerns a high-chair for children with a double table top that carried the risk of entrapment of fingers. The product was assessed by NVWA under the responsibility of the Minister on the basis of NEN-EN 14988-1;2006+A1:2012 and was found in violation of art. 18 (introduction and part a) Commodities act. Because it concerned a low risk, the violation was classified by the NVWA as a C violation after which the economic operator was directed towards its existing obligations to take corrective measures (e-mail of 7 September 2015). This required it to stop selling the product, inform its customers and provide a list of buyers of the chair to the NVWA. The economic operator was subsequently warned by the NVWA by a letter holding that if the economic operator would not comply with the aforementioned legal obligations, administrative or criminal proceedings could be initiated (18 September 2015). The economic operator objected to this warning, stating that both the e-mail as well as the letter qualified as an administrative decision subject to objection and appeal, which should make the objection admissible and that the decision was unjust. The Minister found the objection inadmissible with reference to existing case law. From case CBB 21 July 1998 (AB 1998, 437) and CBB 2 March 1999 (AB 1999, 168 it follows that a request for documents by the authorities does not

[409] In 2009 the NVWA organised a market surveillance project on wishing balloons. No specific norms were available at the time regarding this type of product. Therefore, the NVWA made its own risk analysis and developed norms after consultation with stakeholders. The norms that resulted from this analysis were communicated to the industry, stating that wishing balloons not complying with these norms were prohibited as of 1 January 2010 and that this prohibition would be actively enforced from 1 May 2010 onwards.

[410] It was a criminal lawsuit against a manufacturer of play houses that had a gap between the house and the connected slide. A child had died using this slide because the string of his hoody got trapped in the gap after which he choked. The manufacturer had received earlier complaints regarding the slide, but did not follow up on them. The court uses the Decree on GPS in the reasoning leading to the conviction of the manufacturer to criminally negligent homicide/involuntary manslaughter.

[411] This alternative solution was put forward by the importer of the fireplace. It substantiated its argument with reference to a test performed by KIWA in accordance with DIN 4734, which was accepted. The order to recall subject to a penalty payment was adjusted accordingly by the judge.

qualify as an administrative decision.

Furthermore, the Minister refers to three cases, the first two being of the highest administrative courts and the last one of a court in first instance (Rotterdam): CBB 27 February 2007 (ECLI:CBB 2007:AZ9917), Afdeling bestuursrechtspraak van de Raad van State 8 July 2009 (ECLI:NL:RVS:2009:B]1862) and Rb. Rotterdam 30 June 2011 (ECLI:NL:RBROT:2011:BX8131). Mere warnings by authorities to economic operators directing them to their existing obligations under law in principle do not qualify as decisions as defined in the General Administrative Act because they do not constitute in themselves any legal effects. According to the CBB in its case, an independent and definitive decision on the applicability of a legal provision in a given situation by an authority, may in very special cases be regarded as the performance of a separate legal act under public law, which can be challenged before the competent administrative court. However, such a qualification is not justified in cases in which the decision on the legal position anticipates an administrative decision concerning the person regarding application of legislation which can be challenged in court without there being any question of a legal disproportionately burdensome way to court. In other words, only in case it is disproportionately burdensome for the economic operator to wait for an administrative decision, the initial letter/warning is subject to objection and appeal. In the case of the CBB, the mere notification to an economic operator of its infringement of the Toys decree was insufficient to constitute an administrative decision.

According to the Minister in the decision of 28 April 2016 regarding the high-chair, a mere interest in judicial proceedings/review is insufficient. Furthermore, the Minister does not find the way to court disproportionately burdensome because the chairs may still be traded without the table top. Therefore, the Minister found this part of the objection inadmissible. Superfluously, the objection was also found unfounded because the norm was applicable, applied correctly by the authority after which the economic operator was found in violation thereof. The decision of the authorities to publish the findings regarding the product was also not considered unlawful.

It is interesting to note that an internal committee of the Ministry advised differently in the case of the high-chair.[412] As far as we know, the decision regarding the high-chair by the Minister on the objections was not challenged in court.
It is worth noting that outside the ambit of the GPSD, the legal status of warnings and other letters by authorities to economic operators not aiming at producing legal effects are often discussed in legal proceedings.[413]

There are also cases that do not concern the implementing legislation of GPSD directly, but which still might be relevant for the GPSD and/or the national implementation legislation.

A case which might be of interest in light of the questions regarding alternative benchmarks for assessing safety is Rb. 05-11-2018, ECLI: NL: RBROT: 2018: 8990.[414]

In CBB 09-09-2015, ECLI: NL: CBB: 2015: 311 the Highest Administrative Court accepted the adjustment of an existing test by the NVWA lab with regard to a risk that is not covered by the applicable standards in line with the state of the art.[415]

[412] This committee can be consulted as an advisory board by the Minister regarding submitted objections, before deciding on them. In this case, the committee was consulted by the Minister and it gave an advice to the contrary. Unlike the Minister, the committee found that – based on the same case law – both the e-mail and the letter should qualify as administrative decisions subject to an objection: 'Any other interpretation would lead to the unacceptable result that an economic operator would have to wait for a long time until it can challenge a decision that clearly has consequences for its position. In light of the current prohibition to trade the product, it is impossible for the economic operator to trade the product other than without the alleged table top, or else the economic operator would be forced to provoke a decision including penalty payments. Meanwhile the economic operator has to inform its customers of the prohibition which may cause reputation damage and may trigger possible claims. In light of these circumstances, the economic operator has a real interest in a judicial decision on the applicability of article 18 (introduction and under a) of the Commodities act.'

[413] In CBB 28 December 2016, ECLI:NL:CBB:2016:405 the highest administrative court also held for example that a letter of the Minister holding that it is prohibited in the Netherlands to market a supplement with 100 microgram vitamin D, is not a decision subject to objection and appeal because if regards the observation of an already existing legal situation. See also CBB 23 August 2012, ECLI:NL:CBB:2012:BX6798 regarding a letter of the Minister pointing the economic operator at his recall obligations under art. 19(1) Regulation (EG) 178/2002 regarding meat. This was not considered an administrative decision, neither was a letter by the NVWA holding that it will not pay damages because it contacted customers of the economic operator with the request of destroying the products.

[414] In this case, the court of first instance decided that the NVWA, in assessing whether the manufacturer has classified toys the right way, may rely on documents that are not generally binding regulations, just as so-called NEN standards are not binding regulations. The relevant documents, including CR 14379: 2002 (E) "Classification of toys - Guidelines", may provide a guide for explaining legal standards. That document lacks specific guidelines for the age classification of toy music boxes and toy parking garages. NVWA could therefore reasonably use the document CEN-ISO / TR 8124-8 "Age determination guidelines".

Rb. Rotterdam 24-11-2016, ECLI: NL: RBROT: 2016: 9046 regarded imitation products and the assessment of the risk of (among other things) suffocation, poisoning, perforation or blockage of the digestive tract. Neither the Directive nor the Commodities Act Decree on Imitation Products prescribed how that danger must be determined. According to the court, it was desirable that the assessments by EU countries did not differ because the Decree was the implementation of a directive. Because a PROSAFE report, in which 21 countries participated, expressed a preference for the bite test of NEN-EN 716-2, the court considered it reasonable that the NVWA applied that standard in its tests. The court ignored the test results submitted by the plaintiff, which would indicate that that standard was considered unsuitable, because this test did not show that this was the case. The fact that the choking hazard for children when eating certain cookies, sweets and apples would have been greater was not considered relevant. According to the court, the risk of putting, imitating or swallowing imitation products in the mouth could not be compared with the danger of putting, sucking or swallowing food.

With regard to the use of harmonised standards, ABRvS 28 October 2015, ECLI:NL:RVS:2015:3295 under 3.2 is worth mentioning. This judgement from one of the highest administrative courts confirmed that a market surveillance authority may never issue a measure on the sole violation of a harmonised standard. Measures always need to be based on a legally binding provision.

In CBB 17-05-2016, ECLI: NL: CBB: 2016: 136, another one of the highest administrative courts pointed out that harmonised standards are not binding and that alternative ways of demonstrating conformity with essential requirements must be accepted.[416]

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in the Netherlands concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Not all economic operators are aware of their obligations with respect to traceability and/or can provide details of their suppliers/buyers up and down the supply chain.

It was indicated that the definition of safety in the GPSD is too wide. Because of the fact that the criteria as mentioned in art. 2 (b) and 3 (3) GPSD are not explicitly included in the Decree on GPS and because article 18 (under a) is not limited to consumer products, it is indeed a very wide definition. At the same time, the advantage of the broad safety requirement under article 18 (under a) Commodities act is that virtually any risk created by a product to health and safety of people and/or things is covered. As stated before, it is unclear whether risks other than risks to health and to the safety of objects are covered by the material scope of the GPSD (like risks to economic loss, violations of honour and good name). At this moment, the GPSD appears not to be used actively as a safety net regarding new types of risks regarding risks other than health or safety of objects.

Possible improvements to make the implementation of the GPSD in the Netherlands more effective

The suggestion to introduce a requirement for business operators to keep supply chain records – 'one up one down' traceability – was very much welcomed by the relevant authorities (see also RAPEX below). Some also opted for the suggestion to add a barcode. An obligation to place a batch number on a product was seen as useful. At the same time, its usefulness must not be exaggerated in terms of market surveillance. Taking samples of a certain

[415] It concerned standards applicable to the contact plug part of a battery charger. The court was of the opinion that when testing the battery charger, the predecessor of the NVWA (VWA) took sufficient account of this specific product by adjusting the fall drum test with regard to the number of revolutions. According to the court, the Minister rightly argued that it would be going too far to refer to paragraphs 16-1 and 16-4 of standard EN / IEC 61558-1 (in which it is stipulated for safety transformers) that bending of the pins should be ignored also with regard to the assessment of the test result of the fall drum test of a battery charger. If it had really been the intention that the bending of the pins in the fall drum test for a product like this should be ignored, one would expect, in the opinion of the court, that this would be explicitly stated in the applicable basic standard (EN / IEC 60335-2-29) for the battery charger. The argument of the company that traded the battery charger that the battery charger in question is equivalent to a safety transformer in such a way that the more flexible requirements of EN / IEC 61558-1 and 61558-2-6 with regard to the assessment of the test result of the drop drum test could suffice did not convince the court. The appeal lodged by the Minister was well-founded. The judgments under the appeal were annulled.

[416] The case concerned Christmas lighting candles and the Commodities Act Decree on electrical products. Article 4 (1) of the Decree on electrical products allows the safety standard contained in Article 3 of the Decree to be met through means other than by complying with the standards included in § 5.2.10 of EN 60598- 1 and § 20.10.2 of EN 60598-2-20. It is not decisive whether the legal presumption within the meaning of Article 4, first paragraph, of the Decree is met. What is important is that at least the essential requirements listed in the appendix to the Decree are met. The company had sufficiently demonstrated that the electrical product according to the rules of good workmanship that apply in the EEC / EEA, with proper installation, use according to their destination, and proper maintenance, did not endanger persons, pets or goods. The Minister had not made a plausible case to the contrary. The proceedings were reopened in connection with the determination of the damage.

batch that prove to be non-compliant does not mean that other batches of the same product are also not compliant. Even within one and the same batch, products can differ.

In our professional opinion, a barcode or a unique product code may drastically improve market surveillance with regard to traceability, but to determine its feasibility and possible effectiveness a further assessment would be required. Also, one should determine the possible information that would be linked to this unique product code as well as the persons to whom this information is accessible (also other economic operators for example). At the same time and as indicated before, non-compliance of one product does not automatically result in non-compliance of another product from the same batch which also puts the usefulness of a barcode a bit into perspective. With regard to national market surveillance, it is important that the needed IT is in place with market surveillance authorities as well as economic operators to make such a system a success.

The overall impression is that market surveillance is easiest when specific product norms are available. As soon as a product or technology is not covered by specific technical regulations and/or harmonised standards, the authorities have to resort to other technical regulations and/or standards (national or from other countries), application by analogy or the state of the art. This is explicitly allowed under the GPSD and is also a practice in the Netherlands which the NVWA uses, even though these benchmarks are not implemented explicitly. At the same time, applying the state of the art requires a lot of time, effort and resources at a national level (consultation with scientific expertise, testing facilities as well as industry and stakeholders), while resources are often lacking in this regard. Enforcement requires some specification by the authorities as soon as they want to take specific action. Any knowledge gained in this regard or lack of standards is addressed already in the Administrative Cooperation Groups (ADCOs) regarding specific product groups. Most new IT technologies have clear connections with LVD, Radio equipment and/or EMC. Within the already existing EU regulatory landscape it is hard to determine which role the GPSD has to play, and whether, and if so how, this flow of information regarding new technologies has to be institutionalised.

In the view of the authors of this report, it would be desirable to make use of the knowledge that already exists under vertical instruments (existing ADCOs etc.) next to providing more guidance regarding the exact scope of the GPSD regarding risks that do not concern risks to consumer health and physical safety. Whether the GPSD will be used as a safety net in practice regarding these new types of risks depends on much more than clear scope and definitions. It is unclear whether the national authorities have the capacity to include the state of the art regarding these new types of risk in the policy and project-based market surveillance the way the NVWA sometimes does with regard to new risks that concern physical health and safety of objects.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in the Netherlands.

At the national level:

Market surveillance on all products is split between six national surveillance authorities, each entrusted with its own sector of products. Market surveillance on the safety of consumer products within the ambit of the GPSD rests with one surveillance authority, the Netherlands Food and Consumer Product Safety Authority (NVWA). The NVWA falls under the responsibility of the Ministry of Agriculture, Nature and Food Quality. Three other national authorities are also involved with market surveillance on consumer products, but only for very specific and limited categories of products: The Radio Communications Agency Netherlands (AT, for RED, EMC and Measuring instruments), the Public Service on Road traffic[417] (for type approvals for road vehicles) and the Human Environment and Transport Inspectorate (ILT, for machines, pyrotechnic articles, construction products and recreational crafts). They do not have any explicit competences with regard to the implementation – the Commodities Act and the Decree – and therefore the enforcement of the GPSD.

Because of the revision of the Radio Equipment Directive and ECM Directive, which were implemented in 2016, Low Voltage Directive products (LVD products) with IoT-applications are now under the supervision of AT. This implies that a refrigerator which is connected to Wi-Fi falls under the authority and supervision of AT and a regular fridge falls under the authority of the NVWA. With regard to aspects that are not covered by vertical EU legislation that are covered by the GSPD, the NVWA is the competent authority. This requires a lot of cooperation between

[417] *Rijksdienst Wegverkeer*

these two authorities. The full picture on how this cooperation functions in practice is uncertain.

The NVWA is responsible for the vast majority of consumer products. In practice and in addition to these two authorities, customs have a very important practical role in the border control of products.

There are not market surveillance authorities at sub-national (regional/provincial/local) level

Plans/programmes in place which define priorities for market surveillance of consumer products

Market surveillance is founded on risk-based surveillance. It is focused on the product groups and risks (product and compliance behaviour) that can have the largest impact in terms of impairing and undermining (harming) the public interests protected by European product legislation if the statutory requirements are not met. A number of factors play a role in determining this impact: product volumes (exposure); the extent of the anomalies within the product group (compliance level); the defects that have occurred (serious risk) and the types of suppliers of these products.

The NVWA annually sets its priorities in its annual plan that also concerns food and feed. The annual plan of 2019 mentions that 6% of the NVWA's capacity concerns safety of non-food products. Internet sales have been identified as a horizontal area that requires special attention, which was a priority in 2019. Furthermore, sectoral market surveillance programmes were drawn up.

Accident registration and reports, complaints, market developments, developments in legislation and regulations, signals from (international) colleague supervisors and knowledge institutes and information about (potentially) risky consumer products or (poor) compliance of companies lead to analyses on the basis of which the NVWA makes a risk assessment and prioritisation for supervision. The NVWA then determines the supervision type and a research plan. When an action has been taken and/or a project has been rolled out, the NVWA reports and publishes the results and/or provides policy advice. The NVWA also processes complaints from consumers or companies in its supervision.

The following information was retrieved from the surveillance plan over 2015/2016 which was drafted for the European Commission in light of Regulation (EC) 2008/765, which still is applicable for the NVWA and is also relevant with regard to the GPSD. It is partially based on the Market Surveillance Framework NVWA 2015, which is still applicable, and this approach is also reflected in the 2016 report called the Status of Product Safety. Furthermore, these findings also return in the report for 2014-2017 which was provided to the European Commission in light of art. 18 Reg. (EC) 2008/765:

'The surveillance is risk-based. It focuses on tackling those businesses which, because their products do not comply with product safety legislation, have the greatest impact on the health and safety of consumers. For this purpose, the NVWA uses a priority matrix incorporating the conduct of businesses and types and volumes of their products. As a result, proactive surveillance has gone from being purely product-oriented to more business-oriented in recent years. This is for reasons of efficiency. The target group for proactive surveillance – identified with the use of the matrix – is a core group of around 3 000 enterprises that:

- Are together responsible for 85% of relevant products placed on the market (high-risk products that regularly involve anomalies and therefore present real risks to the consumer); and

- Regularly exhibit failings in terms of compliance.

Many of these businesses are EU importers with large commercial volumes of a huge range of different types of high-risk products. The majority of these products come from China. The specific group of operators needs to ensure compliance for all these product groups. Business-oriented surveillance focuses on encouraging compliance at these companies. This is done, for instance, by checking as many types of products as possible at the same company (business-oriented product surveillance). Another form of business-oriented surveillance that has grown massively is system surveillance. This involves using audits to check a company's quality system, if it has one, and to check whether it is geared to assuring compliance with product safety legislation. Companies with a demonstrably well-functioning system are subjected to less surveillance.

The NVWA helps companies to develop such systems (compliance assistance). System surveillance yields good results at companies those want and are able to invest in compliance and that also trade in many different types of product groups. A good system ensures that all those products comply with the legislation. This is explicitly not a form of ex ante supervision. The surveillance is intended to encourage business compliance with the product safety legislation (requirements that products have to meet and any conformity procedures). For example, there are controls to see whether the business operator ensures that the specifications of the product ordered match the

applicable statutory product and conformity procedures and/or whether he/she checks whether the products supplied meet the specifications, for instance by spot checks. The surveillance also looks at whether the business has a complaints procedure in place. Elements of such a system are to be found in the General Product Safety Directive (Directive 2001/95/EC).

However, not all companies are able to put this kind of system in place, so for those companies supervision takes the form of product testing. Samples of various product groups are taken at the same company wherever possible. Not only does this make the sampling more efficient, it also provides a picture of the general standard of compliance in the company. The capacity saved in this way is used to concentrate on identified recurrent offenders (the 'hard-line where necessary' approach).

Alongside this business-oriented approach – which focuses on the conduct of significant players – there is also purely product-based surveillance. Its purpose is to gain a national picture of the safety of a particular product or product group. The samples needed for this are taken not only from the core group of 3 000 enterprises but rather from as broad a spectrum of operators as possible, including retail outlets and market traders.

Less product-oriented surveillance means less sampling and fewer laboratory tests and more audits and monitoring. The decision has also been taken to concentrate more on external border checks rather than market surveillance.'

To date, the proactive surveillance of the NVWA still takes up approximately 60% of the agency's capacity. The remaining 40% is dedicated to reactive surveillance (RAPEX notifications and consumer complaints, etc.). The NVWA is still involved in European and international ventures with a view to improving the surveillance chain (coordinating export and import checks). The internet sales through web shops and other online platforms appear to have increased.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in the Netherlands with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance on products that contain IoT-technologies is mostly conducted by AT, the authority responsible for IoT and the related vertical instruments (RED, EMC etc.). As indicated before, AT does not have any competences with regard to article 18 (under a) Commodities Act and/or the articles from the Decree on GPS that implement the GPSD.

On a national level, the Ministry of Economic Affairs and Climate together with the Ministry of Justice and Safety have published a report in April 2018, a Roadmap for Digital Safe Hard- and Software, with measures regarding new technologies. The focus is on new standards and certification at the EU level of connected devices partially through the RED Directive. In addition to this, more monitoring on digital safety of products, better market surveillance and information campaigns and empowerment of consumers are on the agenda. The government wants to start a pilot on a shared testing platform, together with business, government and TNO (a Dutch research and advisory organisation). Market surveillance on these products that goes beyond the existing vertical directives and regulations appears to be very limited at the moment.

Market surveillance on C2C products is not actively included in the projects because of budgetary constraints. Any market surveillance regarding C2C products is mostly reactive, based on complaints. A lot of C2C products are offered through the website Marktplaats.nl. The NVWA has entered into a partnership agreement withMarktplaats.nl.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

All market surveillance activities try to include products that are sold online. The estimates regarding the percentage of market surveillance activities that focus on products online differ quite a lot, from 6 up to 40 percent. Exact data are lacking. Products are bought by the NVWA through online retailers' websites, comparisons websites, social networks and online marketplaces. According to most interviewees, products sold online in the Netherlands are included more than once a week, products from other Member States once every six months, and products from outside the EU once a week. A lot of the market surveillance is project-based, which makes it hard to give an estimate.

Most market surveillance of online products is project-based: online samples are taken together with offline samples. Online market surveillance is fully integrated in all NVWA's product-focused projects. All projects are risk-

based, focusing on products that can cause serious damage to health and safety when not in compliance with requirements and businesses offering those products that have a track record of non-compliance. For online sales, this means that the NVWA target expected low compliance shops and platforms and buys samples there. Chinese suppliers and especially platforms like AliExpress and Amazon are part of that selection. With these types of sales, mystery shopping is hardly necessary to get the right i.e. representative and non-manipulated samples (not being golden samples). Mystery shopping is rarely used (once a year or less). It is used when buying through social networks. In exceptional cases, mystery shopping is necessary. There is a small niche: small manufacturers that produce chemical products/substances. In those cases, it is possible that a golden sample is provided.

The bought products are assessed in the laboratories and in case of non-compliance, the website, for example, is informed of the results. Corrective action may be demanded and fines may be imposed.

The biggest challenges regarding online sales are the limited enforcement options and lack of staff and resources. It is hard to find experienced officers with the right internet and machine search skills. The EC Notice on market surveillance of online products and the product safety pledge are seen as helpful.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in the Netherlands (except customs) with respect to product safety

The Dutch market surveillance authorities and the customs authorities discuss topics and activities in a permanent national forum (Alliance working group on product market surveillance and external border checks), which was set up for this purpose in 2008 and is chaired by the NVWA. This is where, amongst other things, the positions of the market surveillance authorities and the customs authorities for input at the EU level (indicative multiannual programme on market surveillance, horizontal issues in ADCOs are agreed upon. The Alliance concerts cooperation at a more strategical level. Meetings with other authorities in the Netherlands are organised once every three months. The NVWA is the RAPEX contact point for other market surveillance authorities such as the AT and ILT. The other authorities are included in preparing the national market surveillance programmes. Furthermore, there is regular exchange of information, meetings and informal cooperation. NVWA does lend expertise and offers laboratory capacity to do sample tests. Furthermore, there are workshops, conferences and joint market surveillance authority (MSA) projects.

Cooperation with customs authorities in the Netherlands with respect to product safety

The NVWA has a long-standing working agreement with customs.[418] Next to this agreement, a list of priority products, countries of origin and - when possible - economic operators is concluded every year between customs and the NVWA. On the bases of digital loading bills, customs duly informs the NVWA when a ship or plane carrying cargo that corresponds with the mentioned priority list is coming in. The NVWA then decides whether or not to inspect the goods in question. The market surveillance authorities then inspect the products upon import (i.e. before they are released for free circulation). Cooperation may also be more on a project basis. This is an efficient solution for the situation in the Netherlands, given the large volume of goods imported into the EU every day through the Port of Rotterdam.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with other EU/EEA countries takes place through RAPEX and ICSMS, coordinated actions at EU level, mutual assistance requests outside of RAPEX, joint training sessions, regular exchange of information and meetings. In specific cases, the authority contacts the economic operator directly, but mostly they communicate via the economic operator in the Netherlands. In cases where an economic operator is from another Member State, the authority gets in contact with the economic operator by mail or letter pointing out that it is offering a product that does not comply with EU legislation/national legislation and urging it to alter or stop offering the product. If there is no adequate reaction from the economic operator, the authority contacts a colleague MSA in the country of the economic operator and asks them to intervene. Authorities in other countries are contacted in cases where a specific product that was found was manufactured in that country, for instance, to see whether they have more

[418] *Het samenwerkingsconvenant NVWA/Douane*

information on the product or manufacturer.

Cooperation with non-EU/EEA countries is only through informal cooperation. In general, no action is taken against economic operators outside the EU/EEA or action is taken knowing that the success rate will be very low. Therefore, the NVWA tries to invest in educating e-shoppers instead. It can also lead to making a specific arrangement with customs targeting their inspections towards a specific product or supplier. The NVWA communicates with economic operators outside the EU/EEA only in cases where economic operator asks them to have contact.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Market surveillance authorities indicated that when a product is found during market surveillance that may pose a risk for a serious injury or a serious health hazard, an official report is drawn up. At the same time, all information to fill in the RAPEX form is collected. Laboratory testing is often part of this process. The RAPEX form is filled and a risk assessment is made. If the result of that risk assessment is a serious risk, then the RAPEX form is sent to the RAPEX contact point. This process in general takes more than two weeks. It takes some time to collect all the information that is needed to fill in the RAPEX form.

There appear to be no particularities regarding the cooperation between the RAPEX contact point at the NVWA and the persons involved in market surveillance.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The NVWA has stakeholder meetings with associations 2 to 3 times a year. In light of previous experiences however, stakeholder associations do not always have a representative view on the problems their individual members encounter. Therefore, the NVWA also sometimes contacts individual companies and market leaders next to stakeholder associations. The biggest challenge is to include SMEs in the process: they are less organised and more difficult to reach. About 90% of all businesses involved in consumer products are SMEs.

Moreover, in the framework of inspections, there is a continuous information flow between the inspector and the company on product safety issues and how to improve compliance. The NVWA also tries to organise stakeholder meetings when projects are being launched and/or measures are being imposed, because in their experience this increases the willingness to comply.

The NVWA also uses company-based inspections (as an alternative to product inspections) focusing on the quality systems of the economic operator, which means a dialogue on how to optimise the system to ensure that only safe products are being distributed or placed on the market. At the same time, the NVWA does not have the capacity to provide extensive guidance, nor is it in the position to act as a consultant.

It was also indicated that businesses and their associations are reluctant to cooperate with the NVWA.

Partnership agreements are also being used, for example with Marktplaats.nl, an online platform for the sales of consumer products and second hand products, and with bol.com, the biggest online shop and platform in the Netherlands for consumer products. These partnership agreements are similar to the EU product safety pledge that has been drawn up at the EU level in cooperation with the four biggest international online platforms.

The NVWA meets with consumer associations once a year. It processes complaints they issue about products and/or follow up on products that they have tested. The association sometimes provides its tests results which may also be used for the basis of the NVWA testing.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

In addition to the cooperation methods mentioned above, awareness of businesses is raised through the NVWA website. All relevant information is there, but the accessibility of the website and its design may be improved. In light of the new Market Surveillance Regulation 2019, the NVWA is currently discussing the ways in which it will further design the product contact points in the Netherlands with the Ministry.

Awareness of consumers is raised through publications on market surveillance projects, such as the hoverboard project in March 2019, which are picked up by media. Other examples of projects were hand disinfectants (April

2019), balloons (February 2019), lighters (September 2018), floating devices for children (July 2018), baby dolls (November 2017), leather gloves (October 2017), painted wooden toys (July 2017), UV-protective swimming gear (July 2017), eye creams (June 2017). A full list can be found on the website.

The NVWA website also includes notifications on dangerous products and other information campaigns, for example on e-shopping. The NVWA has its own Facebook page and Twitter account. A recent information campaign on online sales of products from outside the EU was launched in light of the holiday season and just before Black Friday (national sale) through social media. It was picked up by the news and other media as well (laatjenietinpakken.nl).

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in the Netherlands (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

In general, economic operators cooperate when a non-compliant product is found. In case of a serious risk, an order to withdraw or recall the product is given if an economic operator does not perform a recall voluntarily. If the economic operator is not willing to recall voluntarily, the economic operator is ordered by an administrative warrant often under a penalty payment in case the economic operator still refuses to take action.

The authorities indicated that it is difficult to provide uniform benchmarks or a standardised procedure because the supply chains, types of products and risks differ. For example, web shops are able to contact their buyers directly through email, but regular shops often have to use social media and traditional media. NVWA does check whether an advertisement is adequate, for example, and through which channels it is communicated. NVWA does assess the overall recall strategy of an economic operator. The focus is on how to remove the risk/product from the market as effectively as possible. This requires a different approach in each case.

With regard to the communication to consumers, a recall when done by the economic operator is communicated by placing the recall from the economic operator on the NVWA site and communicating through social media.

A code of good practice regarding recalls does not exist. NVWA does have an internal working instruction (werkvoorschrift) in place that provides some benchmarks. This document is not publically available.

Monitoring of effectiveness of product recalls by market surveillance authorities

The NVWA monitors the recall and requires information from the economic operator on the results. In general, regarding mandatory recalls, the NWVA requests proof of the notifications and advertisements, proof of the recall and of the destruction (e-mails, letters, invoices etc.). If necessary and if a recall takes longer, an economic operator may be asked to provide monthly updates and overviews of the products returned. The results in absolute number of product returns are requested as well as a percentage. Spot checks are also performed.

6. Availability of statistics relevant for market surveillance

Availability of statistics in the Netherlands that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Injury and accident figures from the injury recording system of the Safe Netherlands Foundation (veiligheid.nl) are used to verify the priorities. This database contains data on all injuries in the private sphere obtained from the accident and emergency departments of 15 hospitals spread over the whole country. It shows whether a product was involved in the injury sustained and what role the product had in the circumstances. Other monitoring data on injuries and the products involved come from the National Information Centre on Poisoning (NVIC), the Burns Foundation and Statistics Netherlands (fatalities).

In the NVWA's publication the Status of Product Safety, these sources of information are combined with data on market surveillance over 2012-2015 and contain the number of samples taken and the amounts of measures taken with regard to certain product groups.

The NVWA does not have statistics on recalls readily available. NVWA started the implementation of a new ICT system, but due to serious budget overruns the implementation was stopped by the Minister in April 2019.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in the Netherlands (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders,

recalls)

Regarding overall market surveillance and online:

Online sales remain the biggest challenge for market surveillance at this moment. It is not possible to check each package/shipment at the border.

Furthermore, SMEs remain a challenge. 90% of the economic operators have less than 9 employees. Due to its complexity, EU legislation is a challenge for companies that have no quality or legal units, especially when they have a wide assortment of product groups. As also indicated in the market surveillance report on sector specific market surveillance over 2014-2017, the authorities have the experience that the majority of non-compliance is caused by the economic operator being unaware of the legal requirements.

According to an interviewee, consumers are still unaware of the fact that products on sale could be unsafe and the seriousness of the consequences. They are under the assumption that if products are unsafe, they would not be for sale ("somebody checks this"). They are also often convinced that an unsafe product cannot really do serious harm ("happens to other people"). In combination with the extremely low prices of Chinese web shops and platforms, these assumptions can result in dangerous scenarios. This image also follows from a report published by the NVWA in 2016 on the status of product safety.

Regarding RAPEX:

Overall, RAPEX/ICSMS, currently Safety Gate, are/is considered to function rather well. The problems indicated are:

- The lack of human or financial resources;

- The fact that some products mentioned in RAPEX are still offered online;

- The lack of information or inaccessible information on the risk assessment provided by authorities (no risk assessment at all, poor risk assessment or test results in languages other than English, French or German);

- The lack of information from the authority issuing the notification on the economic operators involved up and down the chain.

These problems make it hard to follow up on notifications at a national level.

Regarding recalls:

Product recalls are considered to be rather effective, but statistics or other information that confirms this is missing. In general, the success rate is considered to vary a lot, depending on the type of product and the risks. For instance, when it concerns a cheap toy, the recall rate is low; consumers probably throw it away or keep using it anyway. When it concerns an expensive gas appliance, the recall rate is high (85%).

Areas to make market surveillance of consumer products in the Netherlands/the EU more effective

Regarding overall market surveillance:

The suggestion to introduce a requirement for business operators to keep supply chain records – 'one up one down' traceability – is welcomed by the authorities. If this information is subsequently added to Safety Gate, it would also make market surveillance in other Member States easier.

It was suggested that it is important to detect hypes and other short-selling products or very popular products at an earlier stage, to be able to anticipate rather than react (too slowly).

It was also suggested that with regard to online sales, the Commission should start talks with the Chinese authorities on possibilities to improve the compliance of products offered by platforms to EU consumers or otherwise stop supplying these goods.

Regarding RAPEX:

It was indicated that test reports from MSAs should be in English. Sometimes the authorities receive test reports in languages that they can't read. The risk assessment is often missing or not extensive enough. Risk assessment is still a developing skill in many countries.

Regarding recalls:

Some interviewees indicated a need for common denominators or general criteria on when a recall may be considered adequate. This was mentioned with regard to the GPSD, but probably also regarding vertically

harmonised product areas. An internal working document on recall (werkvoorschrift) is available at the NVWA, but it is not publicly available.

More information, on applicable benchmarks would be desirable, also for economic operators and also with regard to transparency and proportionality in light of the use of public powers. The corrective action guide from 2005 provides some guidance for industry itself, but is very general in nature and a bit outdated.[419]

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in the Netherlands since 2013

The NVWA has published a report in 2016 called the Status of Product Safety (de Staat van Productveiligheid) in which it combines a couple of indicators to give an indication on how safe consumer products are. The indicators are:

- The number of accidents with injuries and other damage to health related to the use and safety of consumer products;

- The extent to which consumer products meet the legal requirements;

- The extent to which companies take their responsibility to market safe consumer products;

- The signals from society (reports from companies and consumers).

Due to the fact that market surveillance is project- and risk-based, any data on market surveillance in general does not say anything about overall numbers of unsafe (consumer) products on the market.

Consumer product-related accidents are registered on a national level. It is however very difficult if not impossible to quantify the causality between unsafe products and injuries. This is due to the fact that many injuries occur as a result of the behaviour or even misconduct of the consumer. The exact chain of events resulting in the injury is often obscure in the registered data. Many of the consumer complaints that reach the NVWA do not relate to the lack of safety of the product but to the quality of the product or even the conditions of the contract between the consumer and the economic operator.

The impression of all interviewees is that the level of safety of consumer products is largely unchanged. However, it was considered that because more and more harmonised standards under the GSPD are available, one could indirectly say that the level of consumer product safety has increased.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in the Netherlands whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Based on the interviews and research conducted, the overall impression is that all authorities try to address safety issues regarding these new technologies as best as possible, but the budget and means are very limited. Internet purchases and online platforms are areas that are fully included in market surveillance. The interviewees state that more advanced technologies like web crawlers, web scraping and data miners are being used. NVWA is investing in these tools. At the same time, the introduction of a new ICT system of the NVWA was withdrawn, which was a major setback. Furthermore, new ICT tools and in-house as well as external experts are expensive.

New technologies also create uncertainty as to which authority will be made responsible for market surveillance in a new area and will be provided with the relevant budget. This carries the risk of providing unhealthy incentives and competition between authorities with regard to new and existing product groups under their supervision, which could get in the way of the cooperation which is desperately needed.

Views of market surveillance authorities whether approaches in the Netherlands can be considered best practice implementation of the GPSD, which could be of interest to other countries

[419] See https://ec.europa.eu/consumers/archive/cons_safe/action_guide_nl.pdf

Two best practices were indicated:

- The integration of online market surveillance in all projects;

- The way in which consumers are held responsible for not using common sense when buying extremely cheap items by informing them of risks and how to identify the probability of the product being unsafe.

Furthermore, the use of risk based and system market surveillance are actively used and promoted by the authorities in the Netherlands. These approaches may also be considered best practices, as long as governments and authorities stay aware of the fact that good quality assurance is not a watertight guarantee for safe products. Therefore, random unannounced proactive product surveillance will always be necessary.

This research was conducted on the basis of interviews and government documents and reports that are publicly available. Statistical data and internal documentation are not available to assess the current practices as stated by the authorities in further depth.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*95*	*n.a.*	*95*
Total (country)	***95E***	***n.a.***	***95***
Notes:	*Due to the risk-based approach it is not possible to make a distinction between harmonised and non-harmonised. This will change every year. Online sales are incorporated in all of NVWA's product-focused projects. 10 to 15 % of the samples are taken from pure or mainly online sellers*		

B. Number of <u>inspections</u> of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*n.a.*	*n.a.*	**7 000**
Total number of consumer products inspected	*n.a.*	*n.a.*	6 500
Total number of consumer products tested in laboratories	*n.a.*	*n.a.*	4 500
Notes:			

C. Number of <u>recalls</u> of consumer goods (last available year)

N.a.

D. Key sources

Legislation	Commodities Act (Warenwet, https://wetten.overheid.nl/BWBR0001969/2018-11-17) The Decree on General Product Safety (Warenwetbesluit algemene productveiligheid, Stb. 1993, 499, last updated through Stb. 2016, 525) https://wetten.overheid.nl/BWBR0006158/2016-12-28 Regulation on General Product Safety (Warenwetregeling algemene productveiligheid, Stcrt. 2005, 228, last updated through Stcrt. 2012,

	83,https://wetten.overheid.nl/BWBR0019074/2012-01-19) The Decree under the Commodities Act on Administrative Fines (Warenwetbesluit bestuurlijke boeten, https://wetten.overheid.nl/BWBR0011841/2018-07-18) Explanatory notes to the implementation of the GPSD, Kamerstukken II 2004/05, 29 982, nr. 3, p. 6. Economic Offences Act (Wet op de economische delicten WED, https://wetten.overheid.nl/BWBR0002063/2019-11-14) Act on Public Administration and Disclosure of Information (Wet openbaarheid van bestuur, Wob https://wetten.overheid.nl/BWBR0005252/2018-07-28) The General Administrative Code (Algemene Wet Bestuursrecht, Awb https://wetten.overheid.nl/BWBR0005537/2019-11-14) Collecting law on Public health, Welfare and Sport 2018 (Verzamelwet VWS, Stb. 2018, 356: https://zoek.officielebekendmakingen.nl/stb-2018-356.html) Decision on active publication of market surveillance and execution of the Health law and Youth law, (Besluit openbaarmaking toezicht- en uitvoeringsgegevens Gezondheidswet en Jeugdwet, Stb. 2016, 448 https://zoek.officielebekendmakingen.nl/stb-2019-9.html) and the Decision on its entry into force (Besluit van 15 januari 2019, houdende vaststelling van het tijdstip van inwerkingtreding van de wet van 14 november 2016, tot wijziging van de Gezondheidswet en de Jeugdwet teneinde een mogelijkheid op te nemen tot openbaarmaking van informatie over de naleving en uitvoering van regelgeving, besluiten tot het opleggen van sancties daarbij inbegrepen (Stb. 2016, 448) en het Besluit openbaarmaking toezicht- en uitvoeringsgegevens Gezondheidswet en Jeugdwet, Stb. 2019, 30; https://zoek.officielebekendmakingen.nl/stb-2019-30.html) Policy documents: Market Surveillance Framework NVWA (toezichtkader NVWA https://www.rijksoverheid.nl/documenten/richtlijnen/2015/10/16/toezichtkader-nvwa) General Intervention Policy NVWA (Algemeen interventie beleid NVWA https://www.nvwa.nl/over-de-nvwa/documenten/nvwa/organisatie/hoe-de-nvwa-werkt/publicaties/algemeen-interventiebeleid-nvwa Specific Intervention Policy Product Safety, applicable as of 1 September 2017 (Specifiek Interventiebeleid productveiligheid geldig vanaf 1 september 2017: https://www.nvwa.nl/over-de-nvwa/documenten/export/veterinair/ks-documenten/interventiebeleid/specifiek-interventiebeleid-productveiligheid) Annex 2 to the Specific Intervention Policy Product Safety applicable as of 1 September 2017 (Bijlage 2 bij het specifiek interventiebeleid productveiligheid geldig vanaf 1 september 2017: https://www.nvwa.nl/over-de-nvwa/documenten/export/veterinair/ks-documenten/interventiebeleid/bijlage-2-bij-specifiek-interventiebeleid-productveiligheid-geldig-vanaf-1-september-2017) Directive for the Criminal Procedure for the Commodities Act (Richtlijn strafvordering warenwet, https://wetten.overheid.nl/BWBR0030963/2012-01-01)
Studies/reports/articles	Parliamentary reports, Second Chamber, year 2018/2019, 33 835, no. 121, on the position of the NVWA in policy making, and Letter of the Ministers of Agriculture, Nature and Food quality and the Minister of Healthcare of 18 April 2019 (retrieved on 14 November 2019, from: https://zoek.officielebekendmakingen.nl/kst-33835-121.html. Roadmap Digitally Safe Hard and Software (Raport Digitaal veilige hard- en software, retrieved on 25/11/2019 from: file:///C:/Users/Gitta%20Veldt/Downloads/Roadmap+Digitaal+Veilige+Hard-+en+Software.pdf) Annual Plan NVWA 2019 (retrieved on 25/11/2019 from: https://www.nvwa.nl/documenten/nvwa/organisatie/jaarplannen/2019/jaarplan-2019-nederlandse-voedsel--en-warenautoriteit-nvwa) NVWA Report - The Status of Product Safety 2016 (de Staat van Productveiligheid 2016), https://www.staatvan.nl/productveiligheid/ Collection of National Surveillance Data and Assessment 2014-2017, as provided to the Commission: https://www.rijksoverheid.nl/documenten/rapporten/2018/10/29/collection-of-national-surveillance-data-and-assessments
Websites	General Commodities Act Consultation Group (Regulier Overleg Warenwet), website with the minutes of the meetings: https://www.row-minvws.nl/row-nl/productwetgeving-niet-

	levensmiddelen-dpnl/vergaderstukken-dpnl NVWA product based projects, findings and research outlines: https://www.nvwa.nl/onderwerpen/productonderzoeken-op-merknaam NVWA safety notifications: www.nvwa.nl/onderwerpen/veiligheidswaarschuwingen NVWA website on e-shopping: https://www.nvwa.nl/onderwerpen/webwinkels NVWA Facebook: https://www.facebook.com/NVWAonline/ NVWA Twitter: https://twitter.com/_nvwa NVWA partnership agreement with Marktplaats.nl (https://www.rijksoverheid.nl/documenten/convenanten/2019/07/02/samenwerkingsprotocol-nvwa-en-marktplaats) NVWA partnership agreement with Bol.com (https://www.rijksoverheid.nl/documenten/convenanten/2019/07/02/samenwerkingsprotocol-nvwa-en-marktplaats) Press release: NVWA ICT project Inspect dropped: https://www.rijksoverheid.nl/ministeries/ministerie-van-landbouw-natuur-en-voedselkwaliteit/nieuws/2019/04/15/minister-carola-schouten-stopt-implementatie-en-ontwikkeling-ict-systeem-inspect-bij-nvwa
Interviews	5 interviews with NVWA The unpublished case law and decision provided by NVWA

21. Poland

COUNTRY REPORT POLAND

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Act on General Product Safety of 12 December 2003 (Journal of Laws No. 229, item 2275 as amended, that is Journal of Laws from 2016, item 2047)

Trade Inspection Act of 15 December 2000 (Journal of Laws of 2001 No. 4, item 25 as amended, that is Journal of Laws from 2019, item 1668)

Act of 30 August 2002 on the Compatibility Assessment System (Journal of Laws of 2002 No. 166, item 1360 as amended, that is Journal of Laws from 2019, item 155)

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Poland

It needs to be mentioned that, conforming Art. 5(1) GPSD, Art. 10(4) of the Act on General Product Safety obliges producers to act with due diligence when conducting their professional activity with regards to adopting measures that would enable them to be informed of risks which these products might pose as well as to choose to take appropriate actions to avoid these risks. Art. 10(6) of the Act on General Product Safety further specifies that such producers' acts may consist of placing on the product an indication of the producer's identity and his address, as well as identification of the product or its batch, except where not placing of such information is justified. Polish law follows then exactly the text of the GPSD not introducing the requirements of traceability as a binding requirement, but rather giving them as an example.

Pursuant to Art. 11 of the Act on General Product Safety distributors have an obligation to act with due care and to monitor the safety of the product, as required by Art. 5(2) GPSD. Polish law specifies that the monitoring duties of the distributors require them to: 1) take note when consumers notify them about product risks and without undue delay further notify such risks to producers, surveillance authorities as well as to the provincial officers of the Trade Inspectorate[420] (); 2) store and without undue delay make available at the request of the surveillance authority and of the provincial officers of the Trade Inspectorate any documentation necessary to establish the origin of the products.

In practice, product traceability is enforced in Poland through controlling the distribution channels of particular products. This means that during an inspection, provincial inspectors of the Trade Inspectorate check whether the producers' name and contact details are indicated on the product and its packaging, as well as the information provided on the product's model or batch, which allows for further identification of the product. This data is sometimes acquired from a product and its packaging, but also often from invoices and other product documentation. When the producer and the product batch is established, inspectors know which parts of the distribution channel to further target to prevent the product and other samples from the same product batch from being accessible on the market.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

This is a problematic area in Poland as there is uncertainty as to what risks inspectors should be checking for in products applying modern technologies (e.g. drones, see also *Osiecki* in 'Key sources' below). In practice, however, there are no known cases where this has been an actual problem yet. No separate definition of safety has been considered to be necessary (yet) to address new problems.

[420] Wojewódzki inspektor Inspekcji Handlowej

The academic literature indicates the necessity of adjusting the notion of a 'product', so that it clearly covers non-material modern goods as well. It is also emphasised that the safety of modern products, at the moment of putting these products into circulation, does not guarantee the safety of these products when they continue to be used. This would only be assured if producers continued to monitor the product's safety and introduced necessary technological updates to protect consumers against continuously emerging new risks (see *Baranowska & Machnikowski*).

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

This is uncertain as such issues have not yet been identified in practice, thus it is unclear whether the current rules could effectively address potential risks. As the Office of Competition and Consumer Protection[421] (henceforth the OCCP) has noted, none of the emerging threats been considered to have at the moment and there is a feeling amongst provincial inspectors of the Trade Inspectorate that they would not know which risks to control for, as they lack specific knowledge about the use of modern technologies in consumer products, and about the risks that such products could bring about.

In the academic literature, attention has been drawn to the fact that many modern products, e.g. electric and hybrid cars, may cause cybersecurity risks, which at the moment are not monitored by specific public authorities (see *Greser*). Poland introduced the Act of 5 July 2018 on the National System of Cybersecurity (Journal of Laws of 2018, item 1560) but it does not place any obligations to ensure cybersecurity on economic operators who would be introducing such consumer products on the market, nor does it specify the market surveillance of these products.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

The inspectors and authorities take a broad approach to assessing the safety of a product, considering all available knowledge on potential risks in a given product group. This includes European and national (but not international) standards, guidelines on product safety assessments, codes of good practices, state of the art and technology, and reasonable consumer expectations. The OCCP would commission expert opinions to establish the state of the art and technology and whether a specific product presents a risk. As the consulted standards are often very general and not mandatory, it is usually the expert opinion clarifying the state of the art and technology that would determine the presence of a risk in a product. The local office of the Trade Inspectorate mentioned that the national standards are better known than European standards and would be used predominantly.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Poland in case there are consumer product(s) on the market which are found unsafe under the GPSD

In the administrative proceedings, the producer would first be asked to cooperate and voluntarily provide relevant information on the products (traders – information on the supply chain allowing to identify the producer), as well as to take steps to remedy the safety of a potentially risky product (including voluntary recalls). In order to identify unsafe products on the market, local inspectors of the Trade Inspectorate may conduct unannounced on-site inspections and physical checks of products. It is possible to reclaim the costs of administrative proceedings from producers.

What has not yet been applied in monitoring product safety are mystery shopping exercises, nor more widespread controls of goods sold online. This despite the fact that the Polish legislator has regulated the mystery shopping exercise in the Act of 5 August 2015 changing the Act on the Protection of Competition and Consumer (Journal of Laws of 2015, item 1634), which is binding as of 17 April 2016. It seems that the mystery shopping exercise may be perceived as a tool more suitable for use in monitoring whether the trader performs their pre-contractual information duties to consumers, as well as does not mislead consumers, rather than in relation to the assessment of product safety, as this is also how it was regulated by the Polish legislator (*Burnecka-Szczepańska*).

The current regulation of mystery shopping would make it not very practical for determining product safety, as

[421] *Urząd Ochrony Konkurencji i Konsumentów*

employees of the OCCP may only attempt to purchase a consumer product, but not actually purchase it (thus no sample product would be obtained), as well as they can also only conduct mystery shopping with judicial permission, which will be obtained only if some evidence already indicates that a given trader is breaching consumer protection rules (see *Burnecka-Szczepańska*).

Generally, with online traders, control of product safety occurs in practice only if they have a physical storage facility which provincial inspectors of the Trade Inspectorate may go and visit, or through random controls of customs authorities, if goods are imported.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

There is a possibility to place an administrative fine on producers up to the amount of 100 000 PLN (see *Jocz*). This fine is applied in practice, especially with regards to repeat offenders or when the risk caused by an unsafe product was severe and the trader introduced many such unsafe products on the market, spreading the risk. The repetitive character of the offense, severity of the risk, and quantity of the unsafe products on the market are characteristics that will be considered in the evaluation of whether to place a fine on the producer and in what amount.

Recent case law in Poland with respect to or relevant for the GPSD/the national implementation legislation

Judgment of the Supreme Administrative Court[422] of 15 March 2017, II GSK 1663/16, Legalis No. 1605586 – in which the Supreme Administrative Court decided that upon conducting an inspection and finding a product unsafe, the Trade Inspectorate may claim costs of any laboratory and other tests that have been used to determine the lack of product safety from the trader who was being inspected, and does not need to identify the producer of the unsafe product to claim the costs from them instead;

Decision of the Court of Appeals in Warsaw – VI Civil Department of 30 November 2016, VI Acz 2293/16, Legalis No. 1682218 – confirming that if a trader wants to appeal a decision of the President of the OCCP obligating the trader to eliminate product risks and to inform consumers about product risks, the appeal should be made to the District Court in Warsaw – the Court for Competition and Consumer Protection[423] rather than administrative courts;

Judgment of the Supreme Administrative Court of 22 November 2016, II GSK 935/15, Legalis No. 1555039 – ruling that when Polish or EU legal rules determine which tests to use and how these tests should be conducted on the product samples during inspections, it is not allowed for inspectors to conduct other tests, as this would undermine the objective of the inspection.

Judgment of the Court of Appeals in Katowice – I Civil Department of 24 October 2016, I Aca 354/16, Legalis No. 1546700 – in which the Court elaborated on the notion of product safety, stating that any product which requires detonation of an explosive material for its use creates a risk to consumers, both when it is improperly used and when it is properly used but is defective, and therefore, such product should be considered to be potentially dangerous. The fact that a battery used for a fireworks display belonged to a batch of products allowed on the market, as they complied with the necessary norms, does not make that particular battery safe, as the battery at hand was likely not tested for its compliance with the norms, but rather another battery in the batch.

Judgment of the Supreme Administrative Court of 14 January 2014, II OSK 1879/12, Legalis No. 951912 – confirming that a recall of products from the market obliges producers to remove all copies of a given product from their distributors and to ban their distributors from presenting and offering this product to consumers.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Poland concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

There seem to be no real problems related to the implementation and application of the notion of safety; however, as previously mentioned, it has not yet been applied to the issues of emerging technologies. The only registered complaint of the OCCP with regards to the notion of safety related to the notion of an imitation of a food product, which was claimed to be outdated and in need of a legislative change. The local office of the Trade Inspectorate mentioned the need for more knowledge on modern technologies and their risks, as well as clarity as to the

[422] *Naczelny Sąd Administracyjny*
[423] *Sąd Ochrony Konkurencji i Konsumentów*

competences of specific authorities. They also brought up the need to introduce more specificity as to the risks covered by the general notion of safety, especially with relation to modern technologies.

With respect to traceability, the OCCP mentioned the need for a more widespread use of barcodes to help with product identification, for which there is currently no legal requirement in Poland. However, they also acknowledged that the use of barcodes is not always a solution when the data available on the barcode does not match the reality.

In practice, it can also occur that the producers' contact details differ as to the location of its registered seat and the location of its actual place of operation. This hinders provincial inspectors of the Trade Inspectorate, especially in conducting inspections of product safety, as they may not be able to easily identify the producers' warehouses. At the moment, the information obligations regarding the provision of an address of the trader are directed at consumers, which mean that the address given on a product or product documentation is intended to facilitate consumers getting in contact with the trader. It is, therefore, not always suitable for inspectors of the Trade Inspection trying to identify the place where they could conduct an inspection without prior notification to the trader.

Moreover, there are known marketplaces in Poland (e.g. Wólka Kosowska) where goods are being resold within long supply chains, within which it is often impossible to establish who the actual producer is or even to which product batch a given unsafe product belonged. This means that as a result of an inspection of a particular product, that product, if deemed unsafe, may be removed from the market, but it is difficult to draw conclusions as to the whole batch of products or to a particular producer, if the supply data is missing.

Despite interviews not indicating any specific problems with the safety of modern products and emerging technologies, the academic literature mentions that e.g. in 2017 in Poland there were 6 million attempted cyberattacks on consumer products such as laptops, desktops and notebooks. Additionally, attention is drawn to the low level of risk awareness as far as cybersecurity is concerned and the need for additional awareness campaigns in this field (see *Cyfrowa Polska*).

Possible improvements to make the implementation of the GPSD in Poland more effective

The conducted research showed a need for the legislator to address the following concerns:

- The disparity between the address for a registered office of a producer and their actual offices/warehouses (if a label/documentation indicates only the registered offices, this means that inspection cannot easily, and without prior notice, be conducted);
- The need for more strict requirements as to the documentation of the supply chain and of the product batch;
- The need for mandatory use of barcodes on consumer products;
- The lack of clarity regarding risks that modern technologies could bring about in consumer products and in new product distribution channels, as well as which party is competent to monitor the market for these risks;
- The need for the harmonisation of recall proceedings in all Member States, especially with regards to voluntary recalls;
- The outdated framework of Directive 87/357/EEC.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Poland

At national level: President of the Office for Competition and Consumer Protection (OCCP).

At sub-national level: provincial (voivodship) inspectors of the Trade Inspectorate.

The OCCP has the general, national competence in the area of market surveillance of consumer products, with some products being excluded from its authority by specific regulations. These exclusions are all mentioned in the national market surveillance programme of Poland. The authorities responsible for conducting market surveillance in these specific sectors consult with the OCCP on their market surveillance plans, asking for the OCCP's input.

Locally, the OCCP performs its task through cooperation with customs authorities and national market surveillance authorities, which are provincial inspectors of the Trade Inspectorate. Provincial inspectors of the Trade Inspectorate conduct inspections on the basis of market surveillance plans/programmes, as well as when the consumers' interest or the market's interest requires it, i.e. on an *ad hoc* basis (see *Wagner*).

Plans/programmes in place which define priorities for market surveillance of consumer products

Every year the OCCP adopts market surveillance plans, which are consulted on with the Trade Inspectorate, customs authorities and other relevant national and local authorities. These surveillance plans cover all consumer product sectors. The priorities are set based on results of inspections from the previous surveillance period (which may show irregularities requiring further, more intensive market surveillance), RAPEX notifications (from all Member States), numerous consumer and business complaints (e.g. on lower sales level of a particular trader due to inferior, cheaper products flooding the market), accident reports, or media reports on dangerous product.

The priorities for market surveillance are determined on the basis of all the gathered information on risks from other national and local authorities, media reports, signals from other Member States, as well as business and consumer organisations. Following the gathering of this information, the market signals are analysed to identify where there is the highest risk to consumers, considering also whether that risk targets vulnerable consumer groups (e.g. children or elderly), as well as the likelihood and frequency of purchasing and of using consumer products in a given category.

The local offices of the Trade Inspectorate determine its inspection plans on the basis of the annual market surveillance programme provided by the OCCP and the local needs determined by the provincial authorities (voivode) (see *Wagner*).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Poland with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance activities regarding C2C products are not carried out in Poland as there is no legal competence for national and local authorities to organise them. The authorities are limited to controlling the safety of consumer products in B2C transactions.

There have not yet been reports of any safety issues regarding new technologies and there is no knowledge on what risks should be checked for in such products or which national or local authority would be competent to control their safety. Due to the fact that products regarding new technologies may be quite complex and could bring about many different risks, their market surveillance is perceived to be difficult. The OCCP indicated the need for the EU to provide better information on what risks should be accounted for and prioritised in the national market surveillance. They would also like more certainty as to whether such a safety assessment should take place within the working sphere of the rules on GPSD and by one authority, or whether specific risks would be controlled by authorities competent for a given sector. For example, in Poland, risks related to electronic communication ensuring privacy of data could be controlled by the Electronic Communication Office (Urząd Komunikacji Elektronicznej) rather than the OCCP, and there are also separate authorities competent in the area of ensuring cybersecurity (although not yet in relation to consumer product safety) (see *Greser*). Clarity is required as to whether a particular modern technology product would then need to be monitored by more than one authority, in a different scope.

Products sold online may be monitored on the basis of current market surveillance plans; however, their monitoring would only occur in practice if online traders store their products somewhere within the territory of Poland or in another Member State. If online traders do not have such warehouses in Poland or other Member States, or they acquire individual consumer goods and directly forward them to consumers, local inspectors of the Trade Inspectorate may not be able to conduct physical inspections and take samples of such products. What remains then as a method of market surveillance is the involvement of customs authorities, asking them to pay attention to specific shipments of such goods. When the warehouse is located in another Member State, the OCCP may ask authorities of that other Member State to conduct an inspection. This is not an option when the warehouse is located in a non-EU country. With regards to the market surveillance activities undertaken, upon notification of a problem with consumer products sold by a specific website, local inspectors of the Trade Inspectorate could try to locate the warehouse of the online seller and obtain a sample. Moreover, a few times the OCCP participated in a sweep, monitoring the online sale of particular consumer products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery

shopping)

There are no specific statistics and data devoted to the market surveillance of consumer products sold online in Poland, which makes it difficult to establish the frequency with which such market surveillance activities occur. If there are market signals that online traders or online marketplaces provide potentially dangerous consumer products, the local inspectors of the Trade Inspectorate would try to locate their warehouses and obtain a sample of the product. The data gathered suggests that the checks of products sold online occur *ad hoc*, often in connection with the other ongoing safety checks of a particular group of consumer products, and are often hindered by practical difficulties, such as online traders having their warehouses in a non-EU country. The OCCP suggests that it is a rather small percentage of all market surveillance activities that targets products sold online. Moreover, mystery shopping activities have not yet been implemented in Poland in the monitoring of product safety. The OCCP indicated that they have not yet been trained in using this type of market surveillance tool. However, the academic literature indicates that this tool has been previously used in Poland in controlling misleading commercial practices, as well as performance of traders of their pre-contractual information duties, as well as by the Trade Inspectorate (see also above).

There is no dedicated department in the OCCP which would exclusively monitor the safety of products sold online, and thus browsing websites in order to find dangerous products does not take place often. The OCCP did participate in a few sweeps of various online consumer product sectors that were organised across the EU. The local office of the Trade Inspectorate reported that they are only able to monitor consumer products sold online if they manage to get (physical) access to products, thus the channel of distribution or sale does not really matter.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Poland (except customs) with respect to product safety

The OCCP cooperates with other national and local authorities in Poland regularly and considers this cooperation effective. This cooperation extends to getting input from the Trade Inspectorate on what should be included in the market surveillance plan, organising trainings, and discussing the use of RAPEX and ICSMS. The local office of the Trade Inspectorate perceives this cooperation as more informal, but regular. They confirm that regular meetings take place, which enable the transfer of information about inspections carried out. A few times a year, there are some training sessions and meetings organised with other authorities.

Cooperation with customs authorities in Poland with respect to product safety

Both the OCCP and the Trade Inspectorate work closely with customs authorities in Poland and consider this to be a model cooperation. The contact with customs officers is almost daily, allowing for the discussion of ongoing inspections, answering queries in a fast and efficient way. The customs officers are also contacted in cases where it is difficult to identify the establishment of a particular trader, as the packages to that trader may then be checked by the customs authorities. The customs officers also participate in training sessions and provide input on market surveillance plans. There is also a regular cross-border level meeting organised between customs officers of the Visegrad Group countries (Czech Republic, Hungary, Poland and Slovakia).

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The cooperation with other Member States is also good, as reported by the OCCP. They find it easy to reach out and ask for collaboration to ensure a safety of a particular product, identify traders, etc. However, there is no such established cooperation with non-EU countries, which is then more incidental. One of the observed deficiencies was a lack of clear contact points in non-EU countries. For example, the contact with Chinese authorities was only ever made through the intermediation of the EU authorities.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

On average it takes over 2 weeks between the detection of a dangerous product and its notification to RAPEX. There is a specific administrative procedure in place which is supposed to guarantee a timely notification; however, in practice, it can be quite prolonged. Namely, the administrative procedure of declaring a good dangerous may take approx. 4 weeks, as the trader is given a chance to question the test results, and even after the conclusion of this procedure, the trader may still appeal from the decision. Only the final decision in the procedure would be notified to RAPEX. The OCCP would appreciate a possibility to make notifications earlier, before the administrative

decision becomes final, but in order for them to be able to do so, they would need to be indemnified from any potential state liability for the potential costs or losses of a trader as a result of an earlier notification.

Still, overall, the RAPEX system is perceived by the OCCP as functioning well in Poland, due to the fact that it provides clear and specific legislative guidelines on its role and procedure.

Non-safety (e.g. environmental) risks only recently started being taken into account. The OCCP has now conducted a few market surveillance exercises where such non-safety risks had to be considered, which clarified to them what to pay attention to. In academic literature it is highlighted that the definition of a product in product safety rules and rules on environmental protection are not the same, and the risks against which these two sets of rules are to protect are also focused on different objectives. Therefore, these two sets of rules should be applied in parallel (see *Górski et al.*).

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The cooperation with business associations and businesses is rare, as they are often perceived as biased due to pursuing their own interests. If they report goods as potentially unsafe, it is often goods of their competitors, thus inspection would only be conducted if that notification is supported by other objective evidence. Moreover, the Trade Inspectorate needs to be perceived as neutral if it is to conduct successful inspections. The OCCP mentioned that cooperation with businesses occurs approx. twice a year and it is mostly business organisations that ask for such cooperation, e.g. asking for advice or training. The OCCP employees participate in business conferences and meetings, provide information on inspection results, market surveillance concerns, etc.

The OCCP reported that consumer organisations are not very active in this area of consumer protection in Poland, thus cooperation with them is also rare. Their reports of unsafe consumer products are very incidental.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The OCCP may organise training on product safety for businesses, especially when they are asked to do so by business organisations. Moreover, if a business organisation asks for advice, the OCCP may prepare letters with guidance, raising awareness of product safety in a particular sector. There is, however, no specific online portal devoted to product safety that businesses could consult.

Consumer awareness would be raised by the Trade Inspectorate (including through their dispute resolution system and awareness campaigns, e.g. on risks related to the use of seasonal products) and possibly local consumer ombudsmen rather than consumer organisations.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Poland(including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

In Poland there is a possibility for businesses to conduct a voluntary recall procedure, but there is also an option for an administrative decision mandating a trader to organise a recall.

Voluntary recalls need to be communicated to the OCCP, which will then announce them on their website, with information on the risk involved, as well as on measures taken by the traders to combat that risk. However, it is left up to traders to decide what kind of information they will convey to the OCCP and how they will organise a voluntary recall. Only basic information is then required from traders regarding the list of businesses involved in the supply chain and what activities are taken to target consumers.

Mandatory recall is strictly regulated. Administrative decisions force traders to take specific measures as well as provide documentation attesting to the recall having been conducted pursuant to these measures. For example, traders may be required to send protocols documenting the destruction of unsafe products, local inspectors of the Trade Inspectorate may be present during such activities, etc. If the trader does not follow the steps listed in a decision, injunctions may be applied for, followed by administrative fines.

There are no specific codes of good practice on product recalls in Poland.

Monitoring of effectiveness of product recalls by market surveillance authorities

The OCCP does not monitor the effectiveness of voluntary recalls nor does it check whether the trader contacted all consumers potentially affected by the risk. There is also no monitoring of which communication channels traders selected or how long the campaign took. However, the provincial inspectors of the Trade Inspectorate mentioned that sometimes they are asked to monitor whether a voluntary recall took place, but this is then organised *ad hoc*.

With regards to the mandatory recall procedure, the OCCP closely monitors the trader's performance and whether the trader adheres to the required, specific measures. Local inspectors of the Trade Inspectorate are asked to monitor such mandatory recalls, as well.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Poland that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

There are no detailed databases that would help with a statistical evaluation in Poland. Customs authorities collect some data related to dangerous products. Furthermore, the Ministry of Health collects data on consumer injuries. The OCCP does not consider the latter database very useful, as it is not exhaustive. They consider that the hospitals do not prioritise providing data for the injury databases, which means that the number of questionnaires filled in every year about consumer accidents is likely not representative for the scale and scope of injuries that occur in Poland.

However, the OCCP also does not organise consumer complaints that are filed with the OCCP. They do not publish them nor analyse them on the basis of any statistical method.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Poland (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The recurring problem for effective market surveillance is the lack of sufficient knowledge, especially whenever there is a new risk, a new distribution channel, or a new market surveillance method (such as e.g. mystery shopping) involved. For example, there is currently no clarity as to what types of risk are posed by new technologies and who should tackle them. Furthermore, there is a lack of resources (staff, funds) to effectively tackle the market surveillance of modern, more complex consumer products, new distribution channels, etc. A practical impediment is the lack of sufficient resources to conduct laboratory testing of dangerous products, as expert laboratories are often few and may not specialise in the detection of a modern risk. Another practical impediment that has been identified is the difficulty in establishing the identity and the place of establishment of a trader, especially when they are selling their products online. With regards to recalls, there is no data on the effectiveness of voluntary recall procedures, as these are not monitored. However, the OCCP considers this a benefit that may motivate traders to undertake voluntary recalls, which they would like to encourage.

Areas to make market surveillance of consumer products in Poland/the EU more effective

The lack of knowledge could be addressed if more training sessions were organised, if further guidance was issued at the EU level to harmonise practices across the Member States, or if additional funds were made available.

Priority could be assigned by the EU or Polish legislators to conduct market surveillance for products sold online, extend it to products with new technologies, etc. Ideally, such an indication of regulatory priority should be joined by the issuance of specific guidance on how to actually implement testing of new products regarding their safety and which authority is competent to do this.

Market surveillance within the EU would be more effective if cooperation with authorities in non-EU countries increased. At the moment, it is often impossible to even identify contact points in non-EU countries, not to mention cooperate with them.

Whilst the voluntary recall procedure should not be excessively regulated in order to not discourage traders from following it, it would be helpful to further determine to what extent market surveillance authorities should be involved in such procedures, e.g. whether they should monitor the timeline of the recall or communication channels used by traders.

The OCCP also mentioned that the EU could provide more guidance on how to recognise injuries resulting from the use of dangerous products, which could harmonise and increase their reporting to the relevant authorities in each

Member State.

Further, it would be helpful to have more information on what databases of injuries, consumer complaints, etc. should look like, and what data should be included in them. If additional funds were made available, then a department in the OCCP could be charged with collecting and processing such data.

The legal landscape of rules governing product safety could be made more transparent as at the moment there are many legal acts governing it, which means it is difficult for new inspectors to gain expertise in the area.

Moreover, it was mentioned that business awareness could be improved as to the role of provincial inspectors of the Trade Inspectorate, so that the businesses more easily cooperate with their inquiries/inspections. This could be achieved by emphasising the confidentiality obligations of trade inspectors (e.g. as to trade secrets), which are regulated by law for all matters not related to ensuring product safety. In Polish law there are, however, no sanctions for breach of the confidentiality obligations, thus any damages may only be obtained through invoking general civil law rules (see *Szyrskil)*.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Poland since 2013

There is a general feeling that product safety is improving in Poland. This is not necessarily supported by statistics showing that there are fewer accidents, but rather that there is no increase of accidents that are being reported. Moreover it is considered that the provision of more product information ensures better product handling and prevents further accidents.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Poland whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

The first tests of web crawlers are being conducted at the moment by the Trade Inspectorate, but the process of using modern technologies is just beginning. Even the mystery shopping technique has not yet effectively been used in Poland for monitoring product safety by the OCCP.

Views of market surveillance authorities whether approaches in Poland can be considered best practice implementation of the GPSD, which could be of interest to other countries

Nothing specific was mentioned except for the UOKiK naming the cooperation with the customs authorities as a model one.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*15*	*5*	*20*
Responsible authorities at the sub-national level (regional/provincial/local)	n.a.	n.a.	*450*
Total (country)	n.a.	n.a.	***470***
Notes:	*450 inspectors were allocated to inspections in the field of non-food products in 2018.*		

B. Number of inspections of consumer products (last available year)			
	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**1 454**	**905**	**2 539**
Total number of consumer products inspected	5 282	3 389	8 671
Total number of consumer products tested in laboratories	576	81	657
Total number of consumer products inspected in cooperation with the customs	1 114	286	1 400
Total number of dangerous consumer products found	330	110	440
Notes:	*Data from 2018. The last rubric mentions the number of products in which structural irregularities were found.*		

C. Number of recalls of consumer goods (last available year)			
	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	n.a.	n.a.	234
Total number of mandatory recalls	37	n.a.	n.a.
Notes:	*Data from 2018.*		

D. Key sources	
Legislation	Act on General Product Safety of 12 December 2003 (Journal of Laws No. 229, item 2275 as amended, that is Journal of Laws from 2016, item 2047) Trade Inspection Act of 15 December 2000 (Journal of Laws of 2001 No. 4, item 25 as amended, that is Journal of Laws from 2019, item 1668) Act of 30 August 2002 on the Compatibility Assessment System (Journal of Laws of 2002 No. 166, item 1360 as amended, that is Journal of Laws from 2019, item 155) Act of 27 April 2001 on the Environmental Protection (Journal of Laws of 2001 No. 62, item 627 as amended, that is Journal of Laws from 2019, item 1396) Act of 5 July 2018 on the National System of Cybersecurity (Journal of Laws of 2018, item 1560) Act of 5 August 2015 changing the Act on the Protection of Competition and Consumer (Journal of Laws of 2015, item 1634)
Studies/reports/articles	Baranowska, N. & Machnikowski, P., (2017) 'Odpowiedzialność za produkt wobec rozwoju nowych technologii' (Studia Prawa Prywatnego No 2), Legalis. Burnecka-Szczepańska, M., (2016) 'Nowe kompetencja Prezesa UOKiK w sprawach praktyk naruszających zbiorowe interesy konsumentów – instytucja tajemniczego klienta (*mystery shopper*)' in: Czarnecka, M. & Skoczny, T., *Prawo konsumenckie w praktyce* (Issue 1, Warszawa), Legalis. Cyfrowa Polska, (2019) report 'Cyberbezpieczeństwo w Polsce: ochrona urządzeń końcowych przed cyberatakami. Analiza sytuacji i rekomendacje działań.' in: Flaga-Gieruszyńska, K., Gołaczyński, J., Szostek, D. *Sztuczna inteligencja, blockchain, cyberbezpieczeństwo oraz dane osobowe. Zagadnienia wybrane* (Issue 1, Warszawa). Górski, M., Pchałek, M., Radecki, W., (2019), 'Prawo ochrony środowiska. Komentarz' (Issue 3,

	Warszawa), Legalis, Chapter 3. Produkty. Greser, J., (2019), 'Zadania państwa w zakresie cyberbezpieczeństwa a rozwój elektromobilności' in: Kokocińska, K. & Kola, J. (ed.) *Prawne i ekonomiczne aspekty rozwoju elektromobilności w Polsce* (Issue 1, Warszawa), Legalis. Jocz, D., (2013), 'Kara pieniężna za wprowadzenie na rynek produktów niebezpiecznych oraz produktów niespełniających wymogów bezpieczeństwa w świetle orzecznictwa sądów administracyjnych' in: Kisieliewicz, A. & Tarno, J.P.d (eds.), *Sądowa kontrola administracji w sprawach gospodarczych* (LEX 2013), LEX No. 181046. Market surveillance programme Poland 2019 Osiecki, M., (2018) 'Drony – przyszłość lotnictwa i wyzwanie legislacyjne. Kilka uwag o nowych regulacjach unijnych dotyczących bezzałogowych statków powietrznych' (IKAR No 7), Legalis. Sozański, J., (2013), 'Niedostatki unijnej ochrony indywidualnych praw konsumenta w Polsce' (IUSNOVUM No 3), Legalis. Szyrski, M., (2014), 'Analiza wybranych tajemnic związanych z postępowaniami kontrolnymi' (MOP No 18), Legalis. Wagner, A., (2012), 'Inspekcja Handlowa' in: Szmulik, B. & Miaskowska-Daszkiewicz, K., *Administracja publiczna. Ustrój administracji państwowej centralnej* (Issue 1, Warszawa), Legalis.
Interviews	Urząd Ochrony Konkurencji i Konsumentów (Office of Competition and Consumer Protection, OCCP) RAPEX national contact point Wojewódzki Inspektorat Inspekcji Handlowej w Warszawie (Provincial Office of the Trade Inspectorate in Warsaw)

22. Portugal

COUNTRY REPORT PORTUGAL

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

- Decree-Law no. 69/2005 of 17 March 2005 which implemented Directive 2001/95/CE of 3 December 2001.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Portugal

The traceability requirements are provided in national implementation legislation of the GPSD as binding requirements. Article 6 (1) lists the additional obligations of the producer and Article 6 (3) further clarifies the conduct underlying those obligations.

Article 6 (3) (a) of Decree-Law no. 69/2005 of 17 March obliges the producer to make available, on the packaging or on the product, the identity and full address of the producer and the economic operator responsible for placing the product on the market. In addition, the manufacturer must also include instructions for use and product references, including the name, model, and type or batch of products to which it belongs.

In addition to the general obligation of producers to only introduce safe products on the market, there are two other obligations for the producer[424]:

"The obligation to provide relevant information to enable consumers to assess the risks inherent to a product during its normal or reasonably foreseeable lifetime, where these are not immediately perceptible without due warning, and to take precautions against these risks (...); [and] the obligation to take appropriate measures, depending on the characteristics of the product supplied, to provide information on the risks which the product may present and to take appropriate action, such as indicating the producer and the distributor, marking the product or the product batch, enabling it to be identified, carrying out unsampled tests, examining complaints lodged and informing distributors of such monitoring and, if necessary, withdrawing the product from the market itself or recalling it from consumers"[425].

According to the Economic and Food Safety Authority (ASAE), during inspections, it undertakes a documentary inspection, analysing technical and purchase documentation. In case the documents are not in the possession of the businesses concerned, the ASAE notifies them in writing that they are required to provide the documents within a time limit of 5 days.

There are also obligations for the distributor in national legislation. Article (7) of the Decree-Law no. 69/2005 establishes that the distributor is obliged to act with diligence, namely during the storage, transport and exhibition of the products, in order to contribute to the fulfilment of the applicable safety obligations. The distributor must, therefore, in accordance with the limits resulting from the exercise of his activity:

(a) refrain from supplying products which he knows or ought to know, based on the information in his possession and as a professional, do not satisfy that obligation;

(b) to participate in monitoring the safety of products placed on the market, particularly by passing on information on product risks to the competent authorities;

(c) to keep the documentation necessary to trace the source of products throughout their lifetime and provide it when required by the competent authorities;

(d) to initiate appropriate action to eliminate the risks, in particular the withdrawal of the product from the market and its recall from consumers;

[424] João Calvão DA Silva, *Compra e Venda de Coisas Defeituosas*, 2008, pp. 189-190.
[425] Ibid.

(e) to collaborate effectively in any action taken to avoid the risks.

There is no obligation to include a barcode or an electronic identification on products.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

Based on the interviews and research conducted, there is no definition of safety specifically directed towards new technologies in national legislation.

Thus, the general definition of product safety provided for in Article 3 (b) of Decree-Law No. 69/2005 of 17 March raises some applicability problems for products involving new technologies, because the provision was intended to respond to the physical market and is not easy to extend to the technology market. It is not easy to apply the definition of safety to products that involve some kind of incorporated digital content, as reflected in the following example: according to the Directorate-General for Consumer Affairs (DGC), many products that could be included in the spectrum of the provision (e.g. some toys) are not included, because they do not fit in the definition. Example: a good that has incorporated digital content which allows for the geolocation of the person who holds it. This problem was also pointed out by the ASAE.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The national implementation legislation of the GPSD do not cover emerging threats related to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Based on the interviews conducted, specifically according to what was reported by the Directorate-General for Consumer Affairs (DGC), the benchmarks that have been used to assess the safety of a product are based on the European Commission recommendations setting guidelines on product safety assessment and on consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Portugal in case there are consumer product(s) on the market which are found unsafe under the GPSD

Article 26 (1) of Decree-Law no. 69/2005 of 17 March considers the following acts to constitute an administrative offence:

1. The failure to provide relevant information allowing consumers to evaluate the risks inherent to a product every time those risks would not be immediately perceived without warning;

2. The lack of indication of the identity and address of the producer and of the economic operator responsible for the placing on the market, as well as the use instructions, in the product or in its packaging;

3. The lack of an organised record of complaints;

4. The lack of performance, by the producer, of sampling tests where necessary, and lack of information to the distributor about the tests carried out;

5. Providing products which the producers or distributors know or ought to know, according to the information they hold, are not compliant with the general safety requirement;

6. The lack of notification to the competent authorities that the product placed on the market poses risks in violation of the general safety requirement when producers or distributors know or ought to know that this is the case;

7. The lack or refusal to provide information requested by the competent authorities under the cooperation obligation foreseen in this Decree-law;

8. The fail to comply with the measures ordered by the competent authorities, notably those imposing the withdrawal of the market or the recall of the product from consumers.

In practice, ASAE mentions that the most common administrative offences in this area are those provided for in Article 26 (1) (a), (b), (c) and (e), which correspond to points 1, 2, 3 and 5 above.

As stated by the ASAE, it is possible to block the products and/or to apply administrative and restrictive measures according to articles 20 and 21 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008. Adoption of these measures involves prohibition, restriction on making available, withdrawal or recall of a product pursuant to Article 20 of Regulation (EC) No 765/2008 of 9 July 2008 or pursuant to the applicable EU harmonisation legislation intended to harmonise the conditions for placing products on the market referred to in Article 21 of that same Regulation.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

If there is an unsafe product on the market, the administrative offence is punished with a penalty from EUR 2 490 to EUR 3 490 (for natural persons) or EUR 7 480 to EUR 44 890 (for legal entities), according to Article 26 (2)(3)(4) of Decree-Law no. 69/2005 of 17 March. The ASAE is the competent authority to apply the penalty.

Article 27 of Decree-Law also foresees the application of the following ancillary penalties:

1. Public disclosure of the penalty;

2. Loss of items (related to the offence) belonging to the agent;

3. Interdiction of the exercise of professional activities;

4. Exclusion of the right to an allowance or benefit granted by public entities or services;

5. Exclusion of the right to take part in fairs or market places;

6. Exclusion of the right to take part in bids and public contests of public works, of provision of goods and services, the concession of public services, and grants of permits and licenses;

7. Closing of an establishment which is subject to a work permit or license from an administrative authority;

8. Suspension of authorisations, licenses and permits.

All interviewees suggested updating the applicable penalties because they are outdated and unbalanced, especially considering the relative proximity between the applicable penalties for natural persons and legal entities. The legal trend in the forecast of penalties has been in recent years to increase their amount, so it would be appropriate to also do it in this context.

Recent case law in Portugal with respect to or relevant for the GPSD/the national implementation legislation.

There is no relevant case law on this matter, at least as regards judgments of the higher courts, which are the only ones accessible in Portugal.

References to the Decree-Law no. 69/2005 of 17 March are only made in the context of cases of liability for defective products (Council Directive 85/374/EEC).[426]

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Portugal concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The relevant authorities consider that there are no practical problems regarding the traceability of a product considered unsafe, but it should be noted that sometimes professionals have doubts about the information they are required to provide about the products they sell.

The definition of a safe product by national legislation (in the same wording as the GPSD) seems to fit a large part of the products on the market. However, also because it has been 14 years since the transposition of the GPSD, the national definition of a safe product does not provide the necessary elements to e.g. explicitly cover environmental risks, safety risks for persons with disabilities, cybersecurity risks or safety risks due to the child-appealing character

[426] See e.g. http://www.dgsi.pt/jstj.nsf/954f0ce6ad9dd8b980256b5f003fa814/4944bb00ba83133a802583200032fdd4?OpenDocument; http://www.dgsi.pt/jtrc.nsf/8fe0e606d8f56b22802576c0005637dc/330aa482aa0db501802583350057b069?OpenDocument.

of products.

Regarding new challenges concerning emerging safety issues with categories of consumer products, the following can be listed: childcare, jewellery, furniture and electrical equipment. As mentioned above, difficulties are experienced in the application of this Decree-Law because it does not explicitly include certain goods containing embedded technology in the definition of a product.

Possible improvements to make the implementation of the GPSD in Portugal more effective

A key step to be taken to make the conditions for implementing the GPSD more effective would be to establish an institutional obligation of cooperation between the competent authorities when the surveillance authority and the inspection agency are not concentrated in one authority. This point was especially emphasised by the Directorate-General for Consumer Affairs (DGC) regarding the relationship between this entity and the ASAE.

One of the reasons that appears to hinder cooperation between entities is the excessive bureaucratisation and hierarchisation of the entities responsible for the matter. Additionally, as product safety is primarily consumer-focused and is of particular interest to them, closer contact between consumers and the market surveillance authority should be promoted.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Portugal.

The organisation of market surveillance of consumer products in Portugal is spread over different entities, which represents a considerable challenge. Depending on the type of product under consideration, competence is distributed according to its category. Thus, the market surveillance authority may be the ASAE (Economic and Food Safety Authority), IRAE (Regional Inspection of Economic Activities, in Azores Island), ARAE (Regional Authority for Economic Activities, in Madeira Island), INFARMED (National Authority for Medicines and Health Products), DNPSP (National Directorate of the Public Security Police), IMT (Institute for Mobility and Transport) or DGC (Directorate-General for Consumer Affairs).

The ASAE is a department of the criminal police with headquarters in Lisbon, led by an Inspector-General assisted by two Deputy Inspectors-General. It is a central service directly administered by the State within the framework of the Ministry of Economic Affairs and it has administrative autonomy. It carries out surveillance and prevention tasks to ensure compliance with legislation governing the pursuit of economic activities in the food and non-food sectors.

Covering all mainland Portugal, the ASAE has — in addition to its central services in Lisbon — several decentralised units that conduct market surveillance exercises. These are referred to as the Regional Units (UR) for the North (URN) the Centre (URC) and the South (URS) and are based in Porto, Coimbra and Lisbon respectively. These decentralised units have no autonomy.

The tasks of the ASAE include the following:

a) Surveillance of economic activities;

b) Developing, implementing and regularly disseminating the market surveillance programme, in accordance with Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008, in addition to taking restrictive prohibition measures, restricting products from being made available on the market and recalling products that have been made available on the market;

c) Surveillance of the sale of products and services with a view to ensuring the health and safety of consumers, as well as surveillance of compliance with the legal obligations of economic operators;

d) Performing the functions of a coordinating authority and National Contact Point in the framework of the general information support system (ICSMS system);

e) Directly or indirectly cooperating in the exchange of information on products placed or made available on the market that present a serious risk, through the EU rapid alert system (RAPEX);

f) Investigating and applying sanctions in administrative offence proceedings within the areas for which it is responsible.

IRAE Azores is tasked with enforcing all the legislation governing the pursuit of economic activities in the food and non-food sectors, and it exercises its activities throughout the territory of the Autonomous Region of the Azores.

ARAE Madeira is tasked with conducting surveillance and prevention to ensure compliance with legislation governing the pursuit of economic activities in the food and non-food sectors. It is an inspection service directly administered by the Autonomous Region of Madeira.

INFARMED is a public institute integrated under the indirect administration of the State, with administrative and financial autonomy and its own assets, exercising the powers of the Ministry of Health, under the supervision and guidance of the respective ministry. It is a central body, headquartered in Lisbon, with jurisdiction over the entire national territory, and may collaborate with the bodies of the Autonomous Regions, in accordance with its powers. Pursuant to Decree Law No 46/2012 of 24 February 2012, INFARMED's mission is to regulate and supervise the sectors of medicines for human use and health products (medical devices and cosmetic and personal hygiene products), according to the highest standards of public health protection, and to ensure that health professionals and citizens have access to quality, effective and safe medicines and health products. This mission is accomplished through the implementation of powers in the fields of policy definition and execution, regulations, compliance, assessment, authorisation, post-marketing surveillance, investigation monitoring and enforcement, production, distribution and marketing, consumption and use of medicines, medical devices and cosmetic and personal hygiene products. In addition to the above, INFARMED's other powers include the promotion of access for health professionals and citizens to the information necessary for the proper use of medicines, medical devices and cosmetic and personal hygiene products, and the promotion and support of study and research in the fields of science and pharmaceutical technology, biotechnology, pharmacology and pharmacoepidemiology.

DNPSP, through its Arms and Explosives Department (DAE), carries out market surveillance activities at the national level in the product sectors relating to pyrotechnics and explosives for civilian use. The DAE carries out market surveillance activities on these products both independently or in internal and external cooperation with other bodies. Internal cooperation is established between the DAE and the Arms and Explosives Centres (NAE) of each Command (Regional, Metropolitan and District) of the PSP and covers all areas of surveillance concerned. Furthermore, external cooperation mainly takes place with the services of the Tax and Customs Authority (AT) and with the ASAE, when surveillance activities are involved that relate to imports or exports respectively, or when handling irregularities relating to the CE marking of the products concerned. The DAE is also represented in various working groups coordinated by the Commission in the area of pyrotechnics, explosives and their precursors. The DAE representatives in the aforementioned working groups contribute, in terms of information-sharing, to a greater harmonisation at Community level in terms of the surveillance activities carried out.

IMT has incorporated the powers of the SIEV — Electronic Vehicle Identification System, S.A — regarding the operation and management of the electronic vehicle identification system. The IMT's mission is as follows:

a) To carry out technical regulation, licensing, coordination, inspection and planning tasks in the road and river transport sector and in relation to the corresponding infrastructure, and on the economic side of the commercial ports and maritime transport sector;

b) To manage concession contracts awarded by the State in the cited sectors or in other sectors, particularly in relation to air transport and airport infrastructures, with a view to satisfying the need for mobility of persons and goods.

The Directorate-General for Consumer Affairs (DGC) is not considered by law to be a market surveillance authority. It is responsible as the national contact point for the RAPEX System – the European system for the rapid exchange of information on non-food products that pose a serious risk to consumers and users – and for managing the RAPEX network in Portugal and is thus a member of the CSN within the General Product Safety Directive Network.

The DGC is a monitoring entity for products that do not have specific legislation but is not a supervisory entity.

Furthermore, the Decree-law no. 69/2005 established the 'Comissão de Segurança de Serviços e Bens de Consumo' (CSSBC) as the Portuguese authority responsible for monitoring the general safety requirements. Its powers involve deliberating on products and services placed on the market whose risk is not compatible with the high level of health and safety protection for consumers; promoting compliance together with the market surveillance authorities with the general safety obligation, in particular through surveillance programmes which must be periodically carried out; proposing to the Government the necessary measures to prevent and protect against risks that products placed on the market may present, including the compulsory general prohibition on the manufacture, import, export, intra-Community trade, marketing or placing on the market of products or categories of products

likely to endanger the health and safety of consumers by virtue of their composition; notifying the competent authority for investigation of the relevant infringement proceedings of any cases of placing on the market of dangerous products of which it becomes aware; conducting technical and scientific studies on the safety of products and services; issuing public recommendations and warnings; and commenting on product safety issues referred to it by the member of the Government responsible for the area of consumer protection.

The CSSBC is a body with a national base; its competence is determined according to the Decree-Law no. 69/2005 and is extended to every and all products placed on the market. The ASAE has competence within the continental territory of Portugal, the ARAE has competence in the territory of the respective autonomic region (Madeira) and the IRAE has competence in the territory of the respective autonomic region (Azores). The INFARMED and the IMT have competence within the national territory.

Plans/programmes in place which define priorities for market surveillance of consumer products

Priorities for the market surveillance of consumer products are set according to RAPEX notifications, but also considering the coordinated actions on product safety organised by the European Union, consumer complaints, customs information, accident reports, inspection results, information provided by consumer organisations and media reports.

Note that the DGC is currently preparing a technical-scientific study on office supplies, which will start in 2019 and end in 2020.

According to the ASAE, the national market surveillance programme covers all the sectors according to the Regulation (EC) No 765/2008, of 9 of July 2008. The ASAE also considers that ICSMS should be used to exchange information considered helpful for other market surveillance authorities. The data entered in ICSMS should also cover simpler checks than laboratory tests only. Nevertheless, there should be no need to include brief visual checks. As a guideline, checks which are individually documented should also be entered in ICSMS.

INFARMED develops specific campaigns for certain types of cosmetic products.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Portugal with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

The relevant authorities reported that there are no market surveillance activities with respect to the safety of products containing new technologies, products sold online or C2C products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The relevant authorities reported that there are no regular market surveillance activities concerning products sold online.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Portugal (except customs) with respect to product safety

Competent authorities in general product safety issues usually cooperate in activities arising from the common use of ICSMS, common use of RAPEX, sometimes in joint activities for dealing with dangerous products, regular exchange of information and, above all, informal cooperation, according to the requests of each of the entities.

Cooperation with customs authorities in Portugal with respect to product safety

Cooperation on general product safety issues with customs authorities involves weekly communication (or even more than once a week) and a regular exchange of information, with respect to DGC and the ASAE. The frequency is lower for INFARMED, which reports a frequency of cooperation of once every three months.

The DGC informs the customs authorities about all decisions concerning products manufactured in another country presenting a serious risk to consumers.

The information validated by the European Commission under the RAPEX system and data which is sent to the DGC

about the recalls of dangerous products from the national market (provided that they have been manufactured in another country) is transmitted to the Tax and Customs Authority.

The ASAE considers that there is very good cooperation between them and the Portuguese Customs Authority, especially in products covered by European Union harmonised legislation under the Regulation 765/2008 of 9 July. The ASAE also has regular meetings with the other Portuguese market surveillance authorities. According to the ASAE, they establish together a uniform methodology and procedure.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation on general product safety issues with national authorities in other countries, according to the DGC, is essentially done through coordinated actions on the safety of products organised at the European Union level, through the regular exchange of information (outside the European Union) and through regular meetings (outside the European Union-related meetings).

According to the ASAE, with relevant authorities located in other countries, cooperation is done through the ICSMS, the wiki confluence platform, mutual assistance requests made or received outside of the RAPEX, and campaigns and voluntary mutual visit programmes between market surveillance authorities.

The ASAE also mentions that if the market surveillance authority has reasonable grounds to believe that a product does not comply with European Union law or presents a serious risk, they shall request the customs authority to suspend the process for its release for free circulation. If the product is already in free circulation and does not comply with the harmonised European Union legislation, the Portuguese market surveillance authority contacts the market surveillance authority of the other Member State by e-mail or through the ICSMS system to inform them about their decision.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

In Portugal, the national contact point for RAPEX is the DGC.

Relevant information about the recall of unsafe products from the national market submitted by market surveillance authorities or by businesses is transmitted to the European Commission through a national notification or a reaction to a notification from another Member State.

When the DGC is confronted with non-safety risks (e.g. environmental and security risks), it informs relevant market surveillance authorities so they can take action where needed.

Information validated by the European Commission under the RAPEX system and data submitted to the DGC on the recall of unsafe products from the national market (by the authorities or businesses) is transmitted to the competent national market surveillance authorities.

The INFARMED mentions that if it detects a dangerous cosmetic product on the market, it notifies RAPEX within two weeks.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The competent authorities provide advice to businesses where needed. The cooperation with consumer organisations is undertaken to promote awareness about product safety among consumers, through a regular exchange of information, regular meetings and informal cooperation.

As part of its role, the RAPEX National Contact Point (DGC) collaborates with businesses on their respective obligations under general product safety legislation through training and specific clarifications.

According to the DGC, cooperation between consumer organisations and relevant entities in the area of general product safety happens every six months. The DGC participates and cooperates in some events promoted by consumer organisations and collaborates in the preparation and dissemination of product safety publications.

The INFARMED mentions cooperation with business associations once every three months and with consumer organisations once every six months through the regular exchange of information and meetings, some informal cooperation with business and consumer organisations to create awareness for product safety among consumers,

and providing advice to businesses where needed.

The ASAE believes that contact with business associations should not be very close, according to their competences and their need to maintain a certain distance, but claims to promote the empowerment of business associations, especially of sectoral associations, participating in seminars and briefings, in compliance with the preventive part of ASAE's activities.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Market surveillance authorities raise awareness of businesses and consumers with respect to product safety through a national online information system and a website on dangerous products or product safety information, through a link to the European Union *Safety Gate/RAPEX* website on their official website, and through information campaigns, including using social media.

The DGC regularly publishes national alerts about consumer products and motor vehicles that are recalled from the national market on its website (https://www.consumidor.gov.pt/). These alerts are also publicised to institutional partners and on Facebook.

The DGC also publishes all the decisions taken regarding unsafe products on the website. It also publishes the publications regularly developed on consumer safety on the website and sends these to its institutional partners, including the Ministry of Education, consumer associations, arbitration centres, the Public Security Police and municipal consumer information centres. Examples are the following publications: Safe Carnival; Piercings; Tattoos; Safe Easter; World Children's Day; Playing and Swimming Safely in Pools; Elderly Consumer Guide; Outdoor activities; Safe Travels; Clothing and Footwear; Back to School; Christmas Shopping. In addition, as part of the DGC's participation in global awareness-raising campaigns of the Organisation for Economic Co-operation and Development (OECD), information materials were produced and disseminated regarding "Laundry Detergent Capsules"; "Button cells"; and "Blind Pull Cords and Curtains".

Regarding to the ASAE, it provides all the information in its website and in its own newsletter.

According to the INFARMED, it provides a national online information system, promotes information campaigns through social media and makes press releases.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Portugal (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Businesses are asked to conduct voluntary and mandatory recalls and other corrective measures, if needed, aiming at a faster response to the problem. The INFARMED reports that recalls and other corrective measures are organised by authorities if no responsible business operator can be found and mentions that the businesses are required to use all their available customer information for recalls and other corrective measures.

The DGC regularly publishes national alerts on consumer products that are collected from the national market on their website (www.consumidor.gov.pt). These alerts are also advertised to consumer protection partners and on Facebook.

In the case of a recall of a consumer product, DGC states that some collaboration with businesses is required. It concerns the information activities targeted at consumers, cooperation with other businesses involved in the supply chain (e.g. distributors, online marketplaces) and a timeline of the recall process. In the case of a recall, the ASAE mentions the requirement to collect statistics on recall effectiveness (percentage of recalled consumer products actually collected). The INFARMED notes that it also requires a timeline of the recall process and the destruction of the products collected.

Lastly, there are no established codes of good practice on product recalls.

Monitoring of effectiveness of product recalls by market surveillance authorities

Only the INFARMED reports the effectiveness of product recalls through the reconciliation report and proof of cosmetics products destruction or return.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Portugal that is relevant for market surveillance (e.g. concerning dangerous products,

related consumer complaints and injuries)

There are statistics on the RAPEX notifications issued by Portugal and on the reactions to notifications made by another Member State concerning product and motor vehicle recall campaigns on the national market in the context of voluntary and compulsory action by businesses and the national surveillance authorities.

There is also a data collection and analysis system for Home and Leisure Accidents, "Epidemiology and Surveillance of Injury, Trauma and Accidents", which was created in 2000 and is managed by the National Institute of Health Doctor Ricardo Jorge, a public institution under the Ministry of Health. The system collects emergency data from previously selected hospitals through the computer platform “SONHO”.

The injury data in the context of market surveillance is used to choose priority areas for surveillance and as benchmark to identify trends.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Portugal (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The authorities have identified some problems affecting the functioning of market surveillance:

- Limited staff resources for market surveillance;

- Lack of expertise in new technologies;

- Lack of expertise in online market surveillance;

- Lack of financial resources for testing of consumer products;

- Lack of coordination at the national level;

- Lack of statistics to set priorities for market surveillance;

- Lack of awareness of consumers with respect to product safety;

- Lack of cooperation with online players.

The INFARMED also mentions some problems in taking effective action when the responsible business is in another EU or EEA state or outside the EU or the EEA, as well as some problems in controlling products from non-EU/EEA-countries that reach consumers directly.

Besides that, legal constraints and obstacles related to the lack of financial and staff resources have precluded effective online surveillance.

However, the RAPEX system is considered to function moderately well.

Areas to make market surveillance of consumer products in Portugal/the EU more effective

In Portugal, market surveillance of consumer products involves participation from many entities. These entities should communicate with each other in order to complete market surveillance, but there are serious difficulties in achieving this goal due to the limited resources available.

Firstly, the lack of cooperation between some authorities is visible, a situation which may require legislative intervention to ensure that this communication is carried out.

Secondly, it is necessary to rethink how the recalls are carried out. In Portugal, a consumer who purchases a product that is later considered unsafe receives the information that it should be returned. However, according to the information obtained, a large part of consumers do not do that, due to either a lack of information or of due diligence. So, many products that are considered unsafe stay in the market, with the obvious risks that this situation entails.

The relevant authorities are aware of this problem and are seeking to develop appropriate solutions to address this difficulty.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Portugal since 2013

Since 2013, the general trend concerning the level of safety of consumer products is positive. However, according to the interviewed market surveillance authorities, it can be even better in the future.

There are no clear statistics to support this general assertion.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Portugal whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Market surveillance authorities in Portugal do not have tools at their disposal to address new challenges.

Views of market surveillance authorities whether approaches in Portugal can be considered best practice implementation of the GPSD, which could be of interest to other countries

There are no market surveillance approaches in Portugal that can be considered a best practice implementation of the GPSD.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	n.a.	n.a.	73
Total (country)	n.a.	n.a.	**73**
Notes:	Based on data (from 2018) provided by Economic and Food Safety Authority and by the National Authority for Medicines and Health Products.		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**2.073**	**705**	**2.778**
Total number of consumer products inspected	6.939*	n.a.	6.939*
Total number of consumer products tested in laboratories	100	120	220
Total number of dangerous consumer products found	19.614*	20*	19.634*
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	9	n.a.	9

Notes:	Based on data (from 2018) provided by the Directorate General for Consumers Affairs, by the Economic and Food Safety Authority and by the National Authority for Medicines and Health Products. * The incongruity of the data lies in the fact that ASAE only provided the number of inspections and they did not provide the total number of consumer products inspected. Therefore, within the 6.939 products inspected, only Directorate General for Consumers Affairs data are included, since National Authority for Medicines and Health Products did not make these data available either.

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	895	26	921
Total number of mandatory recalls	71	10	81
Notes:	Based on data (from 2018) provided by the Directorate-General for Consumers Affairs, by the Economic and Food Safety Authority and by the National Authority for Medicines and Health Products.		

D. Key sources

Legislation	Decree-Law no. 69/2005 of 17 March 2005
Studies/reports/articles	JOÃO CALVÃO DA SILVA, *Compra e Venda de Coisas Defeituosas (Conformidade e Segurança)*, 5th ed., Almedina, Coimbra, 2008.
Websites	www.consumidor.gov.pt www.asae.gov.pt www.dgsi.pt
Interviews	Directorate General for Consumers Affairs Directorate General for Consumers Affairs, (CNS Contact) Directorate General for Consumers Affairs, (RAPEX / Safety Gate Contact Point) Economic and Food Safety Authority Economic and Food Safety Authority Economic and Food Safety Authority (Safety Expert) National Authority for Medicines and Health Products (INFARMED) via questionnaire

23. Romania

COUNTRY REPORT ROMANIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Romania, the GPSD is implemented by Law no. 245/2004 of June 9, 2004 on general product safety[427]. This law was subsequently amended by Law No. 363/2007 on the prohibition of unfair commercial practices, which transposes Directive 2005/29/EC into the Romanian law. These amendments concern: clarification of the relationship between the general product safety requirements vis a vis other special rules stemming from EU law; the level of fines, which were substantially reduced, and the introduction of new fines; the information obligations of the producers and distributors; the right of the concerned business entities to defend their interest; the export prohibition from the EU of products found unsafe; and the timeline of the information obligation towards the European Commission after it has been established that a product presents a serious risk.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Romania

Under Romanian law, it is general requirement that the name of the producer and their contact details be indicated on the product or on its package. The products or the package must also contain a reference and where applicable the batch of products to which the product belongs. The requirements on traceability of Article 5 (1) (b) of Law 245/2004 are binding and sanctioned with fines ranging from 700 to7000 RON in case on non-compliance.

There is no horizontal legal requirement in place in Romania obliging the companies to use barcodes or other signs on products that allow electronical identification. Nevertheless, the enforcement practices differ at level of authorities. In the field of competence of the National Authority for Consumer Protection (NACP) and of the Institute of Metrology there is no requirement for businesses to indicate a barcode or other machine identifiable signs on products and there are no product specific national requirements on traceability. This is not the case for other specific market surveillance authorities, such as the National Environmental Guard, which indicated that there is a requirement for a barcode and other machine detectable identification on the product or on its packaging.

The NACP considers that it would improve traceability if there were a general requirement to indicate a barcode or other machine identifiable signs on products or their packaging. The Office of Legal Metrology noted the need to require businesses to keep supply chain records.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

In Romania there is no specific legal definition of safety in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The framework legislation implementing the GPSD does not cover emerging threats related to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

When European standards referenced in the EU Official Journal do not exist, the NACP uses the reasonable consumer expectation test and the Commission risk assessment guidelines for assessing product safety. In Romania, there are no specific national standards in place where EU standards are not available. The NACP does

[427] Legea nr. 245/2004 privind securitatea generală a produselor.

not use international standards or the state of art of technology in such cases. No other specific standards were indicated by the NACP.

Only the Labour Inspection Authority uses in addition to the Commission Guidelines the state of art of technology and other EU standards not referred to in the Official Journal of the EU and specific national standards in its field of competence. The National Environmental Guard in such cases uses the Commission Guidelines only. The National Office for Legal Metrology and the Ministry of Health did not indicate any alternative tool used in case no EU standards are available for assessing product safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Romania in case there are consumer product(s) on the market which are found unsafe under the GPSD

Under the Romanian law, the business entities are compelled to provide information on the product, on the supply and distribution chain and on the ownership of the website, where applicable.

According to Article 10 of Law 245/2004, the market surveillance authorities in fulfilling their tasks regarding product safety must implement the following measures:

a) For any products, should organise, even after these were put on the market, checks on safety characteristics, at a relevant scale, until the product reaches the consumers; should ask for information on the product and take samples in order to assess product safety;

b) For products that present risks in certain conditions, should request product marking with adequate warning concerning the risks they may present, in Romanian and in clear, visible, intelligible, and easily understandable language, without excluding such information in a foreign language, and to make sure when the product is put on the market that it is safe;

c) For products that may present risks for specific user groups, may demand that such groups are specifically informed about the risks in due time, in adequate form, including through special warnings;

d) For any products that may be unsafe, should temporarily prohibit, for the time needed for control, analysis and assessment of their safety, that such products are supplied, distributed or exhibited;

e) For any other products, should interdict their placement on the market and order additional measures necessary for the enforcement of such interdictions;

f) For any unsafe products placed on the market, should order their immediate withdrawal and warning of consumers concerning the risks of such products and should request or coordinate, and where necessary organise with the producers and distributors the recall of the products from consumers, and the destruction of such products in adequate conditions by the producer or at its expense.

The measures undertaken by the market surveillance authority must be proportionate to the level of risk and must comply with the requirement of precaution (Article 10 para. 2 of Law 245/2004). The NACP is obliged by law to act promptly in fulfilment of its tasks in cases where a product presents high risks. Such cases are established by the authority upon a case by case assessment, considering the characteristics of the product, according to the RAPEX guidelines.

The NACP may require business entities providing an unsafe product on the market to recall products as well as other corrective measures (restrictions on placing such products on the market, bringing products into compliance with safety requirements, withdrawal of products, stopping the placing of products on the market).

The NACP and the Ministry of Health may carry out unexpected on-site inspections and physical checks of the products. The National Environmental Guard, in addition to demanding from business entities to provide information on the products, the supply and distribution chains, unannounced site inspections and physical checks of the products, may also acquire product samples, including through mystery shopping. The National Environmental Guard with similar competencies as the NACP may order product recalls and impose other corrective measures on business entities infringing product safety requirements in its field of competence.

Only the NACP is entitled to reclaim from the business entities the costs of administrative measures concerning the unsafe products (such as testing and storage, for example). The Labour Inspection Authority and the Romanian Bureau of Legal Metrology do not have the competence to take any such measures.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The Romanian law (Articles 7-8 of Law 245/2004) provides for civil law liability and disciplinary liability, administrative fines and criminal sanctions for the cases of infringement of product safety requirements.

Administrative law infringements include the placing on the market of unsafe products, sanctioned with administrative fines ranging from 3 000 to 30 000 RON[428].

Infringement of the obligation to provide the consumers with adequate information allowing them to assess the risks inherent to the products for the average period of use or foreseeable duration of use, when such risks are not immediately detectable by the consumers without an adequate advertisement, and their obligation to prevent such risks is sanctioned with fines ranging from 1 000 to 3 000 RON (approx. 210 EUR to 630 EUR).

Fines ranging from 1 000 to 3 000 RON (approx. 210 EUR to 630 EUR) were subsequently introduced by Law 363/2007 and may be imposed on distributors who do not comply with the legal duty to store and provide the authorities with the documentation necessary to establish the origin of the products.

Non-compliance with the obligation of not putting on the market products about which the distributors are aware or should be aware of not respecting general product safety requirements, may be sanctioned with fines ranging from 2 000 to 4 000 RON (approx. 420 EUR to 840 EUR). This new fine category was introduced by Law 363/2007.

Fines ranging from 700 to 7000 RON apply for cases when: the producer does not take measures proportionate to the characteristics of the products they supply, concerning the information on the risks presented by the product for the consumers (allowing them to take the necessary measures, including avoidance of the risks, if necessary), and allowing the withdrawal of the products, or does not comply with the requirements of necessary and adequate notification of the consumers about the risks or allowing the return of the products by the consumers.

The National Authority for Consumer Protection is the authority competent to establish the above infringements and to impose the corresponding fines. The NACP may cooperate in this task with other authorities with market surveillance competences and may ask for the support of the police in carrying out its control activity. The legal-institutional framework of such inter-institutional cooperation is settled in bilateral protocols or within the framework of interministerial committees. These documents are notified to the European Commission.

The Labour Inspection Authority, the Ministry of Health and the Romanian Bureau Office of Legal Metrology did not mention specific competences to impose administrative sanctions and fines, whereas the National Environmental Guard indicated fines only, without specifying the level of such fines.

The criminal law sanctions are not detailed by the Law 245/2004.

Recent case law in Romania with respect to or relevant for the GPSD/the national implementation legislation.

The relevant stakeholders indicated a lack of awareness on relevant case law on administrative measures and penalties.

In Romania, cases concerning general product safety, challenging the measures taken by market surveillance authorities restricting/prohibiting the marketing of unsafe products, or ordering product recalls or product withdrawals are ruled by the administrative sections of the courts. Consumers suffering damages as a consequence of unsafe products may ask for compensation from the business entity that put unsafe products on the market within civil law litigations under the rules on product liability.

Market surveillance authorities did not indicate any relevant cases concerning the interpretation of Law 245/2004 that were worthy of commentary.

Survey of the official case law database[429] reveals that there is no settled case law yet or relevant case law in development on the interpretation or enforcement problems of Law 245/2004. The few cases identified only mention Law 245/2004 in general terms, as applicable to the case before the court, or as an unsuitable legal basis, Law 245/2004 being considered by the court or the applicant alongside other consumer legislation (sectoral safety requirements, or product liability) or sectoral legislation involving market surveillance. Altogether 43 court

[428] The offical exchange rate of the National Bank of Romania on December 31, 2019: 1 EUR= 4.7793 RON
[429] See http://portal.just.ro/

decisions were identified during the period of 2010 and 2019 which make a passing or tangential mention of Law 245/2004.

However, one first instance case should be mentioned which raised the question as to whether national standards are relevant in assessing general product safety. In the case before the first instance court of Ploiești (decision no. 13791 of 18 October 2013), a company distributing a plum jam on the Romanian market and being fined by the market surveillance authority for not complying with general product safety requirements challenged in court whether such standards, not published in the Romanian Official Journal, may have binding effect. The court established, invoking Article 3 para. 4 (b) of Law 245/2004 (which allows the consideration of national standards in assessing conformity of the goods with general safety requirements), that the company could have obtained the standards from the Ministry of Agriculture and as a professional should have been aware of standards applicable in its field of activity, such as the challenged SP 334/1996 standard, and found that putting on the market products that do not comply with standards constitutes a misleading commercial practice.

The same finding applies at the highest court level. Only 2 decisions made mention of Law 245/2004 as the legal basis considered in the case before the court, and only in general terms, by referring to the obligations stemming from Article 3, which requires the business entities to put only safe products onto the market, without entering into an analysis of the provision. In decision no. 73/2014 of 14 January, 2014, concerning a case where the business entity challenged the refusal of the Ministry of Agriculture and Rural Development to allow commercialisation of an ecological product put in free circulation in other EU Member States, by invoking the principle of free movement of goods and primacy of EU law, the highest court[430] confirmed the legality of such a refusal on the grounds that according to Law 245/2004, only safe products may be put on the market, and Regulation 834/2007/EC concerning agricultural production and ecological labelling of agricultural products allows Member States to make such types of fertilizers subject to authorisation. The court established that such fertilizers, as in the case before it, that are not mentioned in the Annex I of Regulation 889/2008, cannot be put on the market.

In the second decision no. 3730/2013 of 5 November 2013 mentioning Law 245/2004, the highest court dealt with a case involving a traffic accident in which perishable foods were damaged on their way from the Netherlands to Turkey and became dangerous products in the meaning of the GPSD, presenting a risk for health due to their exposure to temperature fluctuations and humidity. As the business entity challenged the applicability of the general product safety rules and those on food safety by invoking that the goods were not aimed for consumption on the Romanian market, the court established the applicability of Law 245/2004 and of Law 150/2002 (implementing Regulation 178/2002/EC) on the grounds that the goods suffered damages and were transported through the territory of Romania.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Romania concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The relevant authorities did not signal the need for improving safety legislation in Romania and did not indicate emerging safety issues, except the National Authority for Consumer Protection, which indicated as an emerging problem disposable cutlery (such as plastic forks, new types of cutlery such as those made of cellulose) from the field of non-harmonised consumer products.

Concerning product traceability: (1) The National Bureau of Legal Metrology indicated the difficulty in the identification of manufacturers for measures of length, especially those from China; and (2) the National Environmental Guard mentioned frequent cases of incomplete product hazard information.

Possible improvements to make the implementation of the GPSD in Romania more effective

The relevant authorities did not advance proposals on how the Romanian legislative framework could be improved in order to enhance the effectiveness of product safety related market surveillance. In the legal literature on product safety, there is no ongoing debate on regulatory needs in the field of general product safety. Nevertheless, stricter ex-post obligations on business entities to report on the measures taken and ex-post surveillance would improve effective enforcement.

[430] *Înalta Curte de Casație și Justiție*

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Romania.

In Romania, market surveillance in the field of general product safety is centralised. Local branches of the National Authority for Consumer Protection have no specific market surveillance competencies.

The National Authority for Consumer Protection (NACP)[431] is the central implementing authority for general product safety and in addition also for certain sectors such as: electrical equipment designed for use within certain voltage limits; electromagnetic compatibility; airborne noise emitted by household appliances; safety of toys; cosmetic products; detergents; household electric refrigerators, freezers and combinations thereof; energy labelling of household lamps; labelling of the materials used in the main components of footwear; textile products; availability of consumer information on fuel economy and CO2 emissions in respect of the marketing of new passenger cars; quality of petrol and diesel fuels; batteries and accumulators and waste batteries and accumulators; energy labelling of household washing machines; energy labelling of household combined washer-driers; waste electrical and electronic equipment; eco-design requirements for standby and off mode, electric power consumption of electrical and electronic household and office equipment; eco-design requirements for simple set-top boxes; eco-design requirements for no-load condition electric power consumption and average active efficiency of external power supplies; eco-design requirements for non-directional household lamps; eco-design requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps.

Plans/programmes in place which define priorities for market surveillance of consumer products

There is a National Market Surveillance Programme in place in Romania (notified to the European Commission) as well as sectoral programmes. Such programmes, as mentioned by the National Authority for Consumer Protection, are not public, thus they could not be examined for the purposes of the report.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Romania with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

In the field of new technologies, the National Authority for Consumer Protection does not undertake market surveillance. This task is performed by sectoral authorities. For example, the National Environmental Guard is in charge of market surveillance for electronical and electrical equipment under RoHS, WEEE and batteries. The Ministry of Health and the Labour Inspection Authority did not report on such activities.

In Romania, the National Authority for Consumer Protection conducts online market surveillance once every six months regarding products sold online by business entities established in Romania or in an EU/EEA Member State, but not on products sold online from outside the EU/EEA. The Romanian Bureau for Legal Metrology conducted only once such market surveillance activity within the framework of the EU project E-Commerce for NAWI.

The National Environmental Guard is in charge of detecting possible cases of illicit online trade with dangerous substances and equipment using such substances. Such activities take place once a year for products sold online by entities established in Romania and entities established outside the EU, but not for products sold online by entities established in other EU/EEA Member States.

The Labour Inspection Authority and the Ministry of Health do not conduct market surveillance for products sold online.

The Romanian market surveillance authorities do not conduct market surveillance on C2C products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The National Authority for Consumer Protection, the National Environmental Guard and the National Bureau of

[431] *Autoritatea Națională pentru Protecția Consumatorilor*

Legal Metrology organise market surveillance for products sold online by checking retailers' websites and online marketplaces, generally in collaboration with other business entities, which sell dangerous substances or use such substances. In more concrete terms, the NACP checks the websites mainly based on consumer complaints and as part of the national thematic controls, which are aimed at assessing compliance with consumer protection legislation in specific market sectors. During such inspections, the authority checks the information provided to the consumers.

The NACP mentioned its participation in EU Joint Market Surveillance Actions funded by the European Commission, where during the activities carried out as part of these projects products were bought, tested and measured.

The National Bureau of Legal Metrology also assesses distributors and retailers' websites. Within the above mentioned screening project (E-Commerce for NAWI) regarding inscriptions and markings on the products sold online, the National Bureau of Legal Metrology obtained information by analysing pictures of the products posted online.

However, market surveillance activities conducted on products sold online are minor as a percentage in the yearly activity of the authorities. Such activity amounts to 3-5% in the case of the NACP and of the National Environmental Guard, whereas in the case of the National Bureau of Legal Metrology these activities amount only to 1-2%.

None of the relevant market surveillance authorities conduct mystery shopping.

All five sectoral authorities interviewed, including the NACP, have emphasised the lack of human and financial resources as impediments hindering the market surveillance of products sold online.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Romania (except customs) with respect to product safety

In Romania, the RAPEX seem to be preferred channel of communication and cooperation by the authorities involved in market surveillance at the national level.

The National Authority for Consumer Protection cooperates with local authorities, but did not quantify such instances. Such cooperation takes place informally or by other methods, when needed.

The National Bureau of Legal Metrology indicated such cooperation less than once a year, through RAPEX, ICSMS or informal channels. The Labour Inspection Authority participated in such cooperation only once within the framework of formal agreements. The National Environmental Guard uses a much larger palette for cooperation, such as: inclusion of other authorities in the elaboration of market surveillance plans and programmes; formal agreements; joint actions on dangerous products; regular exchange of information; and joint training sessions. The Ministry of Health uses RAPEX and notifications received from other authorities on unsafe products.

Cooperation with customs authorities in Romania with respect to product safety

The National Authority for Consumer Protection cooperates with custom authorities once a month, within the framework of a formal cooperation agreement and also informally. Customs notifies the NACP when has doubts concerning the conformity of a product with product safety requirements, in order for market surveillance inspections to be conducted. Conversely, when a dangerous product is identified, the NACP provides the customs authority with information on product categories in which a serious risk or non-compliance has been identified.

The Romanian Bureau of Legal Metrology reported cooperation less than once a year with customs authorities as provided for by EC Regulation 765/2008. The Bureau conducts proactive surveillance, so that any non-compliant product can be identified as close to the time of their placing on the market as possible. Communication with customs takes place through informal channels.

The Ministry of Health cooperates with customs upon request and also notifies customs of dangerous products, especially in the field of cosmetics. Notification of customs happens within a few days when dangerous products are detected by the Ministry of Health.

The Labour Inspection Authority cooperates with customs once every three months. When customs authorities have doubts about the safety of a product, they inform the territorial labour inspectorate in order to conduct a market surveillance inspection, and when a labour inspection identifies a dangerous product, it provides the customs authority with information on product categories in which a serious risk or non-compliance has been

identified.

The National Environmental Guard cooperates the most with customs (more than once a week) and uses several channels for this purpose (joint setting of priorities in market surveillance with customs, common strategy on product safety enforcement, formal agreements, inclusion of customs in the elaboration of the national market surveillance plan and programmes, and regular exchange of information takes place between the two authorities). Communication takes place by phone or e-mail in order to ensure prompt action of the authorities.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

When unsafe products are detected on the Romanian market, the National Authority for Consumer Protection contacts the single contact point of the Member State where the business entity not complying with general product safety requirements is established. For products originating from outside the EU, the EU importer will be identified and the same rule will apply as above. The single contact point of other Member States is contacted through RAPEX, or on the Wiki confluence platform, or within the framework of coordinated actions. The NACP stressed that in case of online sales, it cannot take any measures against the business entity not complying with the product safety rules. No cooperation was mentioned by the NACP with countries outside the EU/EEA.

The Labour Inspection Authority contacts directly the business entity responsible for placing the product on the market in order to take the necessary measures for the non-conformity situation in both cases (products originating from EU/EEA and non-EU/EEA countries). When the business entity concerned does not take the necessary measures, or is located outside the EU/EEA, the authority will contact the relevant market surveillance authority in the country concerned. If the relevant business entity still does not comply with product safety requirements along the restrictive measures ordered by the foreign authority, the labour inspection will contact the Romanian customs authority in order to block the future import of such products into Romania. Cooperation with EU/EEA authorities is based on formal agreements and also takes place via ICSMS. The labour inspection could not report on similar cooperation taking place with authorities of non-EU/EEA states.

The National Environmental Guard reported that in cases where the business entity not complying with the product safety requirements is from an EU/EEA Member State, then the regulatory authority of the country concerned is informed and it is decided by mutual agreement what measures should be applied. In cases where non-conforming products originate outside the EU/EEA, their access to the Romanian market will be prohibited. The cooperation with authorities from other Member States takes place through various channels: regular meetings (outside EU related meetings), coordinated actions organised at the EU level, regular exchange of information, mutual assistance requests made/received outside the RAPEX system, and joint training (outside EU training). Concerning product safety issues related to products originating from outside the EU/EEA, cooperation with foreign authorities takes place within the framework of cooperation agreements outside EU mechanisms and structures.

The Romanian Bureau for Legal Metrology uses ICSMS or RAPEX for communication and cooperation with authorities in the EU/EEA. When the manufacturer of the non-conforming product is from a country outside the EU/EEA, the importer established in the EU will be considered responsible for the unsafe product. Cooperation takes place within the framework of coordinated actions and mutual assistance requests made/received outside of RAPEX. With authorities located in non-EU/EEA countries, cooperation takes place through informal channels.

The Ministry of Health uses RAPEX only for cooperation with the market surveillance authorities of EU/EEA countries.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

When the territorial office of the National Authority for Consumer Protection or another central authority with market surveillance competence identifies a dangerous product on the Romanian market, the case is reported to the single national RAPEX contact point of the National Authority for Consumer Protection, which verifies the information in order to be submitted to the RAPEX system. The average duration between the detection of the dangerous product and its notification to the RAPEX system is one week, as reported by the NACP.

The Labour Inspection Authority and the Romanian Environmental Guard have so far not used the RAPEX system, therefore could not report on their own experience. The Romanian Bureau of Legal Metrology reported the use of the ICSMS system.

The State Sanitary Inspectorate within the Ministry of Health informs the National Authority for Consumer Protection about dangerous cosmetic products. The average duration between the detection of the dangerous

product and its communication to the RAPEX system is estimated to be 3 days by the Ministry of Health.

Non-safety risks are communicated by the interviewed authorities to the competent market surveillance authorities.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The National Authority for Consumer Protection cooperates with businesses once every six months, in the form of occasional advice to businesses when requested concerning the application of the product safety legislation, or when significant legislative changes occur. Cooperation with consumer associations takes place within the framework of cooperation agreements and in form of meetings organised upon demand by consumer organisations or at the initiative of the NACP. Such cooperation takes place once every six months.

The National Environmental Guard reported continuous cooperation (more than once a week) with businesses, aimed at enhancing business awareness of product safety requirements. For this purpose, the National Environmental Guard organises regular meetings with business associations and also provides advice to businesses where needed. Whenever businesses signal (business entities report) to the Guard that there are non-conformities regarding the safety of products, the Guard reacts to such complaints. Concerning the cooperation with consumer associations, this only takes place occasionally.

The Romanian Bureau of Legal Metrology cooperates with businesses and business associations once every three months, occasionally when economic operators request clarification regarding the application of the legislation in force or when significant legislative changes occur. Such cooperation takes place either informally or in the form of advice provided to the business entities, upon request.

The Labour Inspection Authority cooperates with consumer organisations and business associations and businesses when needed (no data provided on the frequency).

No cooperation was reported by the Ministry of Health with consumer organisations or business associations and businesses.

None of the authorities indicated a webpage where information on such cooperation is publicly available.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Consumer awareness of unsafe products is raised by the Romanian authorities through: press releases (NACP, National Bureau of Legal Metrology, National Environmental Guard); link to the RAPEX system on their official websites (NAPC); information campaigns using the social media (NACP, National Environmental Guard); website of the authority (Romanian Bureau of Legal Metrology); and information campaigns in traditional media such as TV or newspapers (National Environmental Guard).

The Ministry of Environment and the Labour Inspection have not undertaken such activities so far.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Romania (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

The NACP has the competence to require the business entities concerned to voluntarily recall the unsafe products and may also order a mandatory recall of such products and impose other corrective measures. The information channel for the recall may be agreed between the authority and the business entity. The business entities may be asked to use their entire information channel for the purposes of product recalls or other corrective measures. In the case of product recalls, the NACP will check and influence the message to be given to the consumers and the recall strategy of the business entity. The NACP will require from the business entity information on: information activities targeted at consumers, information activities targeted at or in cooperation with other businesses involved in the supply chain, a list of other businesses involved in the supply chain, and a timeline of the recall process. In order to warn the consumers, the NACP uses both traditional media and social media. The producers and distributors concerned must provide the NACP with information about the products recalled by correspondence on paper (containing the stamp of the company and the signature of the representative of the company) and

electronically, in compliance with the requirements of the notification form.[432]

The National Environmental Guard, in addition to its competence to order voluntary and mandatory recalls, may itself recall dangerous products or implement other corrective measures if no responsible business entity can be identified. In fulfilling its tasks, the Guard may require the businesses to use all their available customer information for recalls and other corrective measures. However, it does not require from the business communication on information activities targeted at consumers. The Guard may require information on: information activities targeted at or in cooperation with other businesses involved in the supply chain, a list of other businesses involved in the supply chain, a timeline of the recall process and the destruction or disposal of products collected. For these purposes, the Guard uses both traditional and social media. No knowledge of codes of good practices or guidelines was reported by the Guard. The Guard does not cooperate with businesses in regard to specific product recalls.

The Labour Inspection Authority may ask business entities to conduct a voluntary or mandatory recall of unsafe products and order other corrective measures. It may require information on: information activities targeted at or in cooperation with other businesses involved in the supply chain, a list of other businesses involved in the supply chain, a timeline of the recall process and on the destruction or disposal of products collected. It does not cooperate with businesses regarding specific recalls. It uses traditional channels of media for consumer warning. The authority is not aware of codes of good practices or guidelines.

The Romanian Bureau of Legal Metrology may ask for a voluntary recall and may also order a mandatory recall of such products, may impose other corrective measures and may require business entities to use all their customer information for recalls and other corrective measures. The Bureau applies for product recalls according to the procedure provided for in Article 21 of Regulation 765/2008/EC. It may influence the recall strategy of the company concerned, but not the information to be provided to the consumers. It can also establish the timeframe of the recall depending on the number of products that must be recalled and their area of distribution, as well as the severity of the non-compliance found. The Bureau did not report on codes of good practices or guidelines in place on product recalls.

The Ministry of Health may order mandatory recalls of dangerous products and check and influence the recall strategy of the company concerned. It may demand information on: information activities targeted at or in cooperation with other businesses involved in the supply chain, a list of other businesses involved in the supply chain, and on the destruction or disposal of products collected. The Ministry of Health has no role in informing the consumers on recalls and could not report on codes of good practice in place or guidelines on product recalls.

Monitoring of effectiveness of product recalls by market surveillance authorities

Effectiveness of product recalls is not monitored by the National Authority for Consumer Protection. Nevertheless, such monitoring was reported by the Romanian Bureau of Legal Metrology concerning both voluntary and mandatory recalls. This authority is entitled to ask the company recalling the unsafe product for details on the number of non-compliant products at the final users and to provide evidence of recalling those products (i.e. the number of recalled products). Furthermore, the authority collects information on the absolute number of products collected and the percentage of recalled products that are actually collected. It also conducts checks on shops regarding the withdrawal of products. The Romanian Labour Inspection Authority also collects information on the absolute number of the products recalled and the percentage of recalled products that are actually collected. The National Environmental Guard undertakes the most extensive monitoring activity, including information on the absolute number of products collected and the percentage of recalled products that are actually collected, and checks the shops regarding the withdrawal of products and the information on the consumer warning on product recalls.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Romania that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

In Romania, the RAPEX database is the only central database on dangerous products; the National Authority for Consumer Protection does not keep a separate national database. Data on consumer complaints on dangerous products can be monitored in the public database on consumer complaints. There is no separate injury data

[432] Available at: https://anpc.ro/articol/516/info-privind-obligatii-ale-producatorilor-si-distribuitorilor.

collection by the NACP.

The National Environmental Guard makes mention of a database on consumer complaints by third parties and of data collection on injuries from public health related registers (hospitals), poison centres, mass media and consumer complaints. Such data is considered by the National Environmental Guard when choosing priority areas for market surveillance, for identification of new risks and information of the consumers of such risks. The sources of information for the Ministry of Health on dangerous products are the consumer complaints. The Romanian Bureau of Legal Metrology does not have information of databases on dangerous products and injuries.

None of the authorities indicated the webpage of such databases on dangerous products and injuries, or provided details on how they use the collected data on consumer complaints, or how they process and follow up on product safety consumer complaints. The interviewed authorities do not have information on such data collection or databases at the custom authorities.

The main channel of data collection on dangerous products seems to be consumer complaints in Romania.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Romania (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The Romanian market surveillance authorities consulted all signalled the lack of human and financial resources, the lack of expertise in new technologies and in online market surveillance in carrying out their tasks under the GPSD. The lack of suitable testing laboratories is also a major issue that was signalled by the NACP and Ministry of Health. In addition, the lack of effective control of product safety at the borders was emphasised by the NAPC and the National Environmental Guard. Lack of human resources and finances are identified as major causes of the deficit in expertise in new technologies and online market surveillance.

In addition to the above mentioned difficulties with the Romanian market surveillance related to the GPSD, the National Environmental Guard signals other major deficiencies, such as: the lack of coordination with customs authorities; unclear distribution of market surveillance competencies at the national level and lack of coordination at the national level; the lack of statistics and data to set priorities of market surveillance; problems in controlling the safety of products originating from non-EU/EEA-countries; the lack of awareness of businesses and of consumers on product safety requirements. For the reasons listed above, the National Environmental Guard considers market surveillance rather non-effective.

Although the NACP considers the RAPEX system to be rather well-functioning the National Environmental Guard indicates other major impediments in the well-functioning of RAPEX which question its effectiveness, highlighting the lack of sufficient information to trace notified products and lack of information from other national authorities involved; delays of notifications appearing in RAPEX; technical difficulties with the RAPEX system; and difficulties with the implementing legislation concerning the RAPEX system.

Areas to make market surveillance of consumer products in Romania/the EU more effective

The National Authority for Consumer Protection mentions online sales, goods with digital elements and emerging technologies as areas of market surveillance where there is room for improvement. More specialised laboratories for tests and risk assessment, training for inspectors at the EU level regarding market surveillance, and special funds allocated for tests are considered necessary to improve enforcement of general product safety requirements. The National Environmental Guard considers product recalls an area in need of improvement, suggesting the recording of the quantity of the batch of non-compliant products, imposition on the companies of deadlines for the measure of withdrawal from the market of the whole batch of the non-compliant product, and the subsequent verification of the measure upon expiration of the deadlines.

The Romanian authorities do not make specific suggestions as to how the national legislation on GPSD related market surveillance could be improved, although some (such as the National Environmental Guard) signal that there are problems with the legislation, without specifying the problem. Nevertheless, it was indicated that better liaising among the authorities involved in product safety market surveillance, especially with custom authorities, and more involvement of sectoral authorities possessing better technical expertise than the NACP, could improve the functioning of market surveillance.

Centralisation of enforcement at the NACP, despite the fact that it lacks human and financial resources and expertise, impedes the functioning of effective market surveillance, although other authorities also struggle with a lack of human and financial resources. Lack of expertise and finances demand solutions at NACP. Central data and

up to date statistics on dangerous products and injuries should be developed at the level of NACP in cooperation with sectoral authorities that may contribute to a better information and coordination among the authorities involved in product safety market surveillance. Such databases may also provide better information for businesses, may have a deterrent effect on non-compliant companies and may enhance consumer warnings for unsafe products.

It seems that today the main channel of data on dangerous products and injuries are consumer complaints, whereas other channels (specific market controls conducted on own initiative by the NACP and other authorities) are less often used in a country such Romania, where consumers are not active in defending their interest in the market and lack proper knowledge in product safety. As product safety issues are highly technical and consumers lack information and expertise in identifying dangerous products, centrally developed and publicly available databases would be needed, which would enhance public enforcement.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Romania since 2013

The Romanian authorities are of the opinion that product safety has improved in Romania. In support of this finding, the National Authority for Consumer Protection invokes the increase in the number of unexpected inspection actions and the diversification of inspection issues at national and local level. However, given the lack of a central database and up to date data on noncompliance with safety requirements, it is difficult to quantify the improvement of product safety. Case law on product safety is very limited in Romania and does not offer a real picture of product safety litigation. Litigation culture of Romanian consumers is below the European average; consumers rarely go to court with product safety issues. This requires enhanced public enforcement.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Romania whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

The National Authority for Consumer Protection is unprepared to cope with the challenges of new technologies for consumer safety. It lacks above all the financial and human resources for developing proper tools and procedures and strategies. The need for knowledge and training is acknowledged by the NACP.

Only the National Environmental Guard considered itself prepared to address new challenges and mentioned having the necessary tools and strategies developed (although it did not specify further) and the Romanian Bureau for Legal Metrology, which mentioned only the ICSMS System as a tool applied in this context.

Views of market surveillance authorities whether approaches in Romania can be considered best practice implementation of the GPSD, which could be of interest to other countries

None of the authorities consulted for this report recommended their procedures as best practice. To the contrary, the National Authority for Consumer Protection signalled the need for support from the Commission in creating a forum for bringing together the representatives of the Commission, of Member State customs and of national consumer protection authorities in order to discuss good practices, to analyse the specific problems at the Member State level and "to identify solutions and timely cooperation procedures".

The NACP underlined the major role that customs and the allocation of human and financial resources have in ensuring efficient supervision at borders. Otherwise "it is humanly impossible to carry out large-scale controls on the entire market, given the extremely large number of companies and the diversity on the market. That is why it is very important that a strict sorting of the products entering the EU market should be made by customs", stresses the NACP. In support of this need, the NAPC considers it important to draw attention to the fact that Romania is an important point of entry for products coming from non-EU/EEA-countries in the EU. In this context, the NACP also mentions the major importance of ensuring "a transparent list with the accredited laboratories from non-EU/EEA-countries, and the problem that many traders who distribute imported goods from non-EU/EEA-countries present tests conducted at laboratories from non EU/EEA countries (China, as a rule), laboratories declared to be accredited according to European legislation, but it is impossible to verify this, or some traders even falsify documents. For this

reason, is very difficult to verify the veracity of these documents".

One major reason of the dissatisfaction of the Romanian authorities is the lack of sufficient human resources and financial resources as well the lack of adequate infrastructure (laboratories) and expertise.

This may be the reason behind the enforcement policy in place in Romania, which is characterised by a 'minimalistic' approach.

The Romanian authorities comply with the requirements stemming from the EU directive on general product safety. However, transposition of such requirements at the level of legislation, administrative rules and procedures is kept to a minimum. No specific procedures are developed on assessing product safety. Legal developments are only led by the EU law; for situations not covered by EU safety standards, no specific national rules or procedure were elaborated considering specific regulatory needs.

Consumer law literature is scarce in general, and does not enter into an analysis of the living law and of the enforcement problems concerning general product safety. The economic literature on market surveillance does not devote specific attention to general product safety. General non-food product safety is not discussed at such a practical level that would offer effective guidance to the market surveillance authorities.

Considering the high interdisciplinarity and technicality of non-foo product safety, a proper assessment of regulatory needs in terms of procedural solutions implies in the first place better collaboration and exchange of experience among the authorities involved at the national level in market surveillance. The relevant authorities suggest the lack of an integrated approach on procedures at the national level. The specific competencies and procedures elaborated at the sectoral level show large diversity, which for the business entities may generate multiple reporting or information obligations on one hand, and leave room for procedural gaps that weaken effective market surveillance to the detriment of consumer protection on the other hand. Out of the four sectoral entities involved in the research, it seems that the National Environmental Guard has a leading role in complementing the market surveillance activities conducted by the NACP. However, due to the high technicality and interdisciplinarity of product safety, improvement of effectiveness in product safety related market surveillance does not solely rely on the NACP, but calls for sustained cooperation among all the authorities concerned.

The lack of human resources and finances, combined with lack of innovative procedural solutions, raise serious concerns as to what extent the Romanian authorities are prepared to cope with the risks for consumers generated by the process of fast digitalisation of society. The Romanian authorities consulted for this report all reported the lack of human and financial resources and lack of expertise as impediments hindering the market surveillance of products sold online.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
National level 1. *National Authority for Consumer Protection (NACP)* 2. *National Environmental Guard (NEG)* 3. *Labour Inspection (LI)* 4. *Ministry of Health (MH)* 5. *Romanian Bureau of Legal Metrology (RBLM)*	*National level:* *TOTAL: 3*	*National level:* *TOTAL: 86*	*National level: 3*[1] *TOTAL: 92*
Responsible authorities at the sub-national level (regional/provincial/local)	*TOTAL: 461*	*TOTAL: 335*	*TOTAL: 419*
Total (country)	***467***	***424***	***510***
Of which staff allocated to market	*TOTAL: 338*	*TOTAL: 338*	*TOTAL: 338*

surveillance activities regarding products sold online			
Notes:	*The data reflects the situation in the year 2018.* *At the subnational level, the personnel of local offices of the national authorities is indicated and not the HR of sub regional authorities.* *[1]Data provided by the NACP concerns both harmonised and non-harmonised products, hence no distinction is made between them in the records of the NACP.*		

B. Number of <u>inspections</u> of consumer products (last available year)			
	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	*TOTAL:* 371,571	*TOTAL:* 120	*TOTAL:* 29,539
Total number of consumer products inspected	*TOTAL:* 109,981	*TOTAL:* 238	*TOTAL:* 15,245
Total number of consumer products tested in laboratories	*TOTAL:* 218	*TOTAL:* 0	*TOTAL:* 0
Total number of dangerous consumer products found	*TOTAL:* 68	*TOTAL:* 0	*TOTAL:* 41
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	*TOTAL:* 31	*TOTAL:* 0	*TOTAL:* 41
Notes:	*The data reflects the situation in 2018.* *The data provided by the NACP reflects both harmonised and non-harmonised products. No separate records are kept by the NACP.*		

C. Number of <u>recalls</u> of consumer goods (last available year)			
	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	*TOTAL:* 35	*TOTAL:* 24	*TOTAL:* 59
Percentage of recalled consumer products that were actually collected (estimated average across all recalled products)	*TOTAL:* 20%	*TOTAL:* 10%	*TOTAL:* 10%
Notes:	*The data reflects the situation in 2018.* *Data provided by the NACP concerns both harmonised and non-harmonised product, hence no distinction is made between them in the records of the NACP.*		

D. Key sources	
Legislation	Law No. 245/2004 of June 9, 2004 on general product safety (Legea nr. 245/2004 privind securitatea generală a produselor). Law No. 363/2007 on the prohibition of unfair commercial practices, transposing Directive 2005/29/EC into the Romanian law (Legea nr. 363/2007 privind combaterea practicilor incorecte ale comercianților în relația cu consumatorii și armonizarea reglementărilor cu legislația europeană privind protecția consumatorilor. (*This law also ammends Law 245/2004 on general product safety)*. Government Decision No. 700/2012 on the organization and functioing of the National Authority for Consumer Protection (Hotărârea Guvernului nr. 700/2012 privind orgnaizarea și funcționarea Autorității Naționale pentru Protecția Consumatorilor)

Studies/reports/articles	There is no relevant legal literature to be reported. Consumer law literature is in general scarce in Romania and does not concern general product safety in practical terms.
Websites	Website of the Ministry of Justice on case law: http://portal.just.ro/ Website of the High Court of Cassation and Justice (Înalta Curte de Casație și Justiție): https://www.scj.ro/ Annual reports of the National Authority for Consumer Protection (2010-2018) https://anpc.ro/galerie/file/544/2019/raport_anpc_2018.pdf; https://anpc.ro/galerie/file/544/2018/R2017.pdf; https://anpc.ro/galerie/file/544/2017/Raport_activitate_ANPC_2016.pdf; https://anpc.ro/galerie/file/interes_public/Raport_ANPC_2015.pdf; https://anpc.ro/galerie/file/interes_public/raport_activitate_2014.pdf; https://anpc.ro/anpcftp/interes_public/raport_activitate_anpc_2013_140709.pdf; https://anpc.ro/anpcftp/interes_public/raport_activitate_anpc_2012_130725.pdf; https://anpc.ro/anpcftp/interes_public/raport_activitate_anpc_2011_121212.pdf; https://anpc.ro/anpcftp/interes_public/raport_activitate_anpc_2010_110701.pdf; https://anpc.ro/anpcftp/interes_public/raport_activitate_anpc_2009.pdf
Interviews	Interviews were conducted in written with the Romanian authorities: National Authority for Consumer Protection (European Harmonisation and Partnership Service National Environmental Guard Ministry of Health (National Authority for cosmetic products and biocidal products) Labour Inspection Romanian Bureau for Legal Metrology (Market Surveillance Authority for Non Automatic Weighting Instruments (NAWI) and Measurement Instruments

24. Slovenia

COUNTRY REPORT SLOVENIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Slovenia, the GPSD (Directive 2001/95/EC) was implemented by the "General Product Safety Act" ("ZSVP-1"),[433] Official Gazette of the Republic of Slovenia No. 101/2003, applicable from 1 May 2004.

This is the general act, laying down basic safety requirements, the obligations of producers and distributors, the way the information is forwarded to the EU, the types of product safety surveillance, the supervisory committee (board) as well as the penalties for the breach of duties by the businesses.

In part, the GPSD is also implemented by the government Regulation on the methods of international exchange of information about measures and actions restricting trade in products,[434] Official Gazette of the Republic of Slovenia No. 79/11. The same regulation also implements the Regulation No. 765/2008. There is also other legislation relating to safety of particular groups of products.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Slovenia

It is implemented by Arts. 9 and 10 General Product Safety Act. In Art 9 (1), there is a general requirement that producers (within the limits of their activities) shall provide consumers the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. According to Art. 10 (1) General Product Safety Act, the producers are – within the limits of their activities - obliged to adopt measures enabling them to be informed on potential risks of the product and to choose the appropriate action. The measures *must* include an indication, on the product or its packaging, of precise information about the producer and about the product with reference or the batch of products, unless it is justified for such indication to be omitted as well as, in all cases where necessary, sample testing of marketed products, investigating and keeping a register of complaints and keeping distributors informed of such actions (Art. 10(2) General Product Safety Act.

The requirement of indication of information on producers and the product, including the batch of products, is not optional but mandatory; however, the Act – as does the Directive – allows "justified" exceptions and gives no guidance as to what justifies an exception. There is no case law on the subject.

Art. 11 General Product Safety Act prescribes the duties of distributers. They are obliged under Art. 11 (1) – within the limits of their actions – to carry out measures aiming at product safety with professional diligence (i.e. with the highest level of duty of care). Above all, they are not allowed to deliver products for which they know or could know (taking into account their professional diligence) that they fall short of the safety standards. They must participate in monitoring the safety of products by passing on information on the risks of products, keeping and providing of documentation necessary for tracing the origin of the products, and cooperating in the action taken by producers and authorities to avoid the risks, Art. 11 (2) General Products Safety Act. These requirements are mandatory, not optional.

There are no explicit requirements on the barcodes or electronic identification.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety; Art. 4 (2) General Products Safety Act corresponds to Art. 2 (b) GPSD. The

[433] *Zakon o splošni varnosti proizvodov*
[434] *Uredba o načinu mednarodne izmenjave informacij o ukrepih in dejanjih, ki omejujejo trgovanje s proizvodi*

benchmarks for assessing safety from Art. 3 (3) GPSD are implemented in Art. 7 General Products Safety Act.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Not specifically; however, some emerging threats relating to new technologies are considered to be covered by the existing legislation, such as the malfunctioning of software which is embedded in a product that can affect safety, malfunctioning of non-embedded software in a product that can affect safety and products with AI/machine learning capabilities that can affect safety of consumers.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

There are other European Standards, national standards (although very few existing), some international standards. Commission recommendations (insofar as these exist), codes of good practice and the state of the art and technology.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Slovenia in case there are consumer product(s) on the market which are found unsafe under the GPSD

According to Art. 17 (3) General Product Safety Act, the inspectors are (in addition to general powers of inspectors) entitled to take the following measures[435]:

(a) for any product:

- to organise, even after its being placed on the market as being safe, appropriate checks on its properties affecting safety; such checks shall be carried out on an adequate scale up to the final stage of use or consumption;
- to require all necessary information from the producers or distributors;
- to take samples of products and subject them to safety checks;

(b) for any product that could pose risks in certain conditions:

- to require that it be marked with suitable, clearly worded and easily comprehensible warnings in the Slovenian language on the risks it may present;
- to make its marketing subject to prior conditions so as to make it safe;

(c) for any product that could pose risks for certain persons:

- to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings in the media;

(d) for any product that could be dangerous:

- for the period needed for the various safety evaluations, checks and controls, to temporarily ban its supply, the offer to supply it or its display;

(e) for any dangerous product:

- to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;

(f) for any dangerous product already on the market:

- to order or organise its immediate withdrawal and alert consumers to the risks it presents;
- to order or coordinate and, if appropriate, organise with producers and distributors its recall from consumers and its destruction in suitable conditions;
- to order delivery of the type of product, the sample of which has caused damage; the product must be delivered in unchanged condition with respect to the sample in dispute.

Additionally, under Art. 31 of the Inspection Act (Official Gazette of the Republic of Slovenia No. 56/02, last amendment 43/07) the inspector may reclaim the costs of inspection procedure necessary for the finding of facts proving the breach of the law from the relevant business.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

[435] English translation from: General Product Safety Directive (GPSD) – Comparative Inventory, p. 2013, 2006, (by Baker&McKenzie)

Arts. 21 and 22 of the General Product Safety Act provide for the administrative fines for businesses and their responsible persons are set. There are two categories of penalties: for bigger breaches (in amounts from ca. 2 000 EUR to 40 000 EUR for businesses and from 200 EUR to 2 000 EUR for their responsible persons) and for minor breaches (from ca. 1 000 EUR to 2 000 EUR and from 100 EUR to 1 000 EUR for their responsible persons).

The fines are applied in practice.

Recent case law in Slovenia with respect to or relevant for the GPSD/the national implementation legislation.

In the publicly available case law, only one case of the application of the General Product Safety Act can be found. The High Court of Ljubljana, No. II Cp 2023/2016 from 11.10.2016 confirmed the judgement of the First Instance Court, dismissing a damages claim against the seller of roller blades, which, as the Court found, did not violate the safety standards for roller blades. How the claimant had based its claim is not entirely clear; apparently it had held that the selling of unsafe products falls under general non-contractual tort law (for which there is support in the literature and case-law) rather than under product liability or contractual liability for non-conformity.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Slovenia concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

It was reported that sometimes there is not enough information for searching for dangerous products; there are also some problems in exercising the recalls. In terms of solutions to improve traceability, the following measures were suggested: requirements for all consumer products to indicate the name and contact details on the packaging, requirements for all consumer products to indicate the batch of products on the packaging, requirements for businesses to keep supply chain records as well as to use a barcode on the product or packaging.

No problems were reported regarding the definition of safety.

Emerging safety issues were not reported.

Possible improvements to make the implementation of the GPSD in Slovenia more effective

There were not any reports in this direction from either the interviewees or in the (extremely scarce) academic literature on the subject.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Slovenia.

At the national level:

The fundamental part of market surveillance under the GPSD in Slovenia is conducted by the Market Inspectorate of the Republic of Slovenia (TIRS), which is a body affiliated to the Ministry of Economic Development and Technology.

In addition, surveillance of product safety on the market is performed by other Inspectorates operating within various ministries:

- The Health Inspectorate of the Republic of Slovenia (toy safety (Directive 2009/48/EC), cosmetic products (Regulation No 1223/2009));
- The Metrology Inspectorate of the Republic of Slovenia (Measuring instruments (MID, Directive 2014/32/EU), Non-automatic weighing instruments (NAWI, Directive 2014/31/EU), prepacked products (Directive 76/211/EEC and Directive 2007/45/EC));
- The Chemicals Inspectorate of the Republic of Slovenia (biocides (Regulation No 528/2012), chemical substances under REACH and classification and labelling regulations (Regulation No 1907/2006 and Regulation No 1272/2008), and other chemicals (detergents, paints, etc.), electrical and electronic equipment under Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment);
- The Medical Devices Inspection Service of the Republic of Slovenia (medical devices, directives 93/42/EEC,

98/79/EC and 90/385/EEC);

- The Labour Inspectorate of the Republic of Slovenia (Lifts (Directive 2014/33/EU), Machinery (Directive 2006/42/EC), Personal protective equipment (Regulation 2016/425), Equipment and protective systems intended for use in potentially explosive atmospheres – Atex (Directive 2014/34/EU));
- The Internal Affairs Inspectorate of the Republic of Slovenia (Explosives for civil uses (2014/28/EU), Pyrotechnic articles (Directive 2013/29/EU), Firearms (Directive 91/477/EEC));
- The Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fisheries (mineral fertilisers (Regulation (EC) No 2003/2003));
- The Inspectorate of the Republic of Slovenia for the Environment and Spatial Planning (construction products on building sites - Regulation No 305/2011),; and
- The Infrastructure Inspectorate of the Republic of Slovenia (motor vehicles and motor vehicle parts in accordance with the provisions of Directive 2007/46/EC, Regulations No 167/2013 and No 168/2013 and Regulation No 1222/2009; LPG cylinders, cylinders for industrial gases, cylinder batches, pressure barrels, transportable pressurised containers and related protective and other equipment) placed on the market and in use (Directive 2010/35/EU), safety components on cableway installations for the transportation of people - Regulation 2016/424).

Apart from general product safety tasks under the GPSD, the Market Inspectorate carries out surveillance activities regarding: personal protective equipment (Regulation (EU) 2016/425), construction products (Regulation (EU) No 305/2011), aerosol dispensers (Directive 75/324/EEC), machinery (Directive 2006/42/EC), noise emissions in the environment by equipment for use outdoors (Directive 2000/14/EC), appliances burning gaseous fuels (Regulation (EU) 2016/426), pressure equipment (Directive 2014/68/EU), electrical and electronic equipment under the Electromagnetic Compatibility Directive (EMC, Directive 2014/30/EC), radio equipment (Directive 2014/35/EU (RED)), electrical equipment under the Low Voltage Directive (LVD, Directive 2014/35/EU), accumulators and batteries under Directive 2006/66/EC, waste electrical and electronic equipment (Directive 2012/19/EU), eco-design and energy labelling (Directives 2009/125/EC and 2010/3/EC), recreational craft (Directive 2013/53/EC), non-road mobile machinery (Directive 97/68/EC).

Plans/programmes in place which define priorities for market surveillance of consumer products

Firstly, there is the National Surveillance Programme, required by the Art. 18 (5) of the Regulation No 765/2008 (for 2019, see https://ec.europa.eu/docsroom/documents/36034, 29.11.2019). It is prepared by the Ministry for Economic Development and Technology. The Ministry coordinates the work of the Market Inspectorate and other inspectorates. Also, based on Art. 20 of the General Product Safety Act, an Advisory Board was established with the task of coordinating the surveillance activities of different authorities. The board has 15 members representing the Ministry of the Economy, Slovenian Institute for Standardisation, Market Inspectorate of the Republic of Slovenia, Ministry of Health, Health Inspectorate of the Republic of Slovenia, Labour Inspectorate of the Republic of Slovenia, Chamber of Commerce and Industry of Slovenia – Dept. of Trade, Slovene Consumers' Association, Association of Slovene Laboratories (SILAB); and Slovene Institute of Quality and Metrology. The Advisory Board deals with questions related to general product safety and recommends respective measures for the remedy or reduction of dangers connected to products. In this respect, it encourages and supports voluntary activities of producers and distributors for ensuring product safety and cooperates on drafting codex of respective dealings on certain product safety areas.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Slovenia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

There is little activity with regard to products containing new technologies. Products sold online are being surveilled. Products sold C2C are not being surveilled as no authority appears to have the competency for that.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Surveillance here is mostly based on reports by consumers. Systematic surveillance covers a selection of domestic businesses, mostly retailers selling nationwide. If a product is being surveilled, then online selling channels are surveilled as well. Retailer websites and online marketplaces are targeted. Products sold by businesses in other EU

countries are surveilled occasionally, while products sold online in non-EU/EEA-countries are rarely surveilled.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Slovenia (except customs) with respect to product safety

It is functioning well. Firstly, the Ministry coordinates the surveillance activities of the different inspectorates through the Inspection Council (Art. 14 Inspection Act), a permanent working body of all chiefs of inspectorates in the country, responsible for coordinating the inspection tasks. Secondly and specifically for product safety, the Ministry established the Advisory Board, responsible for enforcing Regulation (EC) No 765/2008, which coordinates the work of the competent inspectorates and ensures the exchange of information (as already mentioned above).

Cooperation with customs authorities in Slovenia with respect to product safety

There is regular cooperation with customs authorities. The customs regularly (on a weekly basis) informs other authorities about the goods detained. The authorities cooperate on different levels: through common strategies for product safety enforcement, formal agreements (only between customs and the Market Inspectorate), inclusion of customs in preparing the national market surveillance programme and priorities, joint training sessions, regular exchange of information, regular meetings and informal cooperation.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

If the business is not based in Slovenia, but in another EU/EEA country, the competent inspectorate sends it a written notice, in which the surveillance findings (i.e. that a product is/might be dangerous) are communicated. Within the EU, the information is exchanged through RAPEX and ICSMS. With respect to businesses outside the EU/EEA, direct communication in writing is more or less the only option.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

This is the subject of EU Regulation No 765/2008, implemented through the Government regulation on the international exchange of information, OJ 79/2011. The average time between the detection of a dangerous product and its notification to RAPEX is one week. The process within the authority is quick. It usually takes one day for the Ministry to approve the notification.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

Twice a month, the market inspectorate informs the businesses from the "list of partners" (bigger retailers, selling nationwide) on possible threats. The information received through RAPEX is communicated to the businesses. Also, the associations of businesses occasionally ask the market inspectorate for information.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

There is regular exchange of information with the Consumers' Association of Slovenia. Apart from the exchange of information concerning specific products and threats between authorities and Consumers' Associations, there are also regular meetings of the Advisory Board (Art. 20 Act on General Product Safety) where the Consumers' Associations are represented. Awareness regarding product safety is also being raised through press releases and information on the webpages of the different inspectorates.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Slovenia (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Firstly, the businesses are asked to conduct voluntary recalls, which include the informing of consumers. If this step is not successful, a mandatory recall is ordered. Businesses are required to use all their available customer information for recalls and other corrective measures. The competent inspectorate checks the information given to

the consumers. A set of information is required from the business: about information activities targeted at consumers, about information activities along the distribution chain, about the timeline of the recall process and the effectiveness of recalls and about destruction/disposal of products collected. Traditional media channels would be used to inform the public in case of imminent danger.

Monitoring of effectiveness of product recalls by market surveillance authorities

The effectiveness is monitored; however, there are no targets set (in terms of time limits of the recall or the number of products returned) for a successful recall. Also, it should be noted that – particularly with regard to relatively low value products – the consumers, rather than returning the product, simply dispose of it.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Slovenia that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

All inspectorates keep records about the surveillance procedures conducted and about the complaints received from the consumers. However, particular statistics is not being recorded. The national health authority (institute for public health) keeps statistics on injuries.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Slovenia (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

In general, it appears that the system of market surveillance in Slovenia is working well. No major problems have been reported. Surveillance is also conducted online, which, according to report of the market inspectorate, amounts to about 10% of surveillance activities. However, being a small country with limited resources, the online surveillance is mainly focused on domestic online retailers.

The RAPEX system was widely considered to be working very well. Here, too, no major problems have been reported. Mystery shopping is not possible as the inspector is required to identify themselves in the beginning of the inspection procedure.

The recalls seem to be working well, too; however, it was noted, that the results in terms of the number of products returned depend on the kind of product: in the case of low-value products, the consumers seem to dispose of them rather than return them.

Areas to make market surveillance of consumer products in Slovenia/the EU more effective

With regard to RAPEX, there were suggestions that the traceability of products could be improved by standardising the information. Regarding the recalls, it was suggested that target values could be set or guidelines provided e.g. concerning the number of products to be returned for the recall process to be completed.

Regarding potential improvements, the lack of testing standards was mentioned. Regarding the traceability of products, which is sometimes difficult due to a lack of information on where the product is sold, the identity of producer, etc., it could be helpful if this information were standardised.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Slovenia since 2013

All interviewees agree that the level of product safety has risen since 2013. The same is true for the awareness of businesses. Statistics are not available.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Slovenia whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

New technologies and new emerging problems are being approached – as well as possible – with existing tools. Technologies such as social networks are not being used for market surveillance activities. New technological approaches are not being developed. Also, there is no clear competence for some areas, such as C2C sales. These seem to be excluded from market surveillance activities.

Views of market surveillance authorities whether approaches in Slovenia can be considered best practice implementation of the GPSD, which could be of interest to other countries

The functioning of the RAPEX network in Slovenia was mentioned, including regular yearly meetings of all competent authorities. Also, the way the "list of partner businesses" is organised in Slovenia was mentioned: based on the findings from past inspection a procedure, a list of partner businesses was drawn up, mainly from the bigger retailers, selling nationwide. They are regularly briefed about RAPEX notifications.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*LVD: 3*	*2 TE*	*n.a.*
Of which staff allocated to market surveillance activities regarding products sold online	*As needed*	*As needed*	*n.a.*
Notes:	*Data from 2018*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**LVD: 298**	**309**	**605**
Total number of consumer products inspected	LVD: 621	728	n.a.
Total number of consumer products tested in laboratories	LVD: 19	1	n.a.
Total number of consumer products inspected in cooperation with the customs	LVD: 15	0	n.a.
Total number of dangerous consumer products found	4	5	9
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	9	5	14
Notes:	*Data from 2018*		

C. Number of recalls of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	18	7	25

Total number of mandatory recalls	*n.a.*	*n.a.*	*n.a.*
Notes:	*Data for 2018*		

D. Key sources	
Legislation	General Product Safety Act ("Zakon o splošni varnosti proizvodov": "ZSVP-1"), Official Gazette of the Republic of Slovenia No. 101/2003, implementing the GPSD. Regulation on the methods of international exchange of information about measures and actions restricting trade in products ("Uredba o načinu mednarodne izmenjave informacij o ukrepih in dejanjih, ki omejujejo trgovanje s proizvodi"), Official Gazette of the Republic of Slovenia No. 79/11. The same regulation implements the Regulation No. 765/2008 and (in part) the GPSD.
Studies/reports/articles	National Surveillance Programme, no author indicated (for 2019, see https://ec.europa.eu/docsroom/documents/36034, 29.11.2019)
Interviews	Market Inspectorate Market Inspectorate, RAPEX contact point Ministry of Economy and Development Health Inspectorate Chemicals Office

25. Slovakia

COUNTRY REPORT SLOVAKIA

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Act No 250/2007 Coll Consumer Protection Act (hereinafter referred to as "Consumer Protection Act")

Regulation of the Government of the Slovak Republic No 404/2007 Coll. on general product safety (hereinafter referred to as "GPS Regulation")

Act No 128/2002 Coll on State Control of the Internal Market in Matters Pertaining to Consumer Protection (hereinafter referred to as "State Control Act")

Act No 294/1999 Coll on Liability for Damages Caused by a Faulty Product

Act No 56/2018 Coll on conformity assessment of the product, making available of a determined product on the market (hereinafter referred to as Product Conformity Assessment Act)

Act No 133/2013 Coll on construction products

Decree of the Ministry of Economy of the Slovak Republic No 109/2008 Coll setting out the requirements on the safety of lighters

Regulations of the Government of the Slovak Republic related to the safety requirements for certain consumer products:

Regulation of the Government of the Slovak Republic No 70/2015 Coll on the making available on the market of pyrotechnic articles

Regulation of the Government of the Slovak Republic No 77/2016 Coll on the making available on the market of recreational craft and personal watercraft

Regulation of the Government of the Slovak Republic No 126/2016 Coll on the making available on the market of non-automatic weighing instruments

Regulation of the Government of the Slovak Republic No 127/2016 Coll on electromagnetic compatibility

Regulation of the Government of the Slovak Republic No 145/2016 Coll on the making available on the market of weighing Instruments

Regulation of the Government of the Slovak Republic No 148/2016 Coll on the making available on the market of electrical equipment designed for use within certain voltage limits

Regulation of the Government of the Slovak Republic No 149/2016 Coll on equipment and protective systems intended for use in potentially explosive atmospheres

Regulation of the Government of the Slovak Republic No 193/2016 Coll on the making available on the market of radio equipment

Regulation of the Government of the Slovak Republic No 262/2016 Coll on marine equipment

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Slovakia

To adopt the concrete measures to implement the obligations of producers referred to in Art. 5(1), the following obligations are imposed on the producers under § 4 art. 1 of the GPS Regulation (within the meaning of the legal wording of this provision, these are binding requirements, however the interpretation of the content of the requirements is left to discretion):

- The producer and distributor who place the product on the market shall label the product in a clear, visible and appropriate form with information that makes it possible to assess the risks associated with its use or with other information relating to the safety of the product. The product must bear the particulars necessary to identify the producer and distributor of the product and, if necessary, the product series (name and contact details of the producer and if necessary, also the batch number are required). They shall also accompany the product with the accompanying documentation; accompanying product documentation are documents that are necessary for the

purchase and use of the product.

- Producers and distributors are obliged to provide truthful and complete information about the characteristics of the products supplied.

- The product information shall include:

a) a full description of the risk posed by the products;

b) all information necessary to perform the inspection of the product;

c) the measures to be taken to avoid any risk to the consumer when using the product.

Any other requirements (e.g. barcode, electronic product identification, product specific traceability requirements or other requirements) are not explicitly formulated by law.

The same obligations as for producers are imposed by legislation also for distributors.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

In general, there is no specific regulation on the safety in the area of new technologies. In connection to the implementation of Directive 2016/1148 concerning measures for a high common level of security of network and information systems across the Union, the Cyber Security Act effective from 1.1.2019 Act No 69/2018 Coll on Cyber Security has been adopted. In comparison to the narrow definition of security of networks and information systems under Art. 4 (2) of the Directive, the Slovak implementation provides a definition of cyber security (§ 3 (g) of the Cyber Security Act). However, it is questionable whether the requirements for cyber security as defined in the implemented Slovak legislation could serve as a supplement to the product safety criteria generally regulated by the provision of § 3 of the GPS regulation.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

In this question, reference is made to the above answer in relation to the Slovak legislation implementing Directive (EU) 2016/1148.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

If specific European standards referenced in the EU Official Journal do not exist, the safety assessment should be based on other European standards or Commission recommendations setting guidelines on product safety assessment, national standards in the sector concerned or general national standards (e.g. in relation to cosmetic products, if certain areas of product safety are not covered by the Regulation (EC) No 1223/2009 on cosmetic products, in assessing the safety of cosmetic products, public health authorities use other available legislative and other norms e.g. in the area of tattoos or bio/natural cosmetic products), best practices in force in the sector concerned, the state of the art and technology and reasonable consumer safety expectations. According to the national market surveillance authorities, no international standards or standards from non-EU/EEA countries are used.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Slovakia in case there are consumer product(s) on the market which are found unsafe under the GPSD

According to § 20 of the Consumer Protection Act, the supervisory authority is obliged to conduct inspections of product or service safety, and for this purpose it is authorised to request the necessary information from the producer, trader, importer or supplier, to take a product or sample from a series of products and examine the safety thereof, to assess whether a product or service introduced to the market contains notifications of the potential risks associated with the use of the product or the provision of the service; to provide timely and appropriate notification to the persons who may be exposed to the risk induced by a product or by a provided service; to temporarily ban the introduction of a product, a series of products or a service to the market or their presentation, offer or sale, if it is reasonable to suspect that the product or service is not safe, for a time period

necessary to perform tests or to examine the suspicion; to ban the introduction of a product, a series of products or a service to the market, or their presentation, offer or sale, if it has been proven that they are not safe; to put in place accompanying measures ensuring that the ban is complied with; to order or organise immediate withdrawal of a product, a series of products or a service from the market or from the consumers, if it has been proven that it is not safe and had been introduced to the market; where necessary, also to order the destruction thereof; to issue binding instructions aimed at the removal of the discovered deficiencies; and to adopt the necessary measures and determine the time period for the submission of a report on their completion. The supervisory authority is also authorised to issue, at the request of the customs authority, a binding opinion on whether the imported product (in case of its correct installation, maintenance and use) poses a serious and immediate risk to health and safety in general, health and safety at work, consumer protection, the environment and the public or whether it has attached accompanying documentation in accordance with a specific regulation harmonising the conditions for the placing of products on the market and is labelled in accordance with such special regulation or whether the imported product has the correctly placed CE label.

According to the GPS regulation, the supervisory authority is entitled, concerning a product that may present a risk under certain circumstances, to require it to be labelled with the correct, clearly formulated and easily understandable warning (notification) of the risks it may present in the state language where the product is sold. The authority is authorised to require that, as an object of trade, a product that may present a risk under certain circumstances complies with the conditions set out above for the purpose of its safety. Concerning a dangerous product that is already placed on the market, the supervisory authority is entitled to arrange or organise its effective and immediate withdrawal from the market and notify consumers about the risks that it presents. All measures pursuant to the GPS regulation and pursuant to a special regulation may be applied by the supervisory authority to the producer, importer, supplier, seller and any other person, if necessary with regard to cooperation on measures taken to prevent the product threats.

The Slovak national market surveillance authorities cannot currently order to block access to websites (as stated by the Slovak Trade Inspection (STI), this power will be given as one of the listed minimal enforcement powers by Article 9 point 4 para g) of the new Consumer Protection Cooperation regulation from January 17, 2020).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Anyone who harms consumer rights by having acted in breach of the Consumer Protection Act or of the specific consumer protection regulations is deemed to have committed an offence (administrative offence) under the Act No 372/1990 Coll on offences. A fine up to the amount of EUR 331 may be imposed for this offence. The supervisory authority shall fine the producer, trader, importer or supplier for the breach of the obligations laid down in the Consumer Protection Act or in legally binding European Union consumer protection acts up to EUR 66 400. Where the breach reoccurs within 12 months, the authority shall impose a fine up to EUR 166 000. Where a defective product caused damage to life or health, the supervisory authority shall impose a fine up to EUR 332 000 upon the producer, trader, importer or supplier who had produced, sold, imported or supplied such a product. The fine may not be imposed upon persons who demonstrate that they could not have avoided such damage despite having exerted all effort which could reasonably be expected.

A disciplinary fine up to EUR 1 660 could be imposed by the supervisory authority upon the producer, trader, importer or supplier who thwarts, disturbs or otherwise hinders the performance of supervision (the fine may be imposed repeatedly).

According to the State Control Act, the inspectorate shall impose on an inspected person who fails to comply measures relating to the destruction of unsafe products, to the ban of supplying, selling or using the products, carrying out business activities or to the ban of using the unverified measuring instruments or relating to the prohibition of the execution or continuation of a sales action, a fine of up to EUR 16 597. For repeated failure to fulfil the obligations within one year from the date of their imposition, a fine of up to EUR 33 194 may be imposed.

Where the inspected person fails to comply with the protective measures imposed by decision of the Inspectorate regarding the suspension of placing the product on the market, the prohibition of placing the product on the market, the withdrawal of those products from the market or from use, the prohibition of the provision of an information society service, the obligation to inform about the danger to life or health, the prohibition of unfair commercial practices, which has not been performed yet, the prohibition of the organisation of sales shares, the inspectorate shall impose the fine up to EUR 33 194. For repeated failure to fulfil the above mentioned obligations within one year from the date of their imposition, a fine of up to EUR 66 388 may be imposed.

The Inspectorate may impose a fine of up to EUR 660, even repeatedly, on an inspected person who obstructs, abolishes or otherwise complicates the performance of the inspection.

In imposing the fines in practice, account shall be taken, in particular, of the gravity, manner, duration and consequences of the infringement.

Special legislation for specific market surveillance authorities may differently regulate the amount of fines imposed, e.g. breach of obligations in the manufacture, import and distribution of a cosmetic product constitutes an administrative offense for which the competent Public Health Authority body shall impose the fine between EUR 100 and EUR 2 000 according to the Act No 355/2007 Coll on protection, promotion and development of public health.

Recent case law in Slovakia with respect to or relevant for the GPSD/the national implementation legislation.

Recent case law concerns the elementary obligations of producers or distributors arising explicitly from the relevant legislation (e.g. the obligation to provide information for the consumer in the state language or the requirement to indicate the name and contact details of the producer).

Decision of the Supreme Court, 6Asan/22/2018 from 17.4.2019 (placing on the market, dangerous product, a conformity assessment body, samples of the product, fines, breach of duty under § 6 of Consumer Protection Act that only safe products may be placed, offered or sold on the market)

Decision of the Supreme Court, 7Sžo/100/2014 from 31.3.2016 (dangerous product, fines, breach of duty to take measures to remedy the deficiencies identified by STI, in particular to draw up safety data sheets for car cosmetics products, to inform their purchaser in writing about the withdrawal of the product from the market and to ensure that the products are not distributed)

Decision of the Supreme Court, 6Sžo/13/2012 from 28.11.2012 (placing on the market, dangerous product, breach of duty under § 13 in relation to § 11 of Consumer Protection Act that the trader is obliged to inform the consumer about the characteristics of the product being sold or the nature of the service being provided, on the method of use and maintenance of the product, on the hazards associated with its incorrect use or maintenance, on storage conditions and on the risk associated with the provided service in the state language)

Decision of the Regional Court Košice (Krajský súd Košice), 6S/43/2017 from 15.2.2018 (administrative fine imposed for breach of the obligation of the trader under § 12 (2) of Consumer Protection Act to ensure that the product sold is clearly labelled, indicating the producer, importer or trader, measure or quantity, method of product use and maintenance and the hazard associated with incorrect use or maintenance of the product, the product storage conditions, as well as the risk associated with the provided service, or information pursuant to separate regulations)

Decision of the Regional Court Trnava (Krajský súd Trnava), 20S/16/2017 from 14.3.2018 (safety of toys, RAPEX, Directive 2009/48/EC, General product safety directive, placing on the market and interpretation of who the distributor is pursuant to Regulation (EC) No 765/2008)

Decision of the Regional Court Žilina (Krajský súd Žilina), 20S/88/2016 from 20.06.2017 (administrative fine imposed for breach of the obligation of the producer or importer under § 12 (1) of Consumer Protection Act to label the product with data that provide the trader with truthful and complete information about the supplied product's characteristics)

Decision of the Regional Court Košice (Krajský súd Košice), 6S/80/2015 from 25.2.2016 (administrative fine imposed for breach of the obligation of the trader under § 12 (2) of Consumer Protection Act to ensure that the product sold is clearly labelled, indicating the producer, importer or trader, measure or quantity, method of product use and maintenance and the hazard associated with incorrect use or maintenance of the product, the product storage conditions, as well as the risk associated with the provided service, or information pursuant to separate regulations)

Decision of the Regional Court Bratislava (Krajský súd Bratislava), 1S/300/2013 from 4.2.2016 (placing on the market, dangerous product, fines, breach of duty under § 6 (1) of Consumer Protection Act that only safe products may be placed, offered or sold on the market)

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Slovakia concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The general definition of a safe product under the Consumer Protection Act seems to be too narrow and outdated under some circumstances. The current concept of safety understood in the "traditional" sense only with regard to their potential harm to the physical integrity of consumers fails to protect them from the security flaws related to connected devices. This restrictive approach also prevents protection from aggrieved third-party subjects (e.g. other road users, such as in cases when the consumers are using some type of vehicles, e.g. hoverboards or other light electric vehicles, that can lead to fatal accidents, not just for the user of these products but also for the other road users, who are not covered by the general definition of a safe product).

Practical problems concerning traceability can be seen mainly in the reluctance or unwillingness of importers to mark products with the required information about the producers, type, model, etc. which are important for traceability.

Relating to emerging safety issues not addressed by current safety legislation, new types of technology-driven products and production processes have to be mentioned – safety of products using connected technologies (e.g. connected toys, smart watches etc.) as well as specific types of products where explicit normative regulation is needed (e.g. tattoo inks, tattoo hygiene procedures).

Possible improvements to make the implementation of the GPSD in Slovakia more effective

In general, the Internet of Things is an area where fundamental consumer product safety concepts need to be normatively reviewed (notion of "product", "safety" or "defect" in connection with such products and artificial intelligence systems that can potentially become unsafe as a result of digital security incidents or, as a result, have the capacity to act completely autonomously, independently of direct instructions from their creators and independently of the human will of their users, or in connection with new means of communicating and gathering data).

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Slovakia.

At the national level:

As follows from the provisions of the relevant acts (§ 26 of Product Conformity Assessment Act, complementary also § 3 of State Control Act and §5 of GPS Regulation), competence to conduct market surveillance belongs to market surveillance authorities (hereinafter referred also as "MSA") determined by this provision and by other specific sectoral regulation. As the result of such an organisation, the competence is scattered among many responsible bodies.

Pursuant to § 29 (1 a)) Product Conformity Assessment Act, the Slovak Office of Standards, Metrology and Testing provides exchanges of information according to Art. 17, 18 and 41 of Regulation (EC) No 765/2008. Under §29 (2) of Product Conformity Assessment Act, the Ministry of Economy is responsible for exchanges of information — Community Rapid Information System pursuant to Article 22 of Regulation (EC) No 765/2008 (the same follows from § 6(1) of GPS Regulation). The rapid exchange of information between the Commission and the Slovak Republic on dangerous products is carried out through the RAPEX system. RAPEX tasks are performed by the Ministry of Economy of the Slovak Republic and the market surveillance authorities.

Current division of the competences among MSAs:

01. Medical devices - National Institute for Drug Control

02. Cosmetics Public - Health Authority of the Slovak Republic

03. Toys - Slovak Trade Inspection

04. Personal protective equipment - National Labour Inspectorate (products for professional use), Slovak Trade Inspection (consumer products)

05. Construction products - Slovak Trade Inspection

06. Aerosol dispensers - Slovak Trade Inspection

07. Simple pressure vessels and pressure equipment - Slovak Trade Inspection (consumer products), National

Labour Inspectorate (professional products)

08. Transportable pressure equipment - National Labour Inspectorate, Ministry of Interior of the Slovak Republic - Presidium of Police Corps[436] (§17 of Act No 254/2011 Coll on Transportable Pressure Equipment)

09. Machinery - Slovak Trade Inspection (consumer products), National Labour Inspectorate (professional products)

10. Lifts - National Labour Inspectorate

11. Cableways - National Labour Inspectorate, Transport Authority

12. Noise emissions for outdoor equipment - Slovak Trade Inspection (consumer products), National Labour Inspectorate (professional products)

13. Equipment and protective systems intended for use in potentially explosive atmospheres - Principal Mining Office,[437] National Labour Inspectorate

14. Pyrotechnics - Slovak Trade Inspection, Principal Mining Office

15. Explosives for civil uses - Principal Mining Office

16. Appliances burning gaseous fuels - National Labour Inspectorate (professional products), Slovak Trade Inspection (consumer products)

17. Measuring instruments, non-automatic weighing instruments and pre-packaged products - Slovak Metrological Inspectorate

18. Electrical equipment under EMC - Slovak Trade Inspection (consumer products), National Labour Inspectorate (professional products)

19. Radio equipment under RED - Slovak Trade Inspection (consumer products)

20. Electrical appliances and equipment under LVD - National Labour Inspectorate (professional products), Slovak Trade Inspection (consumer products)

21. Electrical and electronic equipment under RoHS and WEEE and batteries - Slovak Trade Inspection (consumer products), State Institute for Drug Control

22.1 Chemical substances under REACH and Classification and Labelling Regulations - Principal Mining Office, Public Health Authority of the Slovak Republic, Ministry of Defence of the Slovak Republic,[438] Slovak Inspectorate of the Environment,[439] National Labour Inspectorate (professional products), Financial Directorate of the Slovak Republic - Section of Customs, Slovak Trade Inspection, Ministry of Economy of the Slovak Republic, Centre for Chemical Substances and Preparations.

22.2 Other chemicals (detergents, paints, persistent organic pollutants, fluorinated greenhouse gases, ozone depleting substances, etc.) - National Labour Inspectorate, Slovak Trade Inspection, Slovak Inspectorate of the Environment

23. Eco-design and energy labelling - Slovak Trade Inspection

24. Tire labelling - Slovak Trade Inspection

25. Recreational crafts - Slovak Trade Inspection, Transport Authority

26. Motor vehicles - Slovak Trade Inspection

27. Non-road mobile machinery - Ministry of Transport, Construction and Regional Development of the Slovak Republic

28. Fertilisers - Central Controlling and Testing Institute in Agriculture

29. Other consumer products under GPSD - Slovak Trade Inspection

30. Biocides - Slovak Trade Inspection

31. Textile and Footwear labelling - Slovak Trade Inspection

At the sub-national (regional/provincial/local) level: None

Plans/programmes in place which define priorities for market surveillance of consumer products

Pursuant to §29 (3) of Product Conformity Assessment Act, the responsible MSA shall submit to the Slovak Office of Standards, Metrology and Testing:

[436] www.minv.sk
[437] www.hbu.sk
[438] www.mosr.sk
[439] www.sizp.sk

a) Annually, a market surveillance programme within its scope pursuant to section 26, to which the surveillance programme applies, within the deadline set by the Office;

b) Upon request, summary information pursuant to art 18 (6) of Regulation (EC) 765/2008 concerning the performance of its activity; the content of the information shall be specified by the Office in the call. This information has been submitted by responsible MSAs, but the summary information has not been elaborated upon.

In 2010, the Slovak Trade Inspection (hereinafter referred to as "STI") has elaborated a National general programme for the market surveillance as its response to the entry into force of Regulation (EC) 765/2008. The general programme outlines the basic principles and targets of the market surveillance within scope of STI's competences. Annually, STI and other MSAs prepare plans where they set out priorities in the different areas of surveillance, classified according to the particular directives and regulations of EU.

STI finds the information system ECHO to be very helpful in defining priorities for market surveillance of consumer products. The objective of the system is to actively gather information (rather than rely on ad hoc information from the media) on accidents caused by the use of any non-food products in the household and in leisure and sports activities.

The National Labour Inspectorate (hereinafter referred to as "NLI") prepares annual plans for labour inspectorates. Some of the 8 regional labour inspectorates sometimes also prepare additional regional plans. This institution finds ICSMS to be a helpful tool for defining their surveillance priorities. The Public Health Authority (hereinafter referred as also as "PHA") prepares the Sectoral National Market Surveillance Programme for cosmetic products. The amendments to Regulation (EC) No 1223/2009 on cosmetic products serve as a basis for drawing up the plans, in particular changes to the lists of controlled and authorised substances. Market surveillance authorities usually sum up all relevant information gathered during the recent surveillance period and in such way they draw the inspiration for setting the future priorities in the next surveillance period.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Slovakia with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance activities with respect to new technologies have been identified by the relevant authorities. STI announced that it would start control activities regarding the Internet of Things in 2020. STI regarded new technologies as an emerging safety threat where the need for guidance is urgent. PHA confirms similar trends in the area of new technologies in cosmetics, e.g., nanotechnologies have been recently in the spotlight of their surveillance. For products sold online, the enforcement powers are generally characterised as restricted up until now and the expectation for positive change is connected to the Article 9 of the new CPC Regulation (2017/2394/EU). Unfortunately, the shortcomings in the Slovak legislative process shortly before general elections in February 2020 have been the probable reason why useful implementing legislation drafted by the Ministry of Economy has not been enacted. This may create obstacles for an easier start after the new CPC regulation enters into force. Products sold online have been already under surveillance. STI reported that their share of the total number of controlled products fluctuates at a level between 21 and 30 %. STI inspectors act under a secret identity in the process of ordering the products as consumers. STI concentrates on retailer websites, comparison websites and online markets as well. Cases in which the consumers complain about traders based in countries within the EU could be solved by the ECCs (European Consumer Centres). PHA's surveillance for products sold online currently focuses only on consumer complaints. The reason for favouring reactive control over proactive control is their limited competence to purchase samples sold online (as they lack the competence to purchase products, including as part of mystery shopping). Pursuant to the Act on Public Health, the power to take product samples has been recognised only for on the spot surveillance (Internet sales are not considered to be included) and also for the increased budget demands connected to this form of surveillance (each new sales channel and extension of the control brings additional financial costs). The online share of market surveillance activities of PHA represents only 2% of the total. Market surveillance for C2C products has been rarely conducted mainly due to a lack of complaints by customers. In the relevant cases, cooperation takes place with the police.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

STI concentrates on retailer websites, comparison websites and online markets. With respect to cosmetics surveillance, PHA adds the social networks to the list as sale channels that must inevitably be checked. Use of mystery shopping is restricted by legislative obstacles, and improvement is expected after the empowerment of the

authorities by new CPC Regulation. Market surveillance online is generally conducted once a week by STI and online mystery shopping for domestic contracts is indicated to be once every three months. PHA reported that their surveillance in 2016-2019 concentrated on marketing allegations and statements for cosmetics sold online. PHA's surveillance of cosmetics in brick and mortar shops has been realised in cooperation with the State Veterinary and Food Administration of the Slovak Republic which is a state administration authority responsible for food surveillance.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Slovakia (except customs) with respect to product safety

Legal grounds for cooperation with public authorities with respect to product safety has been established by law or through formal agreement. For example, pursuant to § 10 of the State Control Act *(Cooperation with public authorities and consumer protection organisation*), cooperation for prevention and for the protection of health and safety is prescribed for STI with the listed bodies (PHA, Customs, State Veterinary and Food Administration, local government, market administrators, police corps, Ministry of Transport, Construction and Regional Development and consumer organisations). STI may request from the public authorities the data and explanations necessary for its control activities. Where the nature of the matter so requires, other inspection bodies and authorised persons (MSAs pursuant to § 26 of Product Conformity Assessment Act) shall provide the necessary technical assistance. As other channels important for cooperation, the following are listed: common meetings, common use of RAPEX and ICSMS, and joint processes for dealing with dangerous products.

Cooperation with customs authorities in Slovakia with respect to product safety

MSAs unanimously characterise the cooperation with customs as very satisfactory, e.g. STI cooperates with them almost on a daily basis and they indicate cooperation as taking place more than once a week. The forms of cooperation differ. They are based in law and in formal agreements and are conducted through the common preparation of surveillance programmes, joint setting of the priorities for surveillance, joint processes for dealing with dangerous products, joint training sessions and the regular exchange of information, including the common use of RAPEX. NLI creates a "risk profile of dangerous product" as identified from their surveillance, and provides this information to customs. This is recognised as an effective preventive tool, as after entering these data into the customs system, it enables customs to stop the product at the border. NLI experts are actively involved in customs training once a year and they help custom officers to identify dangerous products before these products are released into the single market. Similar cooperation has been announced by PHA, where PHA and the Financial Directorate of the Slovak Republic (to which customs belongs) have concluded a Cooperation Agreement pursuant to which the customs authorities, based on a risk assessment and on the basis of a prepared risk profile, send a report about the importing of cosmetic products from non-EU/EEA-countries.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

On the EU and international level, the wiki confluence platform, mutual assistance requests outside of RAPEX, regulation meetings, exchange of information, and ICPEN conferences create the basis for cooperation. Due to common roots and linguistic proximity, the close relations with the Czech Republic are still preserved in this cooperation and informal relations may play a role (as reported by PHA). PHA reports unsatisfactory cooperation with surveillance authorities of some other EU Member States and regard the ICSMS system as not functioning properly. In this case, they must use a written form by post or e-mail. The views on ICSMS evidently differ as the other national surveillance authority prefers ICSMS as an effective tool for dealing with dangerous products. Generally, all authorities refer to Regulation 765/2008 as the legal basis as well as the guide for proper mutual cooperation.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

Cooperation is safeguarded by strict compliance with rules set by § 6 of the GPS regulation. The rapid exchange of information between the Commission and the Slovak Republic on dangerous products takes place through the RAPEX system. RAPEX tasks are performed by the Ministry of Economy of the Slovak Republic (hereinafter referred to as the "Ministry") and MSAs. If an MSA takes a measure to prevent the marketing of the dangerous product or requires withdrawal from the market or sale where the product does not pose a serious risk to the health and

safety of the consumer, the MSA shall inform the Ministry without delay, but no later than 12 days after the adoption of the measure. If the MSA takes a measure or agrees with the manufacturer, importer, supplier or seller on a voluntary basis to prevent, restrict or impose specific conditions on the possible sale or use of products presenting a serious risk, it shall immediately, at the latest within eight days of receipt, inform the Ministry. MSAs shall inform the Ministry without delay of the facts which they have learned. MSAs are obliged to determine, based on RAPEX reports, whether the relevant dangerous product is on the Slovak market. If MSAs detect the presence of a dangerous product on the market, they shall immediately inform the Ministry. The Ministry, as a notification body to RAPEX, shall send reports on dangerous products within the set deadlines. The Ministry shall forward the reports sent by the Commission to the Slovak Republic to MSAs.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

As already stated, § 10 of the State Control Act (Cooperation with public authorities and consumer protection organisation) creates the legal base for such cooperation. STI referred to the active participation in business conferences where papers on surveillance and product safety are delivered in every possibility. PHA reported that within the framework of informal cooperation with the associations of producers, importers and sellers of cosmetic products in the Slovak Republic, PHA informs them at least twice a year about new regulations in the field of cosmetic products. PHA explains the text and meaning of relevant regulations and responds to requests for information received from consumer organisations and also from individual consumers. In addition, it cooperates with other organisations in the field of chemistry e.g. the Euroleg Centre, and provides information as part of their regular training and other activities organised for members. NLI reported informal cooperation with business organisations and businesses.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Press releases, special warnings on the websites of the respective surveillance authorities, the RAPEX system, meetings and training sessions. Various forms of informal meetings are used (e.g., a project of NLI "Breakfast with employers" aimed at their obligations pursuant to the Product Conformity Assessment Act (2018).[440] PHA provides information on Facebook or provides reports to TASR and SITA (central press agencies in Slovakia) and to the Advertising Council. Each information release also includes a link to RAPEX. The same applies to the website of STI where warnings for dangerous products in the domestic market are provided.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Slovakia (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and corrective measures may be initiated by the producer at their own capacity or by the market surveillance authority. The recall process is thoroughly regulated by the GPS regulation. STI and other authorities do not publish or create a code of good practice. The producer, importer and/or supplier are obliged to obtain information about the safety of the manufactured or supplied product after delivery of the product to the seller and after its sale to the consumer. Where they find that a product is dangerous, they shall immediately inform the consumer of this fact and inform the competent MSA in the prescribed form and withdraw such a product without delay. A manufacturer, importer and/or supplier who becomes aware that a product which it has manufactured, imported or supplied is unsafe shall be required to immediately request public electronic media to publicly disclose at its own expense that the product is unsafe.

Market surveillance authorities are empowered as regards:

a) For a product that may present a risk in certain circumstances:
   - Require it to be labelled with the risks it may present;
   - Require that, as an object of trade, it complies with the conditions set out in point 1 so that it is safe.

[440] More information available at https://www.ip.gov.sk/udalosti/ranajky-zamestnavatelmi-ipba/

b) For a dangerous product that is already on the market:

- As the first step, to arrange or to organise its effective and immediate withdrawal from the market, and as the second step, to alert consumers about the risks the product poses.

Measures may be applied by the MSA to the manufacturer, importer, supplier, seller and any other person, if necessary with regard to cooperation on measures taken to prevent threats from the product. Supervisory authorities are obliged to develop a standard procedure for the occurrence of a dangerous product whereby the manufacturer, importer, supplier and seller can develop their own procedures to be followed in the event of a dangerous product. PHA's procedure is aimed at preserving the requirements of Regulation (EC) No. 1223/2009. The procedure differs according to the seat of the business. Where the entity responsible for the safety of the cosmetic product has its registered office in the Slovak Republic, the local competent PHA acts, requires them to take appropriate corrective measures on a voluntary basis within the set deadline, and cooperates with them in taking appropriate measures. If business does not take appropriate remedies within the set deadline or if a quick response is required, PHA will take measures to prevent the making available of products on the Slovak market. If the entity responsible for product safety is not established in the Slovak Republic, the local competent authority of public health forwards the findings to the central PHA, which communicates in a similar way with the responsible authority in the EU.

Monitoring of effectiveness of product recalls by market surveillance authorities

When withdrawing products, market surveillance authorities:

- Check physically as to whether the products are no longer on offer;
- Ask economic operators to provide the number of products placed and withdrawn;
- Physically check as to whether voluntary measures or imposed measures have been implemented within the deadline.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Slovakia that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

National MSAs prepare statistics based on various criteria on the occurrence of dangerous products, related consumer complaints and injuries. These statistics usually create part of the annual report of the respective authority. STI collects statistics of dangerous products other than RAPEX and dangerous products intercepted at the borders. The national market surveillance system run by STI (the above mentioned ECHO) also collects consumer reports, but only less than 1% of consumer complaints contained information regarding product safety (or dangerous products). The statistics of STU include injury data. PHA annually issues a report on the supervision of cosmetic products where evidence on the number of non-conforming products as well as on the number of products detained at the border by customs authorities is provided. NLI processes and evaluates data on occupational accidents for statistical purposes regarding national law and run their own database of complaints.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Slovakia (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Regarding market surveillance in general, authorities unanimously place the lack of financial resources and staff as well as the lack of expertise in relation to online markets and new technologies among the most serious problems. PHA noted the non-existence of a properly functioning information system including access to various databases and the slow exchange of information and administrative cooperation between public health authorities. It recommended more prompt provision of information to the media, organisations and consumers within the Slovak Republic and the EU as well as better use of data for planning controls and reduction of administrative burden. PHA reported insufficient cooperation with the National Contact Point for RAPEX (the Ministry of Economy) in the area of coordination, methodological guidance and education. STI reported the same problem, e.g. that their cooperation with the Slovak Environmental Inspectorate and NLI is labelled as problematic.

On recalls, PHA reported that the fact that brick and mortar shops do not have buyer lists and addresses creates an obstacle for purposes of recalls. It is very common that the batch of products in question is sold or consumed by consumers at the time of removal. Regarding RAPEX, products sold as cosmetic products do not meet the definition

of a cosmetic product. There are also differences in the risk assessment of Member States and incomplete documentation, often without product photos. With respect to online surveillance, the "EC Notice on market surveillance of online products" is very helpful for PHA. However there is a general lack of guidance on emerging issues.

Areas to make market surveillance of consumer products in Slovakia/the EU more effective

In relation to RAPEX, some national authorities suggested the creation of better search tools for groups of products, e.g. drills or welders. Concerning recalls, PHA suggests to ascertain whether the identified deficiencies or measures affect other or all batches of products. The possibility of an agreement between the EU and China on dangerous products sold online is seen as a potential improvement. General suggestions for improvement include also higher wages for state employees responsible for the agenda of dangerous products and generally improvement of their working conditions, including information systems, laboratories, technologies, etc.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Slovakia since 2013

The general trend in the level of consumer product safety is deemed to be positive (according to data from the Slovak Trade Inspection, the situation in the area of product safety has improved significantly in recent years and the safety of consumer products is steadily improving). However, trends depend partially on product type or sales channel. While in the years 2007–2008 more than 190 dangerous products were found annually, in the last four years, the findings were on average 60 to 80 detected dangerous products. The percentage rate of the products tested by Slovak Trade Inspection and found to be dangerous has gone from 40 % to 55 %. Improvements could be seen mainly in the area of mandatory product labelling and consumer awareness of safety.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Slovakia whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

None of the market surveillance authorities considered that they currently had the necessary tools (including the personal, organisational and financial policies) to address new technological challenges that would enable for the gathering relevant data, identification the security flaws, identification of new products in the digital environment, etc.

However, the national market surveillance authorities are developing such tools or interim measures, particularly in connection with the new legislative framework (i.e. the CPC regulation coming into force on January 17, 2020). STI is planning to set up an e-lab.

Views of market surveillance authorities whether approaches in Slovakia can be considered best practice implementation of the GPSD, which could be of interest to other countries

The Ministry of the Economy adopted a new national law regarding the safety of playgrounds (Act No 371/2019 on Essential Playground Safety Requirements, effective from 1.1.2020) as a response to the negative results of the checks of playgrounds. The main idea is to eliminate any potential hazards connected with the playground and to ensure the safety of the playground equipment throughout its lifetime. The abovementioned law does not create new technical requirements for playground equipment as these are set in the EU technical standards. The purpose is to set requirements such that the level of imminent risk arising from the very nature of the playground does not exceed the reasonably foreseeable risk magnitude. For this purpose, the act imposes new obligations on owners of playgrounds to avoid improper or incorrect installation or insufficient maintenance, which can turn the playground into a dangerous product, e.g. the owner has to ensure annual checks performed by a qualified person who carries out the assessment. Based on this assessment, the qualified person draws up a report which should also contain proposed measures to remove the shortcomings.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).	
N.a.	
B. Number of inspections of consumer products (last available year)	
N.a.	
C. Number of recalls of consumer goods (last available year)	
N.a.	
D. Key sources	
Legislation	Act No 250/2007 Coll Consumer Protection Act Regulation of the Government of the Slovak Republic No 404/2007 Coll. on general product safety Act No 128/2002 Coll on State Control of the Internal Market in Matters Pertaining to Consumer Protection Act No 294/1999 Coll on Liability for Damages Caused by a Faulty Product Act No 56/2018 Coll on conformity assessment of the product, making available of a determined product on the market Act No 355/2007 Coll on protection, promotion and development of public health Regulation 2017/2394/EU, Official Journal L 345, 27/12/2017 P.1–26. Regulation 764/2008/EC, Official Journal L 218/21, 13/8/2008 P. 21–29. Regulation (EC) No 765/2008, Official Journal L 218, 13.8.2008, p. 30–47
Studies/reports/articles	Dzurová, M., Korčoková, M. (2010), Nebezpečné výrobky a ochrana spotrebiteľa. In: Produktová politika a jej sociálno-ekonomické aspekty. Bratislava: Ekonóm. Karkalíková, M. (2007), Kvalita produktu v službách. Bratislava: Ekonóm. Kollár, V. (2012), Jednotný trh – zodpovednosť a bezpečnosť produktov. In: Globálne existenciálne riziká. Bratislava: Strix. Kollár, V. a kol. (2008), Bezpečnosť produktov a produkcie. Bratislava: Ekonóm. Kollár, V. (2001), Technické požiadavky na výrobky – trhový dohľad – ochrana spotrebiteľa. In: Stratégia obchodného partnerstva v komercializácii produktov. Bratislava: Ekonóm. Kollár, V., Košútová, T. Kristová, Ľ. (2012), Regulovaný trh výrobkov. Bratislava: Ekonóm. Kristová, Ľ., Kollár, V. (2010), Dohľad na trhom. In: Aktuálne výzvy teórie a praxe pre obchod, marketing, služby, cestovný ruch a medzinárodné podnikanie. Bratislava : Ekonóm. Korčoková, M. (2008), Bezpečnosť produktov na úrovni Európskej únie. In: Inovácie marketingových a obchodných činností. Bratislava: Ekonóm. Ministerstvo hospodárstva SR. Návrh Stratégie spotrebiteľskej politiky Slovenskej republiky na roky 2014 – 2020. Bratislava: MH SR, 2014. Retrieved on 15. 10. 2019, from https://www.economy.gov.sk/uploads/files/j7uFbSlI.pdf Ministerstvo hospodárstva SR, Inštitucionálne zabezpečenie spotrebiteľskej polity v Slovenskej republike. Bratislava: MH SR, 2014. Retrieved on 15. 10. 2019, from https://www.economy.gov.sk/uploads/files/oumbZBkf.pdf National Labour Inspectorate, Sectoral national market surveillance programme, 2017. Retrieved on 21. 11. 2019 from https://www.ip.gov.sk/bozp/dohlad-nad-trhom/ Public Health Authority oh Slovak Republic and Regional Public Health Authorities, Sectoral national market surveillance programme – cosmetic products (In Slovak). Retrieved on 21. 11. 2019 from: http://www.uvzsr.sk/en/docs/info/SK_NATIONAL_MARKET_SURVEILLANCE_PROGRAMME_2019.pdf Roman, E. a kol. (2007), Bezpečnosť v produktovej politike. Bratislava: Ekonóm. Roman, E. (2006), Problematika bezpečnosti spotrebiteľa pri rozhodovaní o produkte. In: Obchodné podnikanie v podmienkach teórie a praxe znalostnej ekonomiky. Bratislava: Ekonóm. Slovak Trade Inspection, *National general programme for the market surveillance – general programme. (*In Slovak). Retrieved on 21. 11. 2019 from https://www.soi.sk/sk/SOI/program-

	dohladu/Vseobecny-program.soi Slovak Trade Inspection*, Annual sectoral surveillance pla*n. (In Slovak). Retrieved on 21. 11. 2019 from https://www.soi.sk/files/documents/sektorovy%20program/program_dohladu_soi_nad_trhom_2019.pdf. Slovak Trade Inspection, Information system ECHO. (In Slovak). Retrieved on 21. 11. 2019 from https://www.soi.sk/sk/System-ECHO-informacie-spotrebitelov-o-nebezpecenstve-vyrobkov.soi Slovak Trade Inspection, *Special national programme* 2019. (In Slovak). Retrieved on 21. 11. 2019 from https://www.soi.sk/files/documents/info-verejnost/n%C3%A1rodn%C3%BD%20program%20doh%C4%BEadu%202019.pdf) Šalgovičová, J. (2004), Normalizácia, posudzovanie zhody, certifikácia výrobku a akreditácia. Bratislava: STU.
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Interviews	Ministry of Economy of the Slovak Republic Slovak Trade Inspection National Labour Inspectorate Public Health Authority of the Slovak Republic Special consultation with the Slovak Office of Standards, Metrology and Testing

26. Spain

COUNTRY REPORT SPAIN

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

GPSD was implemented by Royal Decree n. 1801/2003, of 26 December, on general product safety. It was published in the Spanish Official Gazette[441] n. 9 on January 10, 2004, and it came into effect on January 15, 2004.[442]

In application of Article 3.6 of Royal Decree n. 1801/2003, the Decision of June 21, 2004, that publishes the harmonised references of the Spanish Association for Standardisation (UNE standards) was passed.[443]

A basic and horizontal legislation for the consumer protection also exists in Spain: Royal Legislative Decree n. 1/2007, of November 16, approving the revised text of the General Law for the Protection of Consumers and Users and other complementary laws. It was published in the Spanish Official Gazette n. 287 on November 30, 2007, and it came into effect on December 1, 2007. Its rules, which do not distinguish between harmonised and non-harmonised products, apply to all aspects not regulated by specific sectoral legislation.

Finally, Regions (*Comunidades Autónomas*) have also passed rules on consumer protection that contain provisions on consumer product safety.[444]

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Spain

Art. 5(1) GPSD, regarding obligations of producers, was implemented by art. 4 (2) and (3) of Royal Decree n. 1801/2003. The Royal Decree sets forth the obligation of "indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified". Therefore, the following traceability requirements exist in the Spanish legislation for non-harmonised consumer products and for those harmonised products for which EU legislation does not provide specific traceability requirements:

- The general requirement to indicate name and contact details of the producer on the product or its packaging;
- The general requirement to indicate product reference or, where applicable, the batch of products to which it belongs on the product or its packaging;

There is not a general requirement to use a barcode or other machine-readable identification on the product or its packaging in the Spanish legislation.

Other requirements related to traceability are foreseen in the basic and horizontal legislation for consumer protection. Art. 18(2) of Royal Legislative Decree n. 1/2007, on the labelling and presentation of goods and services states that "without prejudice to the specific requirements established in the regulations, all goods and services

[441] *Boletín Oficial del Estado.*

[442] Royal Decree n. 1801/2003 has been modified by Royal Decree 776/2011, of 3 June, which abolishes certain collegiate bodies and establishes criteria for standardisation in the creation of collegiate bodies in the General State Administration and its Public Organizations, and by Royal Decree 85/2018, of 23 February, on the regulation of cosmetic products.

[443] This Decision was updated by Decision of September 27, 2006; Decision of March 8, 2007; Decision of June 20, 2011; Decision of December 26, 2011; Decision of July 23, 2012; Decision of February 12, 2014; Decision of July 31, 2014; Decision of February 26, 2015; and Decision of June 25, 2015.

[444] Andalusia: Act 13/2003, of December 17, on the defense and protection of consumers and users in Andalusia; Aragon: Act 16/2006, of December 28, on the protection and defense of consumers and users of Aragon; Canary Islands: Act 3/2003, of February 12, on the Statute of consumers and users of the Canary Islands; Cantabria: Act 1/2006, of March 7, on the defense of consumers and users; Castilla la Mancha: Act 3/2019, of March 22, on the Statute of Consumers in Castilla-La Mancha; Castilla y León: Act 2/2015, of March 4, which approves the Statute of the Consumer of Castilla y León; Catalonia: Law 22/2010, of July 20, on the Consumer Code of Catalonia; Valencian Community: Act 1/2011, of March 22, which approves the Statute of consumers and users of the Valencian Community; Estremadura: Act 6/2019, of February 20, on the Statute of consumers of Extremadura; Galicia: Act 2/2012, of March 28, Galician general protection of consumers and users; Balearic Islands: Act 7/2014, of July 23, on the protection of consumers and users of the Balearic Islands; La Rioja: Act 5/2013, of April 12, for the defense of consumers in La Rioja; Madrid: Act 11/1998, of July 9, on the protection of consumers and users of the Community of Madrid; Navarre: Act 7/2006, of June 20, on the defense of consumers and users; Basque Country: Act 6/2003, of December 22, on the Statute of Consumers and Users; Asturias: Act 11/2002, of December 2, on consumers and users, of Asturias; Murcia: Act 4/1996, of June 14, on the Statute of Consumers and Users of the Region of Murcia.

made available to consumers must incorporate, accompany or ultimately allow, in a clear and understandable manner, accurate, effective and sufficient information on their essential characteristics, and in particular on the following:

(a) Full name and address of the producer;

(b) Nature, composition and purpose;

(c) Quality, quantity, category or common or trade name, if they have one;

(d) Date of production or supply and batch, when required by regulations, recommended period for use or consumption or expiration date;

(e) Instructions for proper use or consumption, warnings and foreseeable risks".

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

Royal Decree n. 1801/2003 copies in art. 2 (a) the definition of 'safe product' from the GPSD. It therefore contains no express provision dealing with new technologies.[445]

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

National legislation transposing the GPSD does not cover explicitly any of the emerging threats related to new technologies. Spanish authorities did not have an opinion whether they can be considered covered under the national implementation legislation. The General Directorate of Consumer Affairs points out to the need for discussing the product definition in relation to software and its risks.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

According to the General Directorate on Consumer Affairs, if European standards references in the EU Official Journal do not exist, the following benchmarks for assessing the safety of a product are used:

1. Other European standards (not referenced in the EU Official Journal);
2. National standards (not based on European standards);
3. International standards and/or standards from non-EU/EEA countries;
4. Commission recommendations setting guidelines on product safety assessment;
5. Codes of good practice in force in the sector concerned;
6. State of the art and technology;
7. Reasonable consumer expectations concerning safety.

At the regional level, the abovementioned benchmarks are used depending on the Region.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Spain in case there are consumer product(s) on the market which are found unsafe under the GPSD

Arts. 8-10 of Royal Decree n. 1801/2003 set forth administrative measures to restore or guarantee security. If unsafe consumer products are found, the market surveillance authorities have at their disposal the following administrative measures:

1. Require businesses to provide relevant information on the product(s);
2. Require businesses to provide relevant information on the supply chain and the distribution of the product(s);
3. Require business to provide relevant information to ascertain the ownership of websites, where relevant;
4. Carry out unannounced on-site inspections and physical checks of products;

[445] The definitions of "safe product" foreseen by the Royal Legislative Decree 1/2007 (art. 11.2) as well as by the regional Acts on consumer protection are identical or practically identical to the definition established by Royal Decree n. 1801/2003.

5. Acquire product samples, including under a cover identity (mystery shopping);
6. Block websites if needed;[446]
7. Require from economic operators recalls of products and other coercive measures,
8. Reclaim from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s).

These measures are adopted as a rule by the Regions (in some cases, in collaboration with authorities other than those of consumer protection). National authorities can adopt these administrative measures only in two cases: (a) when the only appropriate response to a serious risk for consumer health and safety can be made by adopting measures applicable at the national level; and (b) when, for a given serious risk, the measures adopted or provided by the different Regions are divergent and their divergence is a hindrance to product safety, once the existing instruments of cooperation have been exhausted".[447]

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

At the national level, Royal Legislative Decree n. 1/2007 applies. When rules on consumer protection are infringed, fines are imposed according to the following graduation:

a) Minor infringements, up to 3 005.06 euros.
b) Serious infringements, between 3 005.07 euros and 15 025.30 euros. It is possible to exceed this amount up to five times the value of the goods or services which are the object of infringement.
c) Very serious infringements, between 15 025.31 and 601 012.10 euros. It is possible to exceed this amount up to five times the value of the goods or services which are the object of infringement.[448]

In the event of very serious infringements, closure of establishments, facilities or services may be agreed for a maximum period of five years.

The closure of establishments, facilities or services, or the suspension of their activities, as well as the precautionary or definitive product recall for health and safety reasons, do not have the character of penalties.

Finally, accessory penalties[449] can also be agreed, such as the seizure of merchandise and the announcement of the sanctions imposed, of the identity of the person responsible and of the nature and type of infringement.

Penalties are adopted by the regional market surveillance authorities, which have their own rules on consumer protection (see *supra* I.1). These rules regulate penalties in accordance with the basic national legislation.

Recent case law in Spain with respect to or relevant for the GPSD/the national implementation legislation.

There are few court decisions that expressly apply the provisions of Royal Decree n. 1801/2003:

- Judgment no. 795/2015, of December 9, of the Superior Court of Justice of Madrid (Administrative Chamber): application, among other rules, of art. 2 a) (Definition of safe product) of Royal Decree n. 1801/2003. Existence of a very serious infringement (fine of 30 050 euros) in Irish whiskey packaging because the batch was not indicated.
- Judgment no. 942/2017, of July 24, of the Superior Court of Justice of Castilla y León, Valladolid (Administrative Chamber): application, among other rules, of art. 10 (Administrative measures to guarantee the general duty of product safety), 11 (Process) and 12 (Implementation of these measures) of Royal Decree n. 1801/2003. Infringements were found in European-English travel adapters commercialised by FABRICACIÓN DE MATERIAL ELECTRICO, S.A. (FAMATEL). Cessation of activity was required as a provisional measure.
- Judgment no. 603/2018, of September 28, of the Superior Court of Justice of Madrid (Administrative Chamber): application, among other rules, of art. 3 (Evaluation of product safety) of Royal Decree n.

[446] The power of market surveillance authorities to restrict access to online interfaces has been recognised by Art. 14.4 k) (ii) of Regulation (EU) 2019/1020 of the European Parliament and of the Council, of 20 June 2019, on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011. Regional authorities consider this measure fundamental in cases where a person responsible for a website cannot be identified, does not answer email communications or is based in other country. Moreover, it is increasingly common to find unsafe products or potentially unsafe products offered on online marketplaces, where identification of sellers is not always possible.
[447] Article 14 of Royal Decree n. 1801/2003.
[448] Article 51 of Royal Legislative Decree n. 1/2007.
[449] Article 52 of Royal Legislative Decree n. 1/2007.

1801/2003. Non-conformity in import control. Application to an IKEA filing cabinet of the UNE EN14703/2004 standard (more stringent safety requirements, it refers to office and storage furniture) instead of the UNE EN14749/2005 (laxest safety requirements, it refers to domestic furniture).

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Spain concerning traceability, definition of safety etc. / Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Some practical problems regarding traceability are identified:

- Heterogeneity of the same product in the market.[450]
- Lack of contact details of producers on the product or its packaging.
- Limited advantages of barcodes.[451]
- Difficulties in locating or identifying buyers.[452]
- Volatility of companies.

Regarding the definition of safety, no practical problems seem to have been experienced by national and regional market surveillance authorities.

Some emerging safety issues with categories of consumer products have been identified in Spain in relation to connected toys, smart watches for children, other consumer products that do not incorporate cybersecurity mechanisms and hot water bags.

Possible improvements to make the implementation of the GPSD in Spain more effective

New legislation updated and consistent with the new market reality (online sales, etc.) should be developed. Some authorities consider that some labelling rules, due to the legends and warning pictograms, should be raised to the category of EU Regulations, and that product information required in online sale offers (especially in the sectors of footwear, toys, or textiles) should be clearly established.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Spain.

Two relevant authorities must be distinguished:

1. The national market surveillance authorities;
2. The regional market surveillance authorities.[453]

The distribution of responsibilities between market surveillance authorities in Spain is complex. Each authority at the national level is responsible for the application of certain legislation. Consumer authorities apply basic and horizontal legislation, but they also have responsibilities on some products subject to specific sectoral legislation in those aspects which are not covered by its specific legislation. It may also happen that several national authorities have responsibilities under the same legislation (for instance, harmonisation legislation whose scope of application covers both industrial/professional products and consumer products). In these cases, market surveillance is executed in a centralised or decentralised manner depending on the distribution of responsibilities. Finally, in some regulations, market surveillance responsibilities remain at the central level, while in others (mostly) the execution of market surveillance activities is transferred to the Regions.

Regarding market surveillance of consumer products, the Ministry of Health, Consumer Affairs and Social Welfare[454], through the General Directorate on Health and Consumer Affairs, shall be generally competent at the

[450] According to the General Directorate on Consumer Affairs, production controls should be required and be available to the market surveillance authorities.

[451] For some regional authorities, barcodes are only useful in the distribution sector. Although recalls are usually limited to a batch, in practice they affect all products with the same product reference because retail trade (especially the large commercial distribution area) only uses barcodes to manage products in their warehouses. This generates unnecessary product collection as well as a loss of business reputation.

[452] Exceptionally, some distributors or producers sell products without sales invoices or they only issue receipts. Due to the duty of confidentiality of the Spanish Tax Agency, market surveillance authorities are not informed about the identity of businesses that purchased their products.

[453] See http://www.mscbs.gob.es/consumo/vigilanciaMercado/autoridades.htm; https://www.mscbs.gob.es/consumo/redAlertas/autoridadesCompetentes.htm.

national level. However, at the regional level, the consumer authorities of the Regions will be exclusively competent.[455]

The General Directorate on Consumer Affairs[456] is the body responsible for making proposals for national regulation, for establishing and promoting effective procedures for consumer protection, for inter-territorial institutional cooperation, for promoting consumer associations and for giving support to the Council of Consumers and Users. It has among others the following functions: to perform analysis and tests on the quality and safety of goods and services, as well as to train and to give advice to technical staff about the development of analytical methods; to manage and to maintain the Alert Network for non-food consumer products; to give support to the cooperation bodies with the Regions and to the Consumer Sectorial Conference; to cooperate and give technical support to other consumer affairs services in relation to official control of goods and services to fight against fraud and to protect consumer health and economic interests; and to prepare regulatory proposals and rules on goods and services that facilitate and improve consumer protection, as well as mandatory reporting on standards or proposals that affect consumer services or products.

In the field of consumer affairs, four levels of institutional cooperation must be distinguished:

1. Cooperation with Regions (*Comunidades Autónomas*) is carried out through the following instruments:

- The Consumer Sectorial Conference (CSC)[457]. It is the highest cooperation body between the General State Administration and the Regions in the field of consumer affairs. It defines policies regarding consumer protection at a national level. The executive body of the Consumer Sectorial Conference (CSC) is the Consumer Cooperation Commission (CCC).
- The Consumer Cooperation Commission (CCC)[458]. It depends on the CSC and its purpose is cooperation, communication and information between the General State Administration and the Regions in matters that affect both the defence of consumer rights and the market surveillance. It has the following functions:
    - The adoption of both decisions and measures for the execution of the CSC decisions;
    - The creation and control of Technical Working Groups (Market Control, Regulations, Consumer Arbitration, Information, Training and Education, Consumer associations, Claims);
    - The submission to the CSC of proposals to improve the protection of consumer rights: approval of national campaigns for market control; approval of the Inter-Administrative Continuing Education Plan, evaluation of the work carried out in EU institutions and in matters that affect the functioning of the market and the protection of consumers;
    - The study and discussion of matters to be submitted to the Plenary of the CSC.

2. Cooperation with Spanish entities and institutions (such as the Bank of Spain and the National Securities Market Commission) is based on active relationships, exchange of information and joint preparation of documents.
3. Cooperation with local bodies (*municipios y provincias*) is carried out mainly through the Spanish Federation of Municipalities and Provinces (FEMP) as well as through the dissemination and distribution of relevant information on consumer affairs and the periodic sending of newsletters to the Consumer Information Municipal Offices (OMIC).
4. Cooperation with other EU Member States is based on Regulation (EC) No 2006/2004 of the European Parliament and of the Council, of October 27, on cooperation between national authorities responsible for the enforcement of consumer protection laws.

Finally, advisory bodies for product and service safety also exist:

1. The Technical Commission for Product Safety provided for in article 16 of Royal Decree n. 1801/2003 provides information, upon request by the market surveillance authorities, about possible risks in certain

[454] See Royal Decree n. 355/2018, of June 6, which restructures the ministerial departments; Royal Decree n. 595/2018, of June 22, which establishes the basic organic structure of the ministerial departments; and Royal Decree n. 1047/2018, of August 24, which develops the basic organic structure of the Ministry of Health, Consumer Affairs and Social Welfare and modifies Royal Decree 595/2018, of June 22. Information about the Ministry organisation can be found at: https://www.mscbs.gob.es/organizacion/ministerio/home.htm.

[455] See article 13 of Royal Decree n. 1801/2003.

[456] Powers on consumer affairs that Royal Decree n. 19/2014, of January 17, attributed to the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN), are held since 2018 by the General Directorate on Consumer Affairs.

[457] https://www.mscbs.gob.es/consumo/cooperacionInstitucional/relCCAA.htm. See Articles 147 and 148 of Act 40/2015, of October 1, on the Legal Regime of the Public Sector.

[458] https://www.mscbs.gob.es/consumo/cooperacionInstitucional/relCCAA.htm.

products. Only technical-scientific criteria are considered.

2. The Assessment Committee solves problems raised when different points of view between the competent administrations in the adoption of measures regarding unsafe products exist.

Plans/programmes in place which define priorities for market surveillance of consumer products

Since responsibilities at the national level are attributed on a sectorial basis, several national authorities prepare annual plans/programmes within their sectorial framework.

In the field of market surveillance of consumer products, both a national (sectorial) surveillance plan/program and several regional surveillance plans/programmes exist. . They define two types of actions:

1) National campaigns based on a joint proposal of product and risk categories prepared by both the General Directorate on Consumer Affairs and the Regions. Campaigns that meet certain requirements, such as technical-legal viability or number of administrations interested in participating, are approved by a working group on market control and then by the Consumer Sectorial Conference.
2) Regional campaigns prepared and coordinated by each Region.

Coordination between national and regional authorities is made through the abovementioned CSC and CCC (see II.1).

Priorities for market surveillance in these plans/programmes are set on the basis of the following sources of information:

1. Inspection results
2. RAPEX notifications
3. Coordinated actions on the safety of products organised at the EU level
4. Consumer complaints
5. Customs information
6. Accidents reports/injury data
7. Information provided by both businesses/business associations
8. Information provided by consumer organisations
9. News and media reports[459]

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Spain with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Neither the national authority nor the regional authorities conduct market surveillance activities with respect to the safety of products containing new technologies[460] and C2C products.

Regarding products sold online:

- Regional market surveillance activities concern both consumer products and services sold online. Regarding consumer products, controls focus on compliance with consumer protection laws and with specific information requirements, such as the composition in the case of textile articles or footwear, safety warnings in toys or the energy efficiency labels in household appliances.
- The General Directorate on Consumer Affairs carries out routine and on-demand controls by means of an online consumer observatory service. This service does not have responsibilities on market surveillance. Information obtained is communicated to the regional market surveillance authorities. The General Directorate on Consumer Affairs also coordinates national market surveillance campaigns affecting products sold online that are implemented by the Regions.
- Joint European campaigns often integrate a percentage of surveillance activities for products sold online, including sampling.

[459] Information about the results of both national and regional campaigns, in relation to food products, non-food products and services, can be found for the period since 2013 at: https://www.mscbs.gob.es/consumo/vigilanciaMercado/campannas/home.htm.

[460] The General Directorate on Consumer Affairs does not focus particularly on products containing new technologies but it does not exclude them from its campaigns, which usually show infringements of personal data protection in connected devices.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

While most Regions conduct market surveillance activities regarding products sold online from both sellers established in Spain and in the EU/EEA, they do not usually conduct these activities when sellers are established in non-EU/EEA countries.

Frequency of the market surveillance is difficult to estimate and in practice it depends on the Region (once a year, once a month, once a week, more than once a week).

Online sales channels covered by the market surveillance activities refer generally to retailer's websites and online marketplaces. It must be noted that since 2013 these surveillance activities have gradually increased.

Percentage of market surveillance activities focused on products sold online vary considerably depending on the Region, the number of campaigns and the number of requests (6-40% of the total number of inspections).

Unless legal impediments exist at regional level,[461] some Regions conduct mystery shopping regarding products sold online (for instance, Madrid conduct it once every six months and Catalonia once a month). The online sales channels covered by mystery shopping activities focus on:

- Retailer's websites.
- Online marketplaces.
- Comparison websites.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Spain (except customs) with respect to product safety

The General Directorate on Consumer Affairs coordinates with other relevant authorities more than once a week. Frequency of cooperation between regional market surveillance authorities and other relevant authorities in Spain depends on the Region (once a week, less than once a year).

Cooperation with other relevant authorities located in Spain and in other EU/EEA countries is done through:

- The common use of the national market surveillance IT system (SIRI is the Rapid Information Exchange System in Spain).
- The common use of RAPEX.
- The common use of ICSM.
- Inclusion of other authorities in preparing national market surveillance plan/programme.
- Regular exchange of information.
- Regular meetings.
- Informal cooperation.

As mentioned before, two coordinating bodies exist between the General Directorate on Consumer Affairs and the regional market surveillance authorities: the Consumer Sectorial Conference and the Commission of Consumer Cooperation (see II.1). Several working groups depend on the Commission of Consumer Cooperation and they meet regularly to exchange information.

There is also a relatively frequent exchange of information and inquiries between the General Directorate on Consumer Affairs and other national authorities with responsibilities on product safety. Generally, cases or complaints are exchanged, and sometimes joint market surveillance campaigns are carried out.

Cooperation with customs authorities in Spain with respect to product safety

Border controls are implemented by the Customs Authority of the Tax Agency and the Official Service of Inspection, Surveillance and Exports Regulation (SOIVRE).

Both the General Directorate on Consumer Affairs and the regional authorities cooperate with customs authorities with respect to product safety approximately once a week. In any case, the contact point with customs is the General Directorate on Consumer Affairs.

[461] For instance, identification of inspectors is required in the Valencian Community (article 40 of Act 1/2011 of 22 March, on the Statute of consumers of the Autonomous Community of Valencia).

Cooperation is done through:

- A common strategy for product safety enforcement.
- A formal agreement between market surveillance authorities and customs.
- Joint risk assessment.
- Informal cooperation.

1) Cooperation between the Customs Authority of the Tax Agency and the General Directorate on Consumer Affairs:

a) Cooperation between central offices of both authorities exists when they coordinate actions at the national level, collaborate in certain campaigns, exchange information related to risk assessment of certain products or product categories and/or coordinate positions.

b) Cooperation between the customs offices and the central office of the General Directorate of Consumer Affairs exists when the dispatch of goods is suspended. The office responsible for the dispatch contacts the General Directorate on Consumer Affairs to request a technical evaluation, mainly documentary, of the goods' conformity.

2) Cooperation between the SOIVRE and the General Directorate on Consumer Affairs. It is based on a formal agreement. When the SOIVRE detects an infringement, it is communicated to the General Directorate on Consumer Affairs that in turn communicates it to the regional authorities indicating whether any action is needed to verify the product correction before distribution, to verify previous imports, to recall products of previous imports, to open an investigation and/or to enter an alert. Information obtained by the regional authorities is centralized by the national authority, which in turn refers it to the SOIVRE. [462]

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

When a dangerous product is identified and the economic operator is based in an EU/EEA country, the General Directorate on Consumer Affairs enters information into RAPEX and the EU/EEA authority contacts the economic operator and takes the appropriate measures.

The regional market surveillance authorities in Spain can also contact economic operators based in an EU/EEA country directly. If no response is obtained, the authority responsible for that product in an EU/EEA country is contacted for assistance either using the ICSMS system or through the General Directorate on Consumer Affairs.

If the economic operator is based in a non-EU/EEA country, no response is generally obtained. Contact can be made with importers or authorised representatives and distributors placed in an EU/EEA territory.[463]

The General Directorate on Consumer Affairs cooperates with other relevant authorities located in other EU/EEA countries once a month, while frequency of cooperation at the regional level is once a month or once every six months. Cooperation is done through:

- RAPEX
- ICSM[464]
- Wiki confluence platform
- Coordinated actions on the safety of products organised at EU level

No cooperation exists with authorities located in non-EU/EEA countries at either the national or the regional level.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

A national alert network system for dangerous products exists in Spain (SIRI) in which all regional market surveillance authorities publish their market surveillance activities (notifications, recalls, verification of destruction

[462] Royal Decree n. 330/2008, of February 29, whereby control measures on imports of certain products are adopted with respect to the applicable product safety standards, establishes the powers of the SOIVRE in order to control the security of certain border products (products included in Annex 1 of the Royal Decree). It also regulates coordination measures between the SOIVRE, the customs authorities and the different market surveillance authorities. There is a fluid communication through computer applications, meetings, consultations, discussion forums, etc. The collaboration is especially close with the General Directorate on Consumer Affairs. Joint campaigns have been organised and a joint working group has been established.

[463] The General Directorate on Consumer Affairs points out that agreements between the European Commission and non-EU/EEA-countries would improve and facilitate communication with non-EU/EEA market surveillance authorities.

[464] Some authorities criticise that duplicated notifications in the ICSMS system leads to a duplication of actions, an increase in the workload and an excess of information.

or correction of products if possible).

When a regional authority detects a dangerous product, the other regional authorities are informed through SIRI. The competent regional authority contacts the manufacturer or importer of the dangerous product. If the product has been sold in other EU countries, the General Directorate on Consumer Affairs enters this information into RAPEX.

The average duration between the detection of a dangerous product and its notification through RAPEX is more than 2 weeks.

Regarding non-safety risks notified through RAPEX affecting mobile phones, nautical items, and industrial vehicles, among others, responsibility is on authorities other than those responsible for consumer protection.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The General Directorate on Consumer Affairs cooperates with business associations and businesses more than once a week. Collaboration consists of:

1) A cooperation agreement with business associations whereby annual meetings are organised.
2) Frequent exchange of information with business associations/businesses to know whether they are commercialising products listed in RAPEX.
3) Joint organization with businesses associations of informative campaigns and awareness campaigns addressed to both businesses and consumers.
4) Evaluation of complaints related to non-conforming products as a result of the proactive market surveillance that the business organisations carry out.

The regional market surveillance authorities also cooperate with business associations and businesses once every six months through:

- Cooperation with businesses/business associations to create awareness regarding product safety among businesses.
- Partnership agreements with business organisations.
- Regular exchange of information with business organisations.
- Informal cooperation with business organisations.
- Providing advice to business, when needed.
- Issuing laboratory reports at their request.

As a result of the market surveillance activities, businesses contact regional authorities to review labelling criteria or to conduct specific tests in laboratories.

The General Directorate on Consumer Affairs also cooperates with consumer organisations once every three months, while at the regional level the frequency of this cooperation depends on the Region (once a week, once every three months). Collaboration is done through:

- Partnership agreements with consumer organisations.
- Cooperation with consumer organisations to create awareness for product safety among consumers.
- Regular exchange of information.
- Informal cooperation (for instance, by means of training courses).

The Council of Consumers and Users is an institutional representation and consultation body at the national level to defend the consumers' interests and to influence decision-making by public authorities in relation to consumer policies[465]. In addition, there are specific collaborations whereby consumer associations provide information on market research or studies on certain products. In some Regions, consumer associations develop campaigns to detect unsafe products and to present complaints.[466]

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product

[465] More information about this Council can be found at http://www.consumo-ccu.es/

[466] For instance, about costume products at the time of Carnival and Halloween, school products at the beginning of the academic year and toys and decoration products in the Christmas season.

safety

Market surveillance authorities raise awareness among businesses and consumers with respect to product safety through:

- Press releases.
- National online information system/website on dangerous products and product safety information.
- Link to the EU RAPEX website on official website (information is provided on the Region's website with a link to the alert system).
- Information campaigns in classical media (newspapers, TV, radio).
- Information campaigns and the use of social media.
- In some cases, advertisements must be placed in shops to inform consumers about product recalls and their reasons, and about the acceptance of product returns and reimbursements.

In the webpage of the Ministry of Health, Consumer Affairs and Social Welfare, information to raise the awareness of businesses and consumers with respect to product safety can be found: alerted products entered into SIRI[467]; awareness materials;[468] product safety advice.[469]

Product safety messages are also published through the Twitter and Facebook accounts of the Spanish Ministry of Health, Consumer Affairs and Social Welfare, and the European Consumer Centre.

Finally, a CONSUMOPOLIS school contest, organised by both the national and regional authorities in consumer affairs, exists.[470]

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Spain (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

In Spain, recalls and corrective measures are organised as follows:

- Businesses are asked to conduct (voluntary) recalls and other corrective measures, if needed.
- Businesses are asked to conduct (mandatory) recalls and other corrective measures, if needed.
- Businesses and market surveillance authority agree on the information channels to inform consumers on a recall.
- Recalls and other corrective measures are organised by authorities if no responsible business operator can be found.
- Businesses are required to use all their available customer information for recalls and other corrective measures (including from customer databases, loyalty card information, etc.).
- Online marketplaces are involved in the recall process.

Regional market surveillance authorities are responsible for the recall process and the adoption of corrective measures. They may have their own computer system for monitoring or organising these actions, which are then entered into SIRI. SIRI provides regional authorities with information to find unsafe products in their territories. The General Directorate on Consumer Affairs coordinates and supervises information entered into SIRI and verifies its consistency.

According to the national authority, no cooperation with businesses exists regarding a specific recall, but businesses must cooperate with authorities by providing them information. Cooperation with businesses at the regional level consists of checking and influencing the messages sent to consumers or the recall strategy. Some Regions also offer themselves to collect and destroy dangerous products at zero cost for businesses.

In case of a product recall, the following information is required from businesses:

- Information activities targeted at consumers

[467] https://www.mscbs.gob.es/consumo/redAlertas/productosAlertados/home.htm). Links to the European Alert Network (Safety Gate), international alerts and commercialisation restrictions can also be found.
[468] http://www.mscbs.gob.es/consumo/pec/divulgacion/home.htm
[469] https://www.mscbs.gob.es/consumo/redAlertas/conSegProd.htm
[470] It aims at raising awareness of schoolchildren with respect to the acquisition of goods and services. The contest is annual and has been running for 14 years. More information is available at https://www.mscbs.gob.es/consumo/formacion/concursoEsc.htm.

- Information activities targeted at and cooperation with other businesses involved in the supply chain (e.g. distributors, online marketplaces).
- Lists of other businesses involved in the supply chain (e.g. distributors, online marketplaces).
- Recall effectiveness (i.e. percentage of recalled consumer products actually collected).
- Destruction and disposal of products collected.
- Other information: document that shows that the destruction of products collected has been done by an authorised centre.

The role of the General Directorate on Consumer consists of entering information about dangerous products into the national alert network system[471], of publishing a link to EU alerts (Safety Gate) and international recalls (OECD)[472], and of publishing some decisions on commercialisation restrictions.[473]

The role of regional authorities consists of providing information to consumers through a public recall database or traditional media channels (e.g. TV, press).[474] Sometimes they also impose on businesses the obligation to announce recalls in their establishments.

Finally, no codes of good practice on product recalls, but cooperation agreements, have been established in Spain.[475]

Monitoring of effectiveness of product recalls by market surveillance authorities

The national market surveillance authority does not have powers to monitor effectiveness of product recalls. Most regional authorities monitor this effectiveness by collecting the following information:

- Recall results in terms of the absolute number of products collected.
- Spot checks in shops (regarding withdrawal of the product).
- Awareness of consumers with respect to the recall. Businesses are obliged to announce the recall of a product in their establishments.
- Documents that certify the product recall.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Spain that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

In Spain, three types of statistics related to dangerous products are kept:

- Statistics on dangerous products (other than RAPEX statistics).
- Statistics on dangerous products intercepted by customs at the borders.
- Other statistics (see infra).

The following data sources must be considered:

- SIRI.
- ICSMS.
- Statistics on market surveillance actions organised by sector, by irregularities and by procedures initiated.
- Data from the Centre for Research and Quality Control (CICC).[476]
- The results of market surveillance campaigns are also recorded in a computer system.
- Inquiries or complaints received from consumers.[477]

[471] http://www.mscbs.gob.es/consumo/redAlertas/productosAlertados/alertasNac.htm.
[472] http://www.mscbs.gob.es/consumo/redAlertas/productosAlertados/home.htm.
[473] http://www.mscbs.gob.es/consumo/redAlertas/productosAlertados/restComer.htm.
[474] According to some regional authorities, they do not have a role in communicating information on a recall to consumers.
[475] There are cooperation agreements with two large distributors' associations nationwide to recall unsafe products [for instance, ANGED (National Association of Large Distribution Companies)]. Members of these associations receive information about unsafe products that must be recalled. Information provided is limited to product reference, risks derived from infringement, measures taken and the authority that has adopted them.
[476] It consists of a set of laboratories or analytical units where consumer products in the Spanish market, both food and non-food or industrial products, are analysed. It provides technical and scientific support for the application and development of consumer protection policies. Additional information about the CICC can be found at https://www.mscbs.gob.es/consumo/cicc/sobreCICC/home.htm.
[477] Some Regions collect consumer complaints with respect to unsafe products through regional public databases on consumer complaints. Information from the European Consumer Centre is also considered, but it is generally not possible to identify complaints about unsafe products.

- Complaints from consumer associations.
- The Consumer Markets Expert Group, Consumer Scoreboards or the Marketing Monitoring Survey

No public access exists to customs data or to information about border controls. Data can be obtained at the request of the interested person.

Regarding injury data, systematic data collection exists. Sources of injury data are:

- SIRI (although it is not a specific database for this type of information) and sometimes ICSMS.
- Media monitoring.
- Consumer complaints collected by the Regions.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Spain (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

1) Problems affecting market surveillance in general

According to the General Directorate on Consumer Affairs, the following problems have been encountered:

- Limited staff resources for market surveillance.
- Lack of financial resources for testing of consumer products.
- Unclear distribution of responsibilities for market surveillance at the national level.
- Lack of awareness of consumers with respect to product safety.
- Problems in taking effective actions when the responsible economic operator is located in a non-EU/EEA country.

According to authorities at the regional level, the following problems must be emphasised:

- Limited staff resources for market surveillance.
- Lack of expertise in new technologies.[478]
- Lack of suitable product testing laboratories.[479]
- Lack of awareness of businesses with respect to product safety requirements.
- Lack of cooperation of businesses and business organisations (except for the above-mentioned ANGED association).
- Problems in taking effective action when the responsible economic operator is in another EU/EE country due to a lack of communication.
- Problems in taking effective action when the responsible economic operator is outside the EU/EEA due to a lack of communication.

2) Impediments to effective surveillance online

Three types of impediments have been encountered:

- Legal impediments, due to uncertainty about information requirements in online sales, which involve that authorities must purchase products to verify their conformity.
- Impediments related to staff resources, due to lack of training.
- Technical impediments in relation to mystery shopping.[480]
- Difficulties in identifying online businesses and in preventing commercialisation of dangerous products.

3) RAPEX functioning

[478] Technological tools for the registration of actions are usually unknown.

[479] Several problems are mentioned by interviewees: lack of criteria to solve discrepancies between laboratory results; lack of accredited laboratories for some EN standards in some countries; language and interface barriers; tests do not usually focus on labelling and documents accompanying the product; and some tests from non-EU/EEA countries have been proven false. In order to solve these problems, several proposals are made: a consultation form to identify EU laboratories and accrediting entities; an e-mail address in accredited laboratories to confirm the veracity of documents; the obligation of laboratories to give an answer to requests made by authorities; possible sanctions imposed on laboratories in case of lack of response.

[480] Actual means of payment do not prevent sellers from identifying authorities when they purchase products. Moreover, in some Regions identification of inspectors is required legally. It also becomes difficult for some authorities to have the necessary technical conditions to conduct mystery purchases. Finally, it would be desirable that products were received in the office of the market surveillance authority.

RAPEX is considered to be functioning rather well.

Some aspects for improvement are mentioned by both national and regional authorities:

- Different ways of proceeding in EU/EEA countries exist.
- If another country is involved, a specific list of the companies involved, or distribution data, are sometimes missing.
- In many EU/EEA notifications, there is no record that EU/EEA authorities have contacted the economic operator or have taken measures. In other cases, distributors or retail businesses are not identified, or the documentation is not sent.
- In some cases, decisions adopted by EU/EEA authorities are not entered into RAPEX and the Spanish regional market surveillance authority must contact the EU/EEA authority to confirm the veracity of the decision.

Some impediments when using RAPEX have also been encountered:

- Insufficient human or financial resources for RAPEX.
- Difficulties with risk assessment because it is carried out through hypothetical assumptions on most products.
- Lack of information from national authorities in other countries.
- Lack of information from businesses.
- Lack of information to trace notified products.
- Lack of information about measures taken by other EU/EEA authorities in relation to RAPEX notifications. In some cases, there is the paradoxical situation that a product has been recalled from the market in some EU countries, except in the country where the economic operator is based.

4) Recalls

Product recalls are considered moderately effective by the General Directorate on Consumer Affairs. When collaboration with economic operators does not exist, product collection is not completely successful since products alerted years ago can be found in the market and especially on the online marketplaces.

In the Regions' opinion, recalls are very effective despite management problems (procedure, human resources, technical support). They base their conclusion on the number of product recalls.

Areas to make market surveillance of consumer products in Spain/the EU more effective

1) RAPEX functioning

- It would be interesting to be able to screen through an advanced search. For instance, number of accidents by type of product in a range of dates.
- It would also be necessary to add a field indicating the relevant actions carried out by other countries (especially in case of allegations and evidence provided by the responsible economic operator) as well as a direct link with ICSMS.
- Notifications in the Product Safety Gateway should always be entered into RAPEX.
- Authorities should contact economic operators when they are in their respective countries.
- Information about actions taken by EU/EEA authorities should be available through RAPEX.

2) Recall process

- Measures that help authorities to find a responsible economic operator in the distribution chain should be adopted to promote collection at the national level.
- It would be desirable to encourage responsible economic operators to raise awareness and motivate customers to register in customer registers that inform about product collection.
- Specific software (such as a mobile app) to inform consumers about product collection would be interesting.
- It would be desirable that measures restricting commercialisation were not notified to the retail establishment, but directly to the responsible economic operator in Spain.
- After receiving a notification, authorities from other countries should always act and provide information about their actions.
- More control of the product recall process should be desirable afterwards to ensure that products are not

available in the market.

- Faster communication between public administrations involved in the recall process would be desirable.

3) Potential improvements of market surveillance

- It would be fundamental to evaluate how results of market surveillance activities are currently being communicated and to implement strategies that improve this communication.
- Budgetary limitation for sampling and testing in accredited laboratories should be addressed.
- Products that are usually beyond analytical control (for instance, electrical household appliances) should be addressed.
- Market surveillance of products imported from non-EU/EEA-countries and products sold online, especially through marketplaces, should be improved.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Spain since 2013

According to most interviewed authorities, the general trend is positive (i.e. safety improved). This assessment is mostly based on the following indicators:

- Regional data.
- Consumer associations use the Alert Network, make complaints, and take an interest in the recall procedure for some products.
- Business associations are aware of the existence of the Alert Network.
- Experience and training of those who manage the product recall process.
- Ex ante measures taken by businesses to improve production control and to avoid infringements.

The Catalan authority points out that the trend depends on the product type or sales channel (for instance, safety is more difficult to guarantee in online sales).

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Spain whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

Authorities consider that they do not have tools at their disposal to address new challenges. In relation to C2C sales, consumer authorities do not have tools to know if there is actually a business behind these sales.

In relation to e-commerce, main challenges refer to the need to provide specialized training and material resources as well as to clarify information about products that should be available on websites. It is considered that Regulation (EU) 2019/1020 will provide a legal instrument to address certain issues.

The sale of products through social networks should also be addressed.

Finally, as for the new technologies, a debate about the product definition in relation to software seems fundamental.

Authorities do not use or are developing technological approaches/tools in their market surveillance activities.

Views of market surveillance authorities whether approaches in Spain can be considered best practice implementation of the GPSD, which could be of interest to other countries

Most regional authorities have not identified market surveillance approaches in their Regions to be best practice implementation of the GPSD. The Valencian Community authority has emphasised two best practices:

- SIRI gives information about the responsible economic operator, the person at each stage of the recall process and the status of any notification at any time.
- Contact between the different market surveillance authorities is encouraged and facilitated in order to improve the exchange of information, the request for actions or the reminder of those actions pending.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

Notes: General Directorate of Consumer Affairs: In 2018 and 2019, 4 FTE (2 FTE in alert network and 2 FTE in market surveillance).

Concerning the Valencian Community, 27 FTE are allocated to market surveillance and control activities. They perform their activities regarding both consumer products and services and regarding both products sold online and traditional sales. 2 FTE are allocated to manage the Alert Network (without performing inspections). The staff situation refers to 2019.

No information has been provided by the other regional authorities.

B. Number of inspections of consumer products (last available year)

Note:

Statistics on inspections carried out and on administrative proceedings initiated by Regions between January and September 2019 are available at the webpage of the Ministry of Health, Consumer Affairs and Social Welfare: https://www.mscbs.gob.es/consumo/vigilanciaMercado/resumenes/resumen2019.htm.

Statistics available refer only to the following Regions: Andalusia, Aragon, Canary Islands, Cantabria, Castilla y León, Extremadura, Galicia, Murcia, Valencian Community, Ceuta and Melilla.

No information exists about Asturias, Balearic Islands, Castilla-La Mancha, Catalonia, La Rioja, Madrid, Navarra and Basque Country.

Both statistics are classified by products (food and non-food) and services as well as by infringements.

Non-food products refer to:

1. *Home appliances*
2. *Toys*
3. *Cars and spare parts*
4. *Textiles*
5. *Leather and skin product*
6. *Cosmetics*
7. *Chemicals for domestic use*
8. *Fuels*
9. *Chemical products*
10. *Fat oils*
11. *Various industrial products*

Infringements refer to:

1. *Adulteration and quality fraud*
2. *Weight Fraud*
3. *Commercial transactions*
4. *Prices*
5. *Standardisation and conditions of sale*
6. *Other infractions*

Statistics on inspection activities also include information about positive and negative inspection reports and sampling reports.

	Positive inspection report	***Negative inspection report***	***Sampling report***	***Administrative proceedings initiated***
Home appliances	*231*	*4674*	*85*	*103*
Toys	*1292*	*40817*	*147*	*147*
Cars and spare parts	*100*	*901*	*14*	*79*
Textiles	*558*	*9232*	*81*	*86*
Leather and skin products	*115*	*552*	*2*	*19*
Cosmetics	*88*	*229*	*16*	*9*

Chemicals for domestic use	*82*	*645*	*92*	*13*
Fuel	*210*	*682*	*55*	*17*
Chemical products	*24*	*1799*	*13*	*3*
Fat oils	*1*	*2*	*0*	*0*
Various industrial products	*1800*	*23665*	*263*	*523*
TOTAL	***4501***	***83198***	***768***	***999***

C. Number of recalls of consumer goods (last available year)

*Information about product recalls has been obtained from the Global Portal on Product Recalls OECD (*https://globalrecalls.oecd.org/#/), where voluntary and mandatory recalls are not distinguished.

	2011	***2012***	***2013***	***2014***	***2015***	***2016***	***2017***	***2018***	***TOTAL***
Automotive	*0*	*4*	*6*	*8*	*8*	*15*	*5*	*5*	***51***
Beauty/Personal Care/Hygiene	*0*	*0*	*3*	*4*	*2*	*2*	*1*	*1*	***13***
Camping	*0*	*0*	*0*	*0*	*1*	*0*	*0*	*1*	***2***
Cleaning/Hygiene products	*0*	*0*	*1*	*1*	*1*	*1*	*1*	*1*	***6***
Clothing	*0*	*4*	*12*	*13*	*13*	*6*	*14*	*11*	***73***
Cross segment	*0*	*1*	*2*	*6*	*3*	*0*	*0*	*0*	***12***
Electrical Supplies	*0*	*15*	*15*	*21*	*33*	*30*	*37*	*7*	***158***
Food/Beverage/Tobacco	*0*	*0*	*0*	*8*	*10*	*0*	*0*	*0*	***18***
Footwear	*0*	*2*	*3*	*19*	*16*	*18*	*6*	*4*	***68***
Healthcare	*0*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	***1***
Home Appliances	*0*	*0*	*2*	*0*	*4*	*3*	*2*	*0*	***11***
Household/Office Furniture/Furnishings	*0*	*2*	*6*	*4*	*2*	*8*	*3*	*1*	***26***
Kitchen Merchandise	*0*	*2*	*2*	*3*	*1*	*0*	*2*	*0*	***10***
Lawn/Garden Supplies	*0*	*0*	*0*	*5*	*0*	*3*	*0*	*0*	***8***
Personal Accessories	*0*	*0*	*1*	*0*	*1*	*0*	*1*	*0*	***3***
Plumbing/Heating/Ventilation/Air Conditioning	*0*	*0*	*0*	*0*	*5*	*5*	*1*	*0*	***11***
Safety/Protection-DIY	*0*	*0*	*6*	*7*	*14*	*4*	*7*	*4*	***42***
Safety/Security/Surveillance	*0*	*0*	*1*	*0*	*0*	*0*	*0*	*0*	***1***
Sports Equipment	*0*	*2*	*4*	*4*	*1*	*8*	*4*	*0*	***23***

Stationery/Office Machinery/Occasion Supplies	*0*	*1*	*0*	*0*	*0*	*4*	*2*	*0*	***7***
Tools/Equipment - Hand	*0*	*0*	*0*	*0*	*0*	*0*	*4*	*0*	***4***
Tools/Equipment - Power	*0*	*1*	*0*	*0*	*2*	*0*	*2*	*0*	***5***
Toys/Games	*2*	*27*	*40*	*97*	*99*	*94*	*119*	*79*	***557***
TOTAL	***2***	***62***	***104***	***200***	***216***	***201***	***211***	***114***	***1110***

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27. Sweden

COUNTRY REPORT SWEDEN

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

In Sweden, the GPSD has been implemented through the Product Safety Act (2004:451), PSA, which came into force on the 1st of July 2004 (amended through SFS 2011:1215). The implementation provisions of the GPSD consist of the PSA and the Ordinance on Product Safety (2004:469) along with amendments to several other acts dealing with particular products, e.g. the Work Environment Act (1977:1160, amended through SFS 2016:1160), the Consumer Services Act (1985:716, amended 2018-08-19), the Consumer Purchase Act (1990:932 amended 2018-08-19) etc. The requirements in the Product Safety Act are binding.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Sweden

The traceability requirement is applied through a general requirement to indicate the name and contact details of the producer on the product and its packaging. There are general requirements to indicate the product reference or, where applicable, the batch of products to which it belongs, on the product or its packaging.

According to section 20 in the Product Safety Act (2004:451), producers shall carry out preventative product safety work in order to obtain knowledge regarding the risks of injury associated with the products which they provide or have provided.

For the aforementioned purpose, producers shall:

1. Mark a product or its packaging with the producer's name and address and with a reference to the product or the batch of products to which it belongs, where such a marking is not obviously unnecessary; and

2. Review and maintain a register of received complaints with respect to the risk of injury.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

According to art. 7 – 9 in the Product Safety Act, the following definition is given:

Sec. 7. Goods and services supplied by an undertaking must be safe.

Sec. 8. A product or a service is safe where, in conjunction with normal or reasonably foreseeable use and lifespan, it does not convey any risk with respect to the health and safety of humans, or only a low risk. However, such risk must be acceptable taking into consideration the manner in which the product or service is used and must be compatible with a high level of protection with respect to the health and safety of humans.

A product or service is dangerous if it fails to meet the requirement for a safe product or service set forth in the first paragraph.

Sec. 9. When assessing whether the risk associated with a product is to be deemed acceptable and compatible with a high level of protection, particular consideration shall be given to the following:

1. A product's characteristics, such as its composition and packaging, as well as instructions regarding assembly, installation and maintenance;

2. Other information provided with respect to the product through markings, warnings, use instructions, instructions regarding disposal or in any other manner;

3. The effect of the product on other products, where it may be assumed that it will be used together with such products;

4. Risks which the product may convey for certain categories of consumers, particularly children and the elderly.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The Swedish law transposing the GPSD deals with safety, not security. In other words, the Swedish law makes sure that products on the market are safe and not unhealthy. However, the law does not protect the consumers personal integrity. Therefore the national implementation legislation transposing the GPSD does not cover the different threats related to new technologies. In addition, the Swedish product safety law also does not cover intended misuse as "hacking".

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

Sweden uses European standards other than the ones referenced in the EU official journal. Sweden has national standards that are not based on the European standard. Sweden also uses international standards from non-EU/EEA countries. Codes of good practice in force in the sector concerned are also used, as well as state of the art and technology, and reasonable consumer expectation concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Sweden in case there are consumer product(s) on the market which are found unsafe under the GPSD

In cases where there are consumer products on the market which are unsafe, the authorities require businesses to provide relevant information on the products. The authorities require businesses to provide relevant information on the supply chain and the distribution of the products. The authorities carry out unannounced on-site inspections and physical checks of products. The authorities acquire product samples, including under a cover identity. The authorities require from the economic operators recalls of products and other corrective measures. The authorities reclaim from the relevant economic operator the costs of administrative activities with respect to the unsafe products. The list of measures above is exhausting.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The supervisory authority may issue the orders and injunctions necessary in a particular case in order to ensure compliance with the Act and the regulations promulgated pursuant to the Act, section 27. An order or an injunction pursuant to sections 27-29 shall be issued together with a conditional fine, unless such a fine is unnecessary for special circumstances, section 31.

According to section 37, an undertaking may be ordered to pay a fine where the undertaking or any party acting on behalf of the undertaking deliberately or negligently violates (for example) section 7, which is that goods and services supplied by an undertaking must be safe. Fines may not be imposed in respect of a violation of an injunction or failure to comply with an order, where a fine according to section 31 has been issued.

Fines shall be determined at not less than 5 000 Swedish kronor (approx. EUR 476) and not more than 5 000 000 Swedish kronor (approx. EUR 476 300). Fines may not exceed ten percent of the undertaking's annual turnover. When fines are determined, particular consideration shall be given to the seriousness of the violation and the significance of the provision to which the violation relates. According to the authorities, fines amounting to 1 000 000 SEK (approx. EUR 95 260) are common. Conditional fines and fines are applied in practice.

Recent case law in Sweden with respect to or relevant for the GPSD/the national implementation legislation.

There is no recent case law concerning the GSPD or for the correspondent national legislation. Product safety cases are rare and seldom reach the administrative supreme court.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Sweden concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

There are practical problems. The supervisory authorities are not able to look into marking or traceability of GSPD products that do not pose a serious risk. The supervisory authority only carries out random checks. Therefore it is not possible to check all products on the market and this is why the authority only checks the products that pose a

serious risk. Regarding the definition there are also some practical problems. The supervisory authorities state that the definition of safety is too wide or too general. The definition also suffers from lack of clarity. When it comes to emerging safety issues, there have been problems with toys. The case with the internet- connected toys 'My friend Cayla' and 'I-Que' show how toys can jeopardise integrity rather than safety.[481] This case also showed that it was not clear if these types of products should be assessed under GPSD or integrity legislation.

Possible improvements to make the implementation of the GPSD in Sweden more effective

The supervisory authorities state that there is room for improvement. The Swedish Consumer Agency can only act according to national law in cases when an unsafe product is found. The authority states that it has experienced national businesses/economic operators on the internet who do not take product safety seriously. These companies systematically sell cheap products which often do not fulfil the safety requirements. These companies have a very vast range of products with a constant influx of new models. When the Swedish Consumer Agency acts on a product, the companies often follow the authority's order to stop selling a certain product. However, the surveillance of the authority has little effect. The companies continue immediately to sell other products which do not reach sufficient safety levels. According to section 20 in the Swedish Product Safety Act, the producers shall carry out preventative product safety work in order to obtain knowledge regarding the risks of injury associated with the products which they provide or have provided. The Consumer Agency wants tools to work more systematically with the supervision of how the producers carry out this preventative work.

SWEDAC has pointed out in the National Market Surveillance Plan for 2019 that Art. 18.6 of regulation 765/2008 shows some weakness in both implementation and reporting. Market surveillance is non-existent or very limited in many areas and in most sectors very few resources are allocated to market surveillance activities at the various authorities. This is partly presumed to be because of lack of clarity in the government's instructions to the authorities, in which the market surveillance task is not included. The fact that powers and sanction mechanisms vary between sectors and authorities hampers cooperation between authorities. These factors are mentioned as obstacles for the ability of the authorities to conduct effective market surveillance.

Representatives from the Consumer Unit at the Government Offices, the Swedish Energy Agency, Swedish Chemicals Agency, the National Electrical Safety Board, the Medical Products Agency, on the other hand, state that they do not share SWEDAC's (Swedish Board for Accreditation and Conformity Assessment) opinion, but assess that supervision works well. The authorities consider that they meet the requirements of the Regulation.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Sweden.

The Swedish Consumer Agency is, according to section 3 of the Ordinance on Product Safety, the competent authority under the Product Safety Act. Other authorities like the Authority for Building and Planning, the Public Health Agency, the Chemical Agency, the Environmental Protection Agency may however be the competent authority for specific products according to product specific acts in the Swedish legislation.

The market surveillance is carried out by the competent authority within their specific sector. The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) is responsible for coordination and supporting market surveillance of the Swedish market. One of the ways in which this cooperation is applied is through the Market Surveillance Council, made of up of 16 representative from all the sectors authorities concerned and from trade and industry, consumer organisations, trade unions and employers associations.

Plans/programmes in place which define priorities for market surveillance of consumer products

There are plans in place which define priorities for market surveillance. There are national surveillance plans/programmes covering all products sectors (consumer and professional products) and all consumer product sectors. There are sector surveillance plans/programmes as well as regional/provincial surveillance plans/programmes.

The priorities for market surveillance are set based on inspection results, RAPEX notifications, coordinated actions

[481] See https://www.forbrukerradet.no/siste-nytt/connected-toys-violate-consumer-laws

on the safety of products organised at the EU level, consumer complaints, customs information, accidents reports/injury data and news/media reports.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Sweden with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

There are no market surveillance activities with respect to the safety of products containing new technologies. However, there are market surveillance activities with respect to the safety of products sold online. The supervisory authority conducts surveillance more than once a week regarding products sold online from sellers established in Sweden. Regarding products sold online from sellers established in the EU/EEA, the supervisory authority conducts surveillance once a month. For products from sellers established in non-EU/EEA countries, the surveillance authority conducts surveillance once every six months. The Consumer Agency states that it surveys products sold on the internet when appropriate. The frequency is not set per week, month or so. The surveillance is conducted through retailer websites and online marketplaces.

The Consumer Agency does not have intermediary service providers (for example providers of hosting services, such as online platforms) as counterparts since they are not economic actors in the sense of the GPSD or sector legislation under Regulation 765/2008.

The impediments to effective surveillance online are related to the lack of financial/staff resources. The EC Notice on market surveillance on online products has been moderately helpful. However, it is considered too vague and not addressing the real problem, namely that the counterparts are located in a non-EU/EEA-country, outside the Consumer Agency's territory and jurisdiction. The Product Safety Pledge has also been moderately helpful. The Consumer Agency states that hopefully there will be a national safety pledge by the end of 2020. Work on this will be commenced. The Consumer Agency does not conduct market surveillance regarding products sold by consumers to consumers (C2C).

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The estimation in percentage of the Consumer Agency's market surveillance activities that focus on products online is between 31-40 %. However, it is difficult to make an estimation on the time spent. The work regarding market surveillance is organised in such a way that the staff of the Consumer Agency look at photos and select (and in planned projects, purchase) products that the authority suspects to be non-compliant and/or unsafe. The Consumer Agency can also demand free samples from businesses operators. It is more common to ask for samples in cases where the authority has received a complaint. The authority conducts so-called mystery shopping regarding products sold online when needed or where appropriate. The channels covered regarding mystery shopping focus on retailer websites and online marketplaces.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Sweden (except customs) with respect to product safety

See above section II, and below on impediments.

Cooperation with customs authorities in Sweden with respect to product safety

The cooperation with the customs authorities functions well. There are meetings once a month. There is a inclusion of customs in preparing national market surveillance plans/programmes. There is joint setting of priorities in the market surveillance for customs and market surveillance. There are regular exchanges of information and regular meetings. There is also informal cooperation. The customs subscribe to the Swedish Consumer Agency's weekly email report on RAPEX. It should be noted that the Swedish customs is not a market surveillance authority.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

If a dangerous product is identified and the economic operator is not based in Sweden, the Consumer Agency follows the recommendation in the EC notice and the guide Good Practice for Market Surveillance developed by

ADCO chairpersons in 2017. There is cooperation with relevant authorities located in other EU/EEA countries through RAPEX and through ICSMS and the Wiki confluence platform. There are regular meetings outside the EU related meetings and there is informal cooperation. With authorities outside the EU/EEA, cooperation is through mutual assistance requests made or received. The toy safety expert group ADCO has a mailing list to exchange views on different toys and questions.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

In order to ensure that information concerning dangerous products from the market surveillance activities is effectively entered into RAPEX, the Consumer Agency notifies RAPEX when the risk assessment shows that the product has a serious or high risk. However, first the necessary measures must have been taken. According to section 32 in the Product Safety Act, where measures must be implemented in order to avoid injury to a person caused by a product or service, the supervisory authority shall commence negotiations with the undertaking in order that the latter shall voluntarily undertake the measures required. The aforesaid shall not apply, however, where the matter is urgent or where the circumstances otherwise do not allow for the commencing of negotiations. In most circumstances, however, the authority needs to negotiate with the company regarding the necessary measures. If the Authority deems the risk to be serious, the authority then must file a decision on compulsory measures. Because of the timeframes involved for the negotiation, the notification is not sent directly to RAPEX.

The average duration between the detection of a dangerous product and its notification to RAPEX is more than two weeks. Due to the above-mentioned negotiations with the counterparty, it takes time. The authority deals with the non-safety risk notified to RAPEX in the way that relevant market surveillance authorities are informed and take actions where needed. Other responsible authorities (e.g. environmental authorities) are also informed and take actions.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The market surveillance authority cooperates with business associations and business and consumer organisations on product safety once every three months. The cooperation results in partnerships agreements with business organisations. There are also regular meetings with business organisations. The authority also provides advice to businesses where needed. The authority has also developed a specific portal for safety.[482]

The authority cooperates with consumer organisations once every three months. There are approximately 2-3 meetings per year with the Market Surveillance Council in which the consumer organisations have a representative. The Director General of the Consumer Agency has an assisting advisory board which can deal with product safety. The board has representatives from i.a. the municipal consumer guidance organisation (Konsumentvägledarnas förening), the General Secretary of the Swedish consumer organisations (Sveriges konsumenter) and the PRO - the Swedish National Pensioners Organisation. The cooperation results in partnership agreements with consumer organisations. Through cooperation with consumer organisations, the authorities create awareness on product safety among consumers. There are also regular meetings.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The surveillance authority informs and raises awareness among consumers with respect to dangerous products through press releases and a national online information system/websites on dangerous products and product safety information. There is also a link to EU RAPEX website on the official website. There are also information campaigns or use of social media.[483]

5. Recalls and other corrective measures

[482] See https://www.konsumnetverket.se/for-foretag/produktsakerhet and https://www.elsakerhetsverket.se/yrkespersoner/tillverkare-aterforsaljare/

[483] See for example https://facebook.com/search/top/?=konsumentverket&epa=SEARCH_BOX or https://konsumentverket.se/aktuella-konsumentproblem/nyheter–och pressmeddelanden

Organisation of recalls and other corrective measures in Sweden (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Recalls and other corrective measures are organised in such a way that businesses are asked to conduct (voluntary) recalls and other corrective measures, if needed. According to section 15 in the Swedish Product Safety Act, a producer who supplies a dangerous product shall, without delay, recall the product from the distributors in possession thereof where required to prevent injury. Where such measure is insufficient in order to prevent injury, the producer shall without delay recall the product from the consumers in possession thereof.

Recall shall take place to an extent that is reasonable, taking into consideration the need to prevent injury.

According to section 16, the recall shall take place through the producer offering, subject to certain conditions:

1. To rectify the defect associated with the risk of injury (rectification);

2. To take back the product and deliver another defect-free product of the same or corresponding type (replacement); or

3. To take back the product and provide compensation (right of withdrawal).

A producer that recalls a product shall simultaneously publish the offer and the terms thereof and provide information regarding the risk of injury. The notification shall be governed by the provisions of section 14, second paragraph regarding warning information.

Businesses are also required to conduct (mandatory) recalls and other corrective measures if needed. Businesses and market surveillance authorities agree on the information channels to inform consumers on a recall. Recalls and other corrective measures are organised by authorities if no responsible business operator can be found. The Consumer Agency can only issue warnings if no responsible business operator can be found. Recalls should generally follow the above-listed sequence of rectification, exchange and return, which is not possible for a market surveillance to carry out.

According to section 17, the terms for recall shall be determined such that the offer can be expected to be accepted by the holders. The terms shall entail that the offer shall be executed within a reasonable time and without material cost or inconvenience to persons availing themselves thereof.

In conjunction with withdrawal, the compensation for the returned product shall correspond to the cost for acquiring a new product of the same or corresponding type. Where special cause exists, a deduction may be made from the rescission compensation in respect of the use of the product enjoyed by the holder.

According to section 18, a producer shall, without delay, cause a product which has been taken back in conjunction with exchange or rescission to be destroyed or otherwise rendered non-injurious, where the product is particularly dangerous.

According to section 19, an undertaking which has performed a service which is dangerous shall, without delay, recall the service from the party on behalf of whom the service has been performed, where other measures are insufficient to prevent injury. The aforesaid shall apply with respect to a party which is in possession of property to which the service is related. Recall shall take place to an extent that is reasonable, taking into consideration the need to prevent injury, and shall entail that the undertaking offers, subject to certain conditions:

1. To personally rectify the defect to which the risk of injury relates; or

2. To provide compensation in order that the defect might be rectified by a third party. The compensation shall also cover the cost of restoring to its original condition the property to which the service related.

The Consumer Agency cooperates with the businesses regarding a specific call through check and influence the messages given to consumers. There are also other areas of cooperation.[484]

In the case of a recall, the information required from the businesses are information activities targeted at consumers. Another requirement is list of other businesses involved in the supply chains. There are also requirements for information concerning the recall effectiveness (i.e. percentage of recalled consumer products actually collected). There is also required information as to the destruction or disposal of products collected. The

[484] Please see recall messages published on the Swedish Consumer Agency's homepage, www.konsumentverket.se, and www.marknadskontroll.se.

process varies depending on the actual case. An effective recall is the sole responsibility of the business operator. The Consumer Agency's role is to certify that needed measures are taken The Consumer Agency often publishes links to business recalls on the homepage of the Consumer Agency and on Facebook. There are no codes of good practice which have been established according to art 5 (1) of the GSPD.

Monitoring of effectiveness of product recalls by market surveillance authorities

The Consumer Agency monitors the effectiveness of all recalls, including voluntary recalls. The business operator recalling the product is asked to provide feedback on the recall result after some time. If the result is inadequate, the Consumer Agency can recommend or demand changes in the recall message and/or extend the advertisement. The Consumer Agency collects information on recall results in terms of the absolute number of products collected. It collects information on the recall results in terms of the percentage of recalled products that are actually collected. It also collects information on awareness of consumers with respect to recalls even though awareness checks are very rare.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Sweden that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

There are no statistics on dangerous products in a Swedish database.

There is a national public database of consumer complaints. The Swedish Consumer Agency investigates the vast majority of applications. If a product has relatively many notifications and the Consumer Agency sees that there is a problem in the market with dangerous goods, the authority can choose to initiate a market control where several companies are examined. The Swedish Consumer Agency also emphasises that other market surveillance authorities have similar systems, but in most cases the goods fall under harmonised legislation.

The Injury Data Base (IDB) at national level has been shut down for some years, but the statistics are still useful. It is used to choose priority areas for surveillance.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Sweden (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Some products are not clearly covered by any regulatory area, and it is unclear which market surveillance authority is responsible. Limited staff resources for market surveillance and a lack of awareness of business with respect to product safety requirements problems also impede surveillance. There are also problems in taking effective action when the economic operator is in another EU/EEA country or outside the EU/EEA, as well as problems in controlling products from non-EU/EEA-countries that reach consumers directly.

Areas to make market surveillance of consumer products in Sweden/the EU more effective

RAPEX could be improved by classifying the notifications. For example, if two products pose serious risks, are manufactured or distributed by a large company or brand or trademark and are sold all over the EU, is one of the more unsafe than the other*?* If the authority has to choose which one of the products it should put its resources on first, how does the authority choose*?* Therefore the follow up should be prioritised.

A product sold by medium-sized and regional companies, for instance the Nordic countries, could be easily found in one search. It is also important that notifications be legally correct, see e.g. the case regarding the dolls mentioned in the response to I.5 above.

The recall process could be improved by a photographic illustration of the hazard. Another way to improve them is to make sure that the most effective channels for communication to the consumers are used.

One possibility of improvement would be to clarify which authority in Sweden is responsible. Currently, if this is unclear, or the authorities have different views about which authority is authorised to supervise or do the market control of a particular product, it is usually the case that no authority wants to do the job. The result is that grey zone products are not subject to supervision or market control.

New types of consumer goods, an increased amount of goods, new ways of shopping and a number of new players have constantly increased the need for control. Control operations are considered to be understaffed. An

opportunity for improvement would be to increase the workforce.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Sweden since 2013

No clear trends, and safety is largely unchanged.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Sweden whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

There are no tools to address new challenges in Sweden and new tools are needed. The Swedish Consumer Agency only has jurisdiction in Sweden and it can be hard to have an impact on counterparts outside the EU who do not want to cooperate. Neither national Swedish law nor the GPSD covers C2C sales. Platform economy online intermediary service providers are not subject to the authority's surveillance since they do not make products available. New technologies often raise integrity issues which are not covered by product safety legislation.

Those relevant institutions are not aware of any developing technological approaches or tools for market surveillance activities.

Views of market surveillance authorities whether approaches in Sweden can be considered best practice implementation of the GPSD, which could be of interest to other countries

The Swedish Consumer Agency has standardisation work that could be considered best practice implementation of the GPSD which could be of interest for other countries. The Swedish Consumer Agency has been involved within several standardisation groups both on at the Swedish and the European level. The Consumer Agency participates in the Swedish and European standardisation work through about thirty different technical committees and expert groups. Participation focuses on common consumer products and products used in consumer services such as clothing for children, trampolines, bouncy castles, play equipment, protective equipment, children's articles, furniture, toys and beauty services.

Standards for different product and service categories are a very important tool for the Consumer Agency's product safety work, not at least for the opportunities to exercise effective supervision in the market. The standards adopted address different categories of goods and services from different perspectives and sometimes aim to meet other interests other than consumer interests in security. By participating in the standardisation work, the authority works to ensure that product safety issues are clarified and adequately taken into account in the standards adopted.

The authority also works to design the content of the standards in a manner necessary for them to be used in the authority's ongoing supervisory work. From the work in 2018, it can be noted in particular that the Consumer Agency's initiative to standardise trampoline parks at the European level has led to the establishment of a technical committee and the standardisation work has begun. Another example is fitness facilities. The Consumer Agency has participated as an ANEC representative at European meetings. Since there are a number of practical injury risks when using gym equipment and training at the gym, the authority works continuously to identify these risks and highlight them in the standardisation work.

The weakest point of the standardisation process under the GPSD is that just very few market surveillance agencies are involved in the development of the standards by the ESOs and are therefore fully competent to read and understand standards. The relevant authorities point out that this is a problem for RAPEX notifications. Quite a few notifications are faulty due to a lack of understanding of the standards requirement.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer	Other (non-harmonised)	**Total** (all consumer

	products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**consumer products under GPSD**	products)
Responsible authority/ies at the national level	*2.5*	*5*	*7.5*
Notes:	*Refers to the full year 2018*		

B. Number of <u>inspections</u> of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**104**	**220**	**324**
Total number of consumer products inspected in cooperation with the customs	10 822	36	10 858
Notes:	*From 1 Jan 2019 to 12 November 2019*		

C. Number of <u>recalls</u> of consumer goods (last available year)

	Harmonised consumer products (e.g. toys, cosmetics etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of voluntary recalls	7	15	22
Total number of mandatory recalls	0	1	1
Notes:	*From 1 Jan 2019 to 12 November 2019*		

D. Key sources

Legislation	Directive 93/119/EC, Official Journal L 340, 31/12/1993 P. 0021 – 0034. Product Safety Act (2004:451), PSA, the Ordinance on product safety (2004:469) along with amendments to several other acts dealing with particular products, e.g. the Work Environment Act (1977:1160, amended through SFS 2016:1160), the Consumer Services Act (1985:716, amended 2018-08-19), the Consumer Purchase Act (1990:932 amended 2018-08-19) etc.
Studies/reports/articles	SWEDAC: National Market Surveillance Plan 2019, Sweden Norin, Anders, Ny produktsäkerhetslag, Ny juridik 2004 nr 3. Svensson, Carl Anders, Den svenska marknadsföringslagstiftningen, Zeteo 2019-04-23
Websites	The *National* Electrical Safety Board, www.elsakerhetsverket.se The Swedish Chemicals Agency, www.kemikalieinspektionen.se The Swedish Customs, www.tullverket.se The Swedish Energy Agency, www.energimyndigheten.se SWEDAC, www.swedac.se
Interviews	Filled-in Questionnaire from National Market Surveillance Authorities Two interviews with the Konsumentverket Supplementary interviews with: Consumer Unit at the Government Offices; The Swedish Energy Agency; Swedish Chemicals Agency; the National Electrical Safety Board; the Medical Products Agency

28. United Kingdom

COUNTRY REPORT UNITED KINGDOM

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

Consumer Protection Act 1987 (1987 chapter 43).[485]

General Product Safety Regulations 2005, SI 2005/1803, Pt 4, reg 46(3) (1 October 2005).[486]

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in the UK

In general terms, there is an obligation on distributors to take measures to keep themselves informed of risks associated with products so as to be in a position to choose to take any appropriate action to avoid such risks, including warnings, or withdrawing or recalling the product. Such action will entail measures to assist in enhancing the traceability of products, as by identifying the producer and the product's batch number, and measures to test samples of the product and generally monitor its use and keep distributors informed of such monitoring. These measures are not detailed specifically in the implementing legislation.

There are also product-specific traceability requirements.

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Yes, the safety obligations can apply to threats relating to new technologies.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

National standards and codes of good practice in force in the sector concerned.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in the UK in case there are consumer product(s) on the market which are found unsafe under the GPSD

UK market surveillance authorities (MSAs) have an extensive range of statutory powers to investigate and deal with contraventions as set out in UK legislation. The enforcement of the product safety provisions are subject to detailed provisions in the implemented provisions (such as the General Product Safety Regulations 2005).

If MSAs find a product to be non-compliant, they will usually first seek voluntary compliance from the business, providing support, guidance and advice to help them become compliant. If a business does not voluntarily bring the product into compliance, MSAs will issue formal notices that require businesses to take appropriate corrective action. Compulsory recalls can also occur.

Where it is considered proportionate to take punitive action, MSAs have a range of sanctions available; for example, this might involve imposing a monetary penalty determined by the MSA, or potentially prosecution in court. Prosecutions can result in financial penalties being imposed by the Courts or, in the most serious cases, imprisonment.

[485] See http://www.legislation.gov.uk/ukpga/1987/43/contents
[486] See http://www.legislation.gov.uk/uksi/2005/1803/contents/made

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

There are criminal offences for breaches of the relevant rules. A person who is in breach of the general safety requirement or obligations on distributors or who contravenes a safety notice may be liable to such to an offence with penalties of up to twelve months' imprisonment or a fine of up to £20 000 (approx. 23 700 EUR) or both. There is also a lesser offence for breach of other obligations which is punishable with three months' imprisonment and a fine of up to £5 000 (approx. 5 900 EUR) or both. A defence of due diligence is also provided for.

Recent case law in the UK with respect to or relevant for the GPSD/the national implementation legislation.

Relevant recent case law:

AG for Northern Ireland v Campbell [2014] NICh 28: The Attorney General and Belfast City Council obtained an injunction restraining certain parties from selling particular psychoactive substances from a shop in Belfast. It was decided that the injunction could be upheld under the General Product Safety Regulations 2005 for those who sold or facilitated the sale of the products as the Attorney General and the local authority had made out a strongly arguable case that the products were dangerous.

R (on the application of C) v Financial Services Authority [2012] EWHC 1417 (Admin), [2012] ACD 97; Official Transcript; QBD (Admin). Within the context of s.14 of the Consumer Protection Act 1987, which gives local enforcement authorities the power to serve suspension notices preventing the supply of goods, any challenge to a suspension notice must generally be by way of appeal, rather than on an application for judicial review.

Havering LBC v Masters [2017] EWHC 848: A due diligence defence is available to a person charged with contravening the general safety requirement, a safety regulation, prohibition order, notice to warn, or a suspension notice upon proving, *inter alia*, that 'he took all reasonable steps and exercised all due diligence to avoid committing the defence'. Certain procedural requirements as to the giving of notice must usually be observed before relying on this defence, which is frequently to be found in consumer protection legislation.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in the UK concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

Feedback is that there needs to be greater dissemination and training regarding product safety issues with respect to economic operators. Too many operators are not aware of their obligations. It was also highlighted that there is a problem of accessibility of standards generally; it was felt that costs were too high, e.g. British Standards Institute (BSI) docs were just too costly.

It was also considered that there were some difficulties in ensuring traceability with respect to particular specifications or conformity assessment processes. The current system for product safety relies on the conformity assessment being carried out at the design and production phases for all products. This is documented and should be capable of verification by market surveillance officials. The problem is that often documentation is not made available, or if it is, it is not traceable to the product in question in a way which provides sufficient confidence that the product is in conformity. Specific identifiers for products and manufacturing units are often absent, leading to a lack of confidence that the documentation actually provides the necessary evidence. This has resulted in risk-modelling being significantly more uncertain, even if basic traceability information accompanies the product.

There are also some emerging safety issues with respect to particular categories of consumer products. It was considered that some electrical appliances and equipment under the Low Voltage Directive were particularly concerning, such as drones and hoverboards.

Possible improvements to make the implementation of the GPSD in the UK more effective

In terms of traceability, it was pointed out that specific identifiers for products and manufacturing units are often absent, leading to a lack of confidence that the documentation actually provides the necessary evidence. Modes of production often add further confusion when what appears to be the same product is made to different specifications at different times or even by different producers manufacturing a cosmetically similar product. This makes it very difficult to identify all conforming or non-conforming products of a particular type. It was suggested that if all products were allocated unique identifiers which are referenced in technical documentation then this could be avoided. If production units were allocated some unique identifier, then it would be easier to identify

other products under suspicion or being definitely non-compliant if all other variables appear to be consistent.

It was also felt that the safety level was very dependent upon the origin of the economic operator. The key issue is where the economic operator is based. It was suggested that there should be a requirement to give details on the relevant seller's website as to where the operator is based and to which standards the product conforms in a way which is accessible to the consumer. Information needs to be accessible on a website so that consumers can have access to the information prior to purchase.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in the UK.

Market surveillance in the UK is delivered by a range of both national and local authorities. The Department for Business, Energy and Industrial Strategy (BEIS) has responsibility for the subject matter of most EU Directives and Regulations (regarding the single market for goods). Responsibility for coordinating market surveillance activity in the UK is held by the Office for Product Safety and Standards (OPSS), which sits within the BEIS. The OPSS was established in January 2018 to oversee the regulatory system for product safety and standards, providing a national regulator for product safety for the first time. The OPSS provides additional national capacity for product safety, oversees weights and measures, and acts as an MSA for certain areas of product regulation.

Responsibility for the enforcement of product safety is principally a matter for local government in the UK. Market surveillance is delivered by a range of other bodies, including the Health and Safety Executive (HSE), HSE Northern Ireland (HSENI), the Medicines and Healthcare Regulatory Agency (MHRA), Ofcom, the Marine and Coastguards Agency (MCA), the Driver and Vehicles Standards Agency (DVSA), and the Vehicle Certifications Agency (VCA).

Plans/programmes in place which define priorities for market surveillance of consumer products

There are national surveillance plans/programmes covering consumer product sectors. The UK operates an intelligence-led approach for product safety. Information is entered into intelligence databases and profiles are generated, which enables risk-based targeting of products, economic operators and supply chains by agencies working at ports and borders as well as by inland market surveillance authorities, both at local and national levels.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in the UK with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Few details provided by interviewees. Surveillance is undertaken of products sold online (see below).

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance of products sold online is conducted regularly, but few further details were given by the interviewees. An intelligence-based approach to product safety is being developed with enables risk-based targeting of products, economic operators and supply chains.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in the UK (except customs) with respect to product safety

In terms of cooperation with other authorities with respect to product safety, there is :-

- Common use of a national market surveillance IT system;
- Common use of RAPEX;
- Common use of ICSMS;
- Inclusion of other authorities in preparing the national market surveillance plan/programme;
- Joint processes for dealing with dangerous products;

- Joint training sessions;
- Regular exchange of information;
- Regular meetings;
- Informal cooperation.

Cooperation with customs authorities in the UK with respect to product safety

The cooperation is considered to function well. In the UK, Her Majesty's Revenue and Customs (HMRC) and the Border Force are not designated as MSAs, but they have a significant role to play in market surveillance, given the data and documentation they hold relating to imports from non-EU/EEA-countries. The information contained within customs declarations and the supporting documents can be profiled to target products and economic operators that are likely to present the greatest risk to users. Risk-based criteria using intelligence are used. Cooperation between HMRC and the Border Force and UK MSAs is an important element of the risk-based and targeted approach to border controls. Co-operation involves sharing intelligence and knowledge and the provision of access to inspection facilities for non-food products. The UK has a specific cooperation system via a centrally resourced Ports Project providing intelligence and coordination functions.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Official publications state that the UK highly values international cooperation with both Member States of the European Union and other countries (UK National Market Surveillance Programme: January 2019 – January 2020). The UK has been an active participant in EU level discussions on market surveillance, working with Member States to develop common approaches and share best practices.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

There is clear guidance on the process for submitting a RAPEX notification, and the criteria that this should meet, on the relevant Government website. This includes a RAPEX notification form template for market surveillance authorities to complete with all required information. The RAPEX Unit within the OPSS has a mailbox which is identified on the Government website for queries from authorities. The RAPEX unit quality assures all notifications and keeps an open dialogue with the MSAs to the point of EU validation to ensure queries are answered and notifications are suitable. There can sometimes be risk assessment difficulties – due to the submission by local trading standards in non-RAPEX format. Technical issues can also arise with cases sometimes getting stuck; an email to the European Commission may be necessary to resolve.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

In the UK, high priority is said to be given to business communication and engagement activities by all market surveillance authorities. A Regulators' Code came into effect on 6 April 2014, which provides a principles-based framework for how regulators should engage with those they regulate. The Code promotes the development of an open and constructive relationship between regulators and those they regulate, including the transparency of policies, accessibility of information and guidance, and provisions which require regulatory activities to be based on risk.

Businesses also can form a legally recognised partnership with a local authority, which then provides robust and reliable advice to the business on matters of regulatory compliance. Known as 'Primary Authority', this is a means for businesses to receive assured and tailored advice on meeting environmental health, trading standards or fire safety regulations through a single point of contact. There are approximately 90 000 businesses that currently benefit from Primary Authority and these range from single site independents to large multi-site corporations.[487]

The BEIS has also indicated that ensuring that regulators and policy departments better understand the views of the business community is a key goal. It has thus created a Business Reference Panel which is dedicated to

[487] See www.gov.uk/government/publiscations/primary-authority-overview

regulatory issues and is comprised of experts from over 150 business organisations, trade associations and professional bodies. The panel helps to ensure that the voices of business are heard by giving the opportunity to provide feedback on Government ideas and proposed work programmes, as well as to air priorities and concerns. The panel meets four times a year, and 'expert panels' are established intermittently to focus in detail on specific regulatory issues.

The Citizens Advice Bureau also provides a service for consumer complaints about aspects relating to consumer protection. Product safety complaints are logged through this service as a matter of course, and it is then up to the relevant market surveillance authority to identify and act on these.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

See previous answer.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in the UK (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

- Businesses are asked to conduct voluntary recalls and other corrective measures, if needed;
- Businesses are asked to conduct mandatory recalls and other corrective measures, if needed;
- Businesses and market surveillance authority agree on the information channels to inform consumers of a recall;
- Businesses are required to use all their available customer information for recalls and other corrective measures.

Monitoring of effectiveness of product recalls by market surveillance authorities

The data collected varies on a case by case basis depending on the nature of the recall and previous history of the business.

6. Availability of statistics relevant for market surveillance

Availability of statistics in the UK that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

No information was given by the interviewees.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in the UK (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

There are clearly concerns about the impact of the significant reduction in public sector resources for product safety related issues, particularly at a local level. It was indicated that there are simply no longer enough trading standards officers to actually do the market surveillance e.g. in sensitive product areas such as fireworks or toys. It was also indicated that there were insufficient officers on the ground with the necessary knowledge of product safety and risk assessment.

The lack of resources has also had an impact on recalls as well, with trading standards simply not having the necessary funding. It was considered that there was also a fragmentation and inconsistency of approach, as well as a degree of risk aversion in recommending or taking corrective actions by managers of these services, most of whom have a very limited knowledge of product safety and are highly reluctant to apply the precautionary principle correctly. This is compounded by organisational issues. Issues were also noted relating to competency at a local level, though this may also have been impacted by a lack of resources.

It was also considered that the highly decentralised organisation of market surveillance activities could lead to inconsistencies of approach and/or prioritisation. The establishment of the Office for Product Safety and Standards has mitigated this to a degree but these issues remain an ongoing challenge for the effective enforcement of product safety law in the UK. The OPSS complements the trading standards provision but does not replace it,

offering specific funding and assistance for routine market surveillance and also complex or high profile cases.

Another theme was that of e-commerce, which was considered to create particular challenges, resulting in products being delivered on an individual basis and escaping customs scrutiny. The difficulties of determining country of origin on the various websites and online platforms also created a lack of transparency and degree of confusion on the part of consumers. It was considered that there should be compulsory labelling of location or origin of the economic operator.

Areas to make market surveillance of consumer products in the UK/the EU more effective

See previous answer. The key issue seems to be the allocation of sufficient resources to product safety. The need for resources and upskilling of officers was pointed out. Better organisation at a national level is also required.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in the UK since 2013

The general feeling seems relatively positive but there are also serious concerns about the impact of the significant reduction in resources, particularly at a local level. It was indicated that there are simply no longer enough trading standards officers to actually do the market surveillance work e.g. in sensitive products areas such as fireworks or toys. It was also considered that the legislation had not been used as effectively as it could have been due to organisational challenges, lack of skills and the significant reduction in resources.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in the UK whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

It was recognised that new technology poses particular difficulties.

E-commerce was considered to create particular challenges, resulting in products being delivered on an individual basis and escaping customs scrutiny. The difficulties of determining country of origin on the various websites and online platforms also created a lack of transparency and degree of confusion on the part of consumers.

Views of market surveillance authorities whether approaches in the UK can be considered best practice implementation of the GPSD, which could be of interest to other countries

It was noted that in the UK, economic operators see trading standards as being helpful, and that in other countries, the approach was on the contrary more adversarial. Businesses can form a legally recognised partnership with a local authority via the "Primary Authority" scheme which has worked well.

The intelligence-based approach to product safety is also considered to be effective. Information is entered into intelligence databases and profiles are generated, which enables risk-based targeting of products, economic operators and supply chains by agencies working at ports and borders as well as inland market surveillance authorities, both at the local and national levels.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

N.a.

B. Number of inspections of consumer products (last available year)

N.a.

C. Number of recalls of consumer goods (last available year)

N.a.

D. Key sources	
Legislation	**Legislation** Consumer Protection Act 1987 (1987 chapter 43), http://www.legislation.gov.uk/ukpga/1987/43/contents General Product Safety Regulations 2005, SI 2005/1803, Pt 4, reg 46(3) (1 October 2005), http://www.legislation.gov.uk/uksi/2005/1803/contents/made Health and Safety at Work etc Act 1974, http://www.legislation.gov.uk/ukpga/1974/37/contents Product Liability Directive (85/374/EEC), https://eur-lex.europa.eu/legal-content/En.a.LL/?uri=CELEX:31985L0374 **Subordinate Legislation** Furniture and Furnishings (Fire) (Safety) Regulations 1988, SI 1988/1324. Babies' Dummies (Safety) (Revocation) Regulations 1989, SI 1989/141. Food Imitations (Safety) Regulations 1989, SI 1989/1291. Furniture and Furnishings (Fire) (Safety) (Amendment) Regulations 1989, SI 1989/2358. Tobacco Products Labelling (Safety) Regulations 1991, SI 1991/1530. Oil Lamps (Safety) (Revocation) Regulations 1992, SI 1992/23. Cigarettes (Maximum Tar Yield) (Safety) Regulations 1992, SI 1992/2783. Furniture and Furnishings (Fire) (Safety) (Amendment) Regulations 1993, SI 1993/207. Tobacco Products Labelling (Safety) Amendment Regulations 1993, SI 1993/1947. Plugs and Sockets etc (Safety) Regulations 1994, SI 1994/1768. Motor Vehicle Tyres (Safety) Regulations 1994, SI 1994/3117. Fireworks (Safety) (Revocation) Regulations 1995, SI 1995/415. N-nitrosamines and N-nitrosatable Substances in Elastomer or Rubber Teats and Dummies (Safety) Regulations 1995, SI 1995/1012. Dangerous Substances and Preparations (Safety) (Consolidation) (Amendment) Regulations 1996, SI 1996/2635. Motor Vehicle Tyres (Safety) (Amendment) Regulations 1996, SI 1996/3227. Motor Vehicle Tyres (Safety) (Amendment) Regulations 1997, SI 1997/815. Cigarette Lighter Refill (Safety) Regulations 1999, SI 1999/1844. Road Vehicles (Brake Linings Safety) Regulations 1999, SI 1999/2978. Dangerous Substances and Preparations (Safety) (Consolidation) and Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2000, SI 2000/2897. Packaging (Essential Requirements) Regulations 2015, SI 2015/1640. Medical Devices Regulations 2002, SI 2002/618. Motor Vehicle Tyres (Safety) (Amendment) Regulations 2003, SI 2003/1316. Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003, SI 2003/1680. Medical Devices (Amendment) Regulations 2003, SI 2003/1697. Motor Vehicle Tyres (Safety) (Amendment) (No 2) Regulations 2003, SI 2003/2762. Road Vehicles (Brake Linings Safety) (Amendment) Regulations 2003, SI 2003/3314. Fireworks Regulations 2004, SI 2004/1836 (made under sub-s (3)). Medical Devices (Amendment) Regulations 2007, SI 2007/400. Medical Devices (Amendment) Regulations 2008, SI 2008/2936.

	Aerosol Dispensers Regulations 2009, SI 2009/2824. Pedal Bicycles (Safety) Regulations 2010, SI 2010/198. Furniture and Furnishings (Fire) (Safety) (Amendment) Regulations 2010, SI 2010/2205. Toys (Safety) Regulations 2011, SI 2011/1881. Medical Devices (Amendment) Regulations 2012, SI 2012/1426. Product Safety (Revocation) Regulations 2012, SI 2012/1815. Product Safety Amendment and Revocation Regulations 2012, SI 2012/2963. Medical Devices (Amendment) Regulations 2013, SI 2013/2327. Aerosol Dispensers (Amendment) Regulations 2014, SI 2014/1130. Aerosol Dispensers (Amendment) Regulations 2018, SI 2018/29. **Scotland** Fireworks (Scotland) Regulations 2004, SSI 2004/393 (made under sub-s (3)).
Studies/reports/articles	Cartwright P. (2018), The General Product Safety Regulations 2005: Implementing Directive 2001/95-EC in the UK in Howells, G., Nordhausen, A. editor, Parry, D. editor, Twigg-Flessner, C. editor. The Yearbook of Consumer Law 2007 (1st ed.). Cartwright, P. (2006), Total recall? The future of consumer product safety regulation. Lloyd's Maritime and Commercial Law Quarterly, (3), 390-403. Cartwright, P. (2001), Consumer Protection and the Criminal Law: Law, Theory, and Policy in the UK. Cambridge: Cambridge University Press. doi:10.1017/CBO9780511494758 Cartwright, P. (2000), The Regulation of Product Safety', in G. Howells (ed.), The Law of Product Liability, London. Cotter, B. (1992), "Due diligence: the disappearing defence" New law journal (0306-6479), 142, p. 170. Fairgrieve, D., Howells, G. (2006), General Product Safety - a Revolution Through Reform? The Modern Law Review, 69(1), 59-69. Harvey, B., Parry, Deborah L. (2000), The law of consumer protection and fair trading. (6th ed. / Brian W. Harvey, Deborah L. Parry ed.) London: Butterworths. Hodges, C. (2005-05-19), European Regulation of Consumer Product Safety: Oxford University Press. Hodges, C. (2001), Safety of Consumer Products, European Business Law Review, 12(11/12), 274-280. Howells, G. (2018), Consumer product safety / Geraint Howells, (Routledge revivals). Howells G. (2014) Product Safety—A Model for EU Legislation and Reform. In: Purnhagen K., Rott P. (eds) Varieties of European Economic Law and Regulation. Studies in European Economic Law and Regulation, vol 3. Springer, Cham Howells, G. G., & Birds, J. (2007), The law of product liability (2nd ed.), London: LexisNexis Butterworths. Miller, C., Mildred, M., & Chong, A. Swee L., (1979), Miller: Product Liability & Safety Encyclopaedia / by C J Miller, Mark Mildred, A Chong, C G J Morse. Opinion of the Economic and Social Committee on 'General Product Safety', *Official Journal C 051 , 23/02/2000 P. 0067 – 0073,* by rapporteur W. Alma, Retrieved on 8 Oct. 2019, from https://eur-lex.europa.eu/legal-content/En.a.LL/?uri=CELEX%3A51999IE1131 Parry, D. L. (1995), "Judicial approaches to due diligence", Criminal law review, p. 695. Schaldemose Report EU Parliament Report on the Revision of the General Product Safety Directive and Market Surveillance, 24/2/2011, A/-0033/2011.

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Interviews	Office for Product Safety, Department for Business, Energy and Industrial Strategy (BEIS), UK Chartered Trading Standards Institute (Professional Body); Office for Product Safety Product Safety Centre

29. Iceland

COUNTRY REPORT ICELAND

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The legal basis for market surveillance in Iceland is the Act No. °134/1995 on Product Safety and Official Market Control, as amended by Acts No. 82/1998, 76/2002,68/2004, 62/2005, 108/2006 and 98/2009 Act on Product Safety and Official Market Control.

In addition, there are several ministerial decrees that lay down further provisions regarding various general issues which may have some relevance in certain cases.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Iceland

There is a general requirement to indicate the name and contact details of the producer on the product or its packaging (Art 4 (1) of the above mentioned law about the Product Safety and Official Market Control) and a general requirement to indicate the product reference or, where applicable, the batch of products to which it belongs on the product or its packaging. In Article 10 (3) of the Act on Product Safety and Official Market Control No 134/1995 it is stipulated that in case there is not special requirements in relevant lex specialis legislation the Minister can lay down further rules by ministerial decree regarding such further requirements, cf. "Markings, guidances and information on the use and disposal of a product, warnings as to potential risks when using the product and any other indication or information to the consumer." Currently there is no Ministerial decree that does stipulate that traceability information shall be indicated on the package as stipulated in Art 5(1) 4th indent (a). There is however this legal base in the national transposition that could be used to make further requirements in the Icelandic transposition. Furthermore in Article 20(1) of the Act No 134/1995, there is also an article that makes enforcement possible if such further rules would be adopted by Ministerial decree, cf. "A surveillance authority may by means of substantiation withdraw, remove from the market or prohibit the sale or delivery of a product if it does not meet formal conditions, such as concerning markings, guidances, certificates, declarations concerning conformity or testing and inspection reports".

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

Based on the national implementation legislation of the GPSD, the Consumer Agency of Iceland decides where a serious risk relates to a cybersecurity issue (risk of hacking for example). In this case, it would be at the discretion of the Agency to interpret the national implementation legislation of the GPSD accordingly (i.e. on a case-by-case basis). The only exceptions noted by the Consumer Agency are emerging threats related to poor security of consumer products that may expose a network to potential attacks (e.g. routers that can be easily infected with malware), which are not covered.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

In Iceland, the following benchmarks are used: other European standards (not referenced in the EU Official Journal); national standards (not based on European standards); international standards and/or standards from non-EU/EEA countries; Commission recommendations setting guidelines on product safety assessment; codes of good practice in force in the sector concerned; state of the art and technology; and reasonable consumer

expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Iceland in case there are consumer product(s) on the market which are found unsafe under the GPSD

Administrative measures available in Iceland include: requiring businesses to provide relevant information on the product(s); requiring businesses to provide relevant information on the supply chain and the distribution of the product(s); carrying out unannounced on-site inspections and physical checks of products; acquiring product samples; requiring from economic operators recalls of products and other corrective measures (such as restrictions for placing products on the market or bringing products into compliance, stopping products being placed on the market, withdrawal of products, etc); reclaiming from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s) (e.g. for carrying out testing, storage, etc).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Market surveillance authorities in Iceland can take any measures as necessary to prohibit or restrict the products being made available on the market, such as laying down an order to withdraw or recall products from the market, cf. Art 21 of Regulation (EC) 765/2008. In addition to the general restrictive measures regarding products being placed on the market, infringements of the Act No 134/1995, as amended, are punishable with fines or imprisonment for up to 2 years if an infringement is not punishable by more severe penalties according to another Act, cf. the provision of Article 41 of the Regulation (EC) 765/2008. The Consumer Agency and other market surveillance authorities (MSAs) in Iceland, however, seek voluntary compliance by economic operators if a product is found to be unsafe or not in compliance with the legislation.

Recent case law in Iceland with respect to or relevant for the GPSD/the national implementation legislation.

No relevant case law was identified in Iceland.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Iceland concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

The Consumer Agency encountered some practical problems with respect to product information, which is often lacking on the products.

With respect to the definition of safety in line with Art 3(3) GPSD, the Agency suggests that the definition could include the cybersecurity aspects more clearly, as they have already identified emerging safety issues with particular categories of products relating to the Internet of Things (IoT) and embedded software in products (child telephones, smart watches, refrigerators etc.).

Possible improvements to make the implementation of the GPSD in Iceland more effective

The Consumer Agency reported that there is a need for clarification as to what triggers the safety net function of the GPSD and which authority would be responsible in such a case. Further clarification is also needed as to the role of the GPSD as safety net for harmonised products.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Iceland.

The Consumer Agency, according to Act No 134/1995, is the competent authority for market surveillance in accordance with the general product legislation, cf. the General Product Safety Directive (GPSD) 2001/95/EC. Furthermore, the Agency is the competent authority for market surveillance according to various sector specific EU Directives as transposed into national legislation. The same Act stipulates that the Consumer Agency is the RAPEX contact point of Iceland. The Consumer Agency is also the national contact point for the ICSMS database (Article 14 of Act No 134/1995). According to the same Act, the Consumer Agency is responsible for general coordination of official market controls in the field of product safety in cooperation with other market surveillance authorities in

Iceland.

Market surveillance authorities in Iceland are all organised as central structures (national authorities) that are responsible for market surveillance at national level and in various sector specific fields of the EU legislation with horizontal responsibilities, and they shall ensure strategic and effective market surveillance and take legal measures if necessary (Article 15).

In Iceland, there are currently 9 market surveillance authorities responsible for market surveillance in the area of product safety and compliance, namely: the Consumer Agency, the Icelandic Medicines Agency, the Administration of Occupational Safety and Health in Iceland, Iceland Construction Authority, the Post and Telecom administration in Iceland, the Icelandic Food and Veterinary Authority, the Icelandic Transport Authority, the Environment Agency of Iceland and the Icelandic Radiation Safety Authority.

In general, the MSAs in Iceland are all, with one exception, based in the capital of Reykjavík. In some cases, these national authorities may have some inspectors located in different local towns in Iceland, although their activities are in the capital of Reykjavík.[a)]

Plans/programmes in place which define priorities for market surveillance of consumer products

The Consumer Agency has the responsibility to establish a Cooperation Committee in order to ensure effective cooperation with other market surveillance authorities. The Cooperation Committee shall meet and discuss market surveillance plans of all MSAs as well as other relevant organisational issues. At present, the Agency has only convened one Committee with representatives of all other MSAs and Customs Iceland. At these meetings, the annual National Market Surveillance Programme (NMSP) is discussed as well as other issues regarding development of EU legislation in the field of product safety and other issues that concern national legislation implementing EU product legislation (Article 16 of Act No 134/1995).

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Iceland with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

The market surveillance activities also cover products containing new technologies e.g. the case of children's safety regarding smart watches, i.e. watches intended for children that include a telephone, GPS and software.[488] The Consumer Agency initiated a recall activity of this product in coordination with other responsible market surveillance authorities in Iceland (namely the post-and telecommuniations authority and the personal data protection authority). The investigation of the product led to a RAPEX notification and recall of the product due to lack of security measures.

More recently increased activity is also regarding on-line sales of various products cross border but also at national platforms that either act as middle men for importers to Iceland and/or are importing their own goods to sell at these platforms.

The Consumer Agency also conducts market surveillance regarding C2C products. These are mostly related to handcrafted products offered on Facebook etc., for example childcare articles, where safety standards are simply lacking (e.g. small removable parts, etc).

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Market surveillance activities on products sold online are conducted quite frequently (once every week) from sellers established in Iceland and in the EU/EEA as well as in non EU/EEA countries, in combination with website checks conducted in the CPC (Consumer Protection Cooperation) framework.

The Consumer Agency, as well as other MSAs, give priority to notifications received from EEA Member States as well as notifications received directly from consumers and other market participants.

Online market surveillance activities in Iceland are increasing. The percentage of activities that focus on products sold online is between 11 to 20%. The authority monitors retailer websites, online marketplaces and social networks and sends inquiries to the sellers or order the product under the real name of the authority where

[488] RAPEX reference number A12/0157/19.

relevant. The Consumer Agency is currently not allowed to purchase products "under cover" (i.e. conduct real mystery shopping), which is also not feasible due to financial constraints and staff resources as well as a lack of trained personnel.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Iceland (except customs) with respect to product safety

As mentioned above, the Consumer Agency has the obligation to ensure general organisation of official market control and market surveillance of products in cooperation with other sector specific market surveillance authorities in order to ensure effectiveness and coordination of market surveillance activities (Article 14 of Act No 134/1995). In practice the cooperation could be more intensive but other MSAs also struggle with resources and continuous training of staff which may also explain that the cooperation is not as much as would be desirable and possible on current legal basis in the Act No 134/1995, see for example Chapter III of the Act No 134/1995.

Cooperation with customs authorities in Iceland with respect to product safety-

The cooperation with the customs is ensured through their involvement in preparing the national market surveillance programme and by having regular and informal exchanges of information and meetings almost on a monthly basis.

The market surveillance authorities are dependent on good cooperation with customs in order to prevent dangerous products, or products not in conformity, from entering the market. In addition to the provisions of IS Regulation No 566/2013, the Icelandic Customs Act No 88/2005 does contain provisions found in Article 60 of the Act that enables the customs of Iceland to stop the import of goods and consult relevant and competent authorities if the import of these goods is in breach of national legislation and/or administrative provisions that apply and are relevant to goods. The officers of the customs authority are however not experts and do not have any specific knowledge of the product fields covered by various Icelandic MSAs, but these officers can play an important role for detection of unsafe or non-compliant products that are imported to Iceland. The Icelandic customs authorities therefore contact national competent authorities in various sector specific fields when necessary.

In Iceland, the flow of information between market surveillance authorities and customs is very good and it is rather easy to get in contact with one another. The majority of the products that come to Iceland are from Europe and the odds that they meet the requirements are quite high. The officers at customs are considered to be a valuable source of information on imported products. The information contained in customs declarations is normally quite detailed and provides information for the authority with respect to the import of goods. It should be noted that Iceland has no access to the European Union Common Customs Risk Management System (CRMS) that provides a mechanism to exchange risk-related information directly between Member States, which is considered to be a major disadvantage. Currently the customs authority uses the ICSMS.

In Iceland today there are, according the NMSP, mainly two different methods when it comes to cooperation with customs. Firstly, in order to monitor imports upon the request of market surveillance authorities, the customs authority can filter certain customs codes and send this information to the requesting market surveillance authority. Upon receipt of this information, the market surveillance authority in question can more easily get in contact with the importer and receive documentation immediately and before clearance by customs, in order to verify the conformity of the product with the legislative requirements. Secondly, the customs authority can also on their own initiative send information to the market surveillance authority with names of importers of goods in certain custom codes that also can be very helpful for investigations or special actions that the MSA carries out at various points in time.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

The Consumer Agency has participated in various joint actions in order to enhance cooperation with other MSAs and gain valuable experience and knowledge. Information provided by the Commission and other MSAs are also of great value for market surveillance in Iceland. The Consumer Agency also cooperates frequently (once a week) with relevant authorities located in the EU/EEA through one or more of the following means: RAPEX; ICSMS; the Wiki confluence platform; mutual assistance requests made/received outside of RAPEX; formal cooperation agreements with other Member States outside EU mechanisms/structures e.g. with the Nordic countries (Denmark, Finland, Sweden and Norway); regular exchange of information (outside EU fora), informal cooperation, e.g. with neighbouring Member States.

Cooperation with China was established in 2015 with the signature of a Memorandum of Understanding (MoU) with the Ministry of the Interior and the General Administration for quality, supervision, inspection and quarantine of the People's Republic of China (AQSIQ) on product safety issues. However, due to the changes in institutional structure in China, the Consumer Agency is no longer able to cooperate directly with the relevant authority in China. The Agency currently sends its requests/inquiries to its Chinese counterparts through the Chinese Embassy in Iceland if needed (occurring less than once a year).

At high level meeting of officials and minister of China and Iceland the wish to update and renew the current MoU on product safety cooperation was confirmed. An update would replace the MoU that was done by AQSIQ and SAMR (State Administration for Marketing and Regulations in China) would be the new counterpart in the renewed MoU. This is due to the fact that AQSIQ does not exist anymore and its responsibilities in the field of product safety are now with the new State Administration for Marketing (SAMR).

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

According to Article 14 of Act No 134/1995 on General Product Safety, the Consumer Agency is the national RAPEX Contact Point. In 2012, the GRAS-RAPEX platform was introduced to all other national market surveillance authorities and their direct access to be able to create notifications in the system was ensured. The Consumer Agency is the national "validator" of notifications submitted by other MSAs in Iceland. During the validation process, the national RAPEX Contact Point of Iceland notifies the EFTA Surveillance Authority (ESA) that a validation and reactions are pending. After consultation between the Consumer Agency and ESA, the Consumer Agency validates the notifications that have been pending. The average duration between detection and notification takes more than two weeks. The authority reports having encountered difficulties with risk assessment; lack of sufficient information to trace notified products; and technical issues with the RAPEX system itself (mostly with respect to the previous version of the system, as operation has improved since then).

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

The Consumer Agency provides information to the economic operators about their general responsibilities in cases where they have distributed or placed dangerous or non-conforming products on the market. The Agency has for example promoted and introduced the CAG (Corrective Actions Guide) prepared in the frame of joint actions funded by the Commission and the Business Application website of the EU, as well as the Blue Guide and other important information materials that are of relevance for economic operators. The Agency also places information on the authority's Facebook website and provides press releases to the media. Other tools used include: a portal with RAPEX notifications translated into national language(s), a link to the EU RAPEX website on its official website, information campaigns in traditional media (newspapers, TV, radio), and other means (such as printing of leaflets in Icelandic).

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

The Consumer Agency and other authorities (where relevant) provide information on their own websites to consumers, the media, and economic operators on product safety issues and the EU regulatory framework relating to the safety of goods being placed on the single EEA/EU market, as well as information on conformity assessment procedures.

If a product is found on RAPEX and the Consumer Agency thinks that it is likely that the product exists in Iceland, e.g. through internet shopping, shopping while travelling, etc., the Agency publishes a notification on its Facebook site to inform consumers.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Iceland (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

In cases where there is a need for corrective measures, the responsible MSA sends the distributor or the importer a letter or an e-mail about the product with photos. In some cases it can be necessary to follow up on the e-mail with a phone call if there are emergency measures. Most of the operators take voluntary actions according to the

notification, and in some cases some of them have even already taken actions. The Consumer Agency then publishes information with respect to these products on its website and sends a reaction to the RAPEX system. If the operator does not take voluntary actions, the Consumer Agency will take legal action whenever necessary.

In case that the Consumer Agency finds a product on the market that is dangerous has not been notified to RAPEX it is the duty of the Agency to send a notification to the RAPEX system in same way as EU and EEA Member States do.

Monitoring of effectiveness of product recalls by market surveillance authorities

There is currently no system in place to monitor the effectiveness of corrective measures such as recalls. However, based on its observations the Agency considers product recalls as being rather not effective.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Iceland that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

There is a national market surveillance system that also registers relevant complaints made by consumers and a general national public database of consumer complaints.

There is no system to keep statistics on dangerous products nor on related injuries.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Iceland (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Problems affecting market surveillance mainly relate to the lack of resources (financial and staff) and also to the fact that market surveillance issues are not a high priority at the policy level. Practical problems related most importantly to the ineffective control of product safety at the borders. In addition, problems relate to the lack of awareness of businesses (and/or lack of interest) with respect to product safety requirements and the lack of awareness of consumers with respect to product safety in general.

Areas to make market surveillance of consumer products in Iceland/the EU more effective

A more active role of economic operators and a greater interest at the political level for product safety would be required.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Iceland since 2013

The general trend is positive with respect to importers in that they sell better products on the market and the CE marking is better respected. Information availability in general has also increased through the Internet. Therefore, generally consumers are now much better informed about the safety of products.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Iceland whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

To be able to address the challenges (new and existing), there is a need for improved legislation, and an increase in resources and training of personnel. According to the Agency, the current GPSD only needs limited modification and it considers it to be a clear advantage to have this instrument in the form of a directive and not regulation and this should be continued if possible. The need for improvement would for example be to review the definition of a "safe" product in order to include embedded software (and updates). Also, it should be mandatory for on-line sales to always provide the same information regarding the product at an on-line point of sales (the platform and webpage) which is mandatory in brick and mortar shops when the consumer can see the packaging and

information provided according to legal obligations, e.g. CE-mark, name of producer, suitable age if applicable etc.

Views of market surveillance authorities whether approaches in Iceland can be considered best practice implementation of the GPSD, which could be of interest to other countries

The Consumer Agency as a single liaison office ensures coordination between the various MSAs within the country since the present Act No. °134/1995 on Product Safety and Official Market Control was adopted. This is considered to function well, and could therefore be considered a good practice.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total Consumer Agency	***n.a.***	***n.a.***	***4***

Data for Consumer Agency 2019.

B. Number of inspections of consumer products (last available year)

n.a.

C. Number of recalls of consumer goods (last available year)

n.a.

D. Key sources

Legislation	Act No. °134/1995 on Product Safety and Official Market Control, as amended by Acts No. 82/1998, 76/2002,68/2004, 62/2005, 108/2006 and 98/2009 (https://www.neytendastofa.is/lisalib/getfile.aspx?itemid=2159) ACT on the Consumer Agency and Consumer Spokesman with later amendments (https://www.neytendastofa.is/lisalib/getfile.aspx?itemid=1402)
Studies/reports/articles	National Market Surveillance Programme 2019, Iceland, Reykjavík, February 2019
Websites	https://www.neytendastofa.is https://www.neytendastofa.is/english/safety-division/
Interviews	Consumer Agency or Neytendastofa

30. Liechtenstein

COUNTRY REPORT LIECHTENSTEIN

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The legal basis for market surveillance in Liechtenstein is the law about the marketability of goods, which also transposes the GPSD (LR 947.1).[489]

In addition, there is a regulation per sector / product defining how competences are regulated. Examples include: the Ordinance on the Marketing of Toys in European Economic Area (LR 947.102.231)[490] and the Regulation on the Marketing of Electrical Equipment throughout the European Economic Area (LR 947.102.101).[491]

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Liechtenstein

There is a general requirement to indicate the name and contact details of the producer on the product or its packaging (Art 4c, Abs 3c of the above mentioned law about the marketability of goods, LR 947.1).

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

The Office of Economic Affairs of the Principality of Liechtenstein (see Annex, hereafter referred to as 'Office of Economic Affairs) did not have an opinion whether emerging threats related to new technologies (e.g. cyber security/software related threats) are covered under the national implementation legislation.

So far this has not been an issue in practice. If a need would arise it would be within the discretion of the Office of Economic Affairs to interpret the national implementation legislation of the GPSD accordingly, which it considers possible. However, any such interpretation could in this case be subject to judicial review.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

The following benchmarks are used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist: Other European standards (not referenced in the EU Official Journal); National standards (not based on European standards); International standards and/or standards from non-EU/EEA countries; Commission recommendations setting guidelines on product safety assessment; Codes of good practice in force in the sector concerned; State of the art and technology; Reasonable consumer expectations concerning safety.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Liechtenstein in case there are consumer product(s) on the market which are found unsafe under the GPSD

[489] *LR 947.1 – Gesetz vom 22. März 1995 über die Verkehrsfähigkeit von Waren*, LGBl. 1995 Nr. 94, in der Fassung vom 01.01.2019.
[490] *LR 947.102.231 - Verordnung vom 19. Februar 1996 über den Verkehr mit Spielzeugen im Europäischen Wirtschaftsraum*, LGBl. 1996 Nr. 35.
[491] *LR 947.102.101 - Verordnung vom 9. Mai 1995 über den Verkehr mit elektrischen Betriebsmitteln im Europäischen Wirtschaftsraum*, LGBl. 1995 Nr. 143.

Administrative measures available include: Requiring businesses to provide relevant information on the product(s); Requiring businesses to provide relevant information on the supply chain and the distribution of the product(s); Carrying out unannounced on-site inspections and physical checks of products; Acquiring product samples, including under a cover identity (mystery shopping); Requiring from economic operators recalls of products and other corrective measures (such as restrictions for placing products on the market or bringing products into compliance, stopping products being placed on the market, withdrawal of products etc); Reclaiming from the relevant economic operator the costs of administrative activities with respect to the unsafe product(s) (e.g. for carrying out testing, storage etc).

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

Penalties are provided in Art. 9 to 14 of the national implementation legislation of the GPSD (the law about the marketability of goods, LR 947.1), and include financial penalties and the seizure of products.

Recent case law in Liechtenstein with respect to or relevant for the GPSD/the national implementation legislation.

No relevant case law could be identified in Liechtenstein.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Liechtenstein concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

There are no practical problems encountered with the definition of safety in line with Art 3(3) GPSD and with respect to emerging safety issues. The Office of Economic Affairs is not aware of practical problems with respect to traceability, which is at least partly due to the fact that points of sale / traders in Liechtenstein usually sell only branded products.

Possible improvements to make the implementation of the GPSD in Liechtenstein more effective

The Office of Economic Affairs does not consider that there is any area of the legislative framework that could be improved to make the implementation of the GPSD in Liechtenstein more effective.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Liechtenstein.

Liechtenstein is a member of the EEA, but also maintains a customs union with Switzerland. Due to the customs union treaty, most consumer products enter the Liechtenstein market via Switzerland. The larger department stores are also in Liechtenstein and sell the same products as in Switzerland. In some sectors there is an administrative agreement with the responsible market surveillance authorities in Switzerland regarding market surveillance in Liechtenstein. The country therefore benefits to a large extent from Swiss market surveillance activities, which are considered to work well.

In Liechtenstein itself, in addition to the Office of Economic Affairs, several other authorities have responsibilities concerning market surveillance, including the Office of Public Health (medicinal products), the Office of Communication (radio equipment), Office of Environment (REACH) and the police (pyrotechnic articles).

Due to the size of Liechtenstein there are no sub-national authorities.

Plans/programmes in place which define priorities for market surveillance of consumer products

Liechtenstein has sectoral surveillance plans/programmes in place, the priorities of which are defined by use of the following sources of information: Inspection results; RAPEX notifications; Coordinated actions on the safety of products organised at EU level; Consumer complaints; Information provided by businesses/business associations; Information provided by consumer organisations.

At a general level, however, market surveillance activities have been in the past largely reactive, and proactive market surveillance activities are very limited, which is also due to the fact that problems in this area are rare and

branded products dominate the Liechtenstein market.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Liechtenstein with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

Online market surveillance is conducted once per year (focusing on retailers' websites and online marketplaces). Due to the market structure and the size of the market, 4 to 5 products are defined in advance in individual sectors. The website or online marketplace is searched for the products defined in advance. Subsequently, the economic operators will receive a letter for the delivery of conformity documents. So far online market surveillance activities have mostly focused on whether or not specific electricity plugs are provided with the selected products, or not, as in Liechtenstein (similar to Switzerland) plugs differ from the rest of Europe and only fixed power adapters are allowed.

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Liechtenstein (except customs) with respect to product safety

Cooperation with other relevant authorities in Liechtenstein regarding product safety is very limited (less than once per year), and only at an informal level. It is therefore considered necessary to improve cooperation, e.g. regarding the information flow between authorities for notifications to RAPEX.

Cooperation with customs authorities in Liechtenstein with respect to product safety

The Swiss Customs Administration is responsible for customs control, on the basis of the customs treaty, with bi-annual coordination meetings taking place in which Liechtenstein authorities are involved.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with authorities in other EU/EEA countries is very limited (less than once a year) and no cooperation takes place with non-EU/EEA countries other than Switzerland. Outside Consumer Safety Network meetings at the EU level, cooperation mostly takes place through RAPEX and ICSMS.

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

The Office of Economic Affairs considers that this is not safeguarded due to the limited cooperation between Liechtenstein authorities in this matter. As Liechtenstein only provided two RAPEX notifications in the 2013-2018 period (concerning a travel plug adapter in 2014 and a motorcycle helmet in 2013), there is little experience available among the authorities in this regard.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations on product safety (regarding businesses: other than for requesting corrective action)

There is no cooperation with business or consumer organisations.

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Through press releases and additional online information, see
https://www.llv.li/inhalt/11393/amtsstellen/marktuberwachung
https://www.llv.li/inhalt/1878/amtsstellen/ruckrufe-und-sicherheitsinformationen

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Liechtenstein (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

Product recalls are mostly conducted by retailers that conduct such recalls at the same time for Switzerland and Liechtenstein, so the authorities in Liechtenstein are not actively involved in most cases. In the past, the Office of Economic Affairs was more involved and in several cases contacted the general importer of the product in question in Switzerland to exchange information on a specific recall or relevant RAPEX information. Moreover the (low number, often only one to two) relevant shops in Liechtenstein were visited to check whether the recall was effective or not. But there is less need for this at present, due to the integration of the Liechtenstein market into the Swiss market, and the dominant position of branded products.

Monitoring of effectiveness of product recalls by market surveillance authorities

Currently, there is little monitoring of recall effectiveness taking place (see above). Based on previous experiences and the information available, recall effectiveness is assessed as being moderately effective.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Liechtenstein that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

There is no data available on dangerous products (other than RAPEX statistics) and also no data on dangerous products intercepted by customs at the borders (see above). Also, consumer complaints concerning product safety are not systematically collected. With respect to injury data, it was observed that due to Liechtenstein's size and structure, it is difficult to obtain reliable figures, as citizens would often go directly to a hospital or doctor in Switzerland or Austria, and therefore no information would be available in Liechtenstein regarding these cases.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Liechtenstein (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

The Office of Economic Affairs considers the following issues to be the most relevant: Limited staff resources for market surveillance; Lack of financial resources for testing of consumer products; Lack of coordination at the national level; Lack of statistics/data to set priorities for market surveillance; and lack of awareness of consumers with respect to product safety.

Areas to make market surveillance of consumer products in Liechtenstein/the EU more effective

Improvements that could make market surveillance more effective include better coordination between national authorities regarding product safety. Also, at a general level, there is limited sensitivity regarding product safety issues, due to the relatively high level of protection in Liechtenstein (as indicated before, this is caused by its – passive – integration into the Swiss market surveillance system, and its specific market structure (branded products)).

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Liechtenstein since 2013

The Office of Economic Affairs reports that the trend in terms of safety depends on product type or sales channel. In their experience, products sold online tend to be cheaper and less safe.

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Liechtenstein whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

In Liechtenstein, no technological approaches or tools are used in or developed for market surveillance activities. The Office of Economic Affairs considers that they therefore do not have tools at their disposal to address new challenges in their country (e.g. related to e-commerce, C2C sales, platform economy, new technologies etc).

Views of market surveillance authorities whether approaches in Liechtenstein can be considered best practice implementation of the GPSD, which could be of interest to other countries

No.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*0.025*	*0*	*0.025*
Responsible authorities at the sub-national level (regional/provincial/local)	*0*	*0*	*0*
Total (country)	***0.025***	***0***	***0.025***
Of which staff allocated to market surveillance activities regarding products sold online	*0.005*	*0*	*0.005*
Notes:	*2019 data*		

B. Number of inspections of consumer products (last available year)

	Harmonised consumer products (e.g. toys etc)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Total number of inspections	**2**	**0**	**2**
Total number of consumer products inspected	10	0	10
Total number of consumer products tested in laboratories	0	0	0
Total number of consumer products inspected in cooperation with the customs	0	0	0
Total number of dangerous consumer products found	1	0	1
Total number of dangerous consumer products found following communication of measures by other EU/EEA countries	3	1	4
Notes:	*2019 data (until November)*		

C. Number of recalls of consumer goods (last available year)

Due to the customs treaty, most consumer products enter the Liechtenstein market via Switzerland. The larger department stores are also in Liechtenstein and sell the same products as in Switzerland. In Switzerland there are recalls which apply indirectly to Liechtenstein. No statistics are available in this respect.

D. Key sources

Legislation	Law about the marketability of goods (LR 947.1 – Gesetz vom 22. März 1995 über die Verkehrsfähigkeit von Waren, LGBl. 1995 Nr. 94, in der Fassung vom 01.01.2019). Ordinance on the Marketing of Toys in European Economic Area (LR 947.102.231 - Verordnung vom 19. Februar 1996 über den Verkehr mit Spielzeugen im Europäischen

	Wirtschaftsraum, LGBl. 1996 Nr. 35) Regulation on the Marketing of Electrical Equipment throughout the European Economic Area (LR 947.102.101 - Verordnung vom 9. Mai 1995 über den Verkehr mit elektrischen Betriebsmitteln im Europäischen Wirtschaftsraum, LGBl. 1995 Nr. 143)
Studies/reports/articles	WTO - Trade Policy Review: Switzerland and Liechtenstein (https://www.wto.org/english/tratop_e/tpr_e/s355_e.pdf)
Websites	www.gesetze.li www.llv.li
Interviews	Filled in questionnaire by the Office of Economic Affairs of the Principality of Liechtenstein Interview with Office of Economic Affairs of the Principality of Liechtenstein

31. Norway

COUNTRY REPORT NORWAY

I. Implementation of the GPSD

1. Implementation legislation of GPSD

National implementation legislation of the GPSD

The GPSD is implemented into national legislation through the Product Control Act.[492] Market surveillance activates in the non-harmonised area are governed by this law and national product legislation and fall under the main responsibility of the Ministry of Justice and the Ministry of Climate and Environment.[493] There are some non-harmonised products for which national legislation exists.

2. Application of Art 5 GPSD regarding traceability

Application of Art 5 GPSD regarding traceability in Norway

The national legislation specifies only a general requirement to provide customer relevant information. Although there is no specific clear obligation to provide the name and contact details on the product or its packaging, any person can ask this information from the operator, who has the "duty to provide information on demand".

3. Definition of safety in Art 2(b) GPSD and benchmarks for assessing safety in line with Art 3(3) GPSD

Existence of specific definition of safety used for the application of the national implementation legislation of the GPSD in the area of new technologies

There is no specific definition of safety used for the application of the legislation in the area of new technologies.

Coverage of emerging threats related to new technologies (e.g. cyber security/software related threats) in the national implementation legislation of the GPSD

With respect to new technologies, it is not always clear whether the Norwegian legislation does cover any of the related threats such as hacking of software or products with artificial intelligence (AI), including cyber security. Moreover, some of the sector-specific legislation falls under the responsibility of more than one market surveillance authority (as day to day market surveillance is carried out by 14 market surveillance authorities responsible for different sector-specific legislation, see below). In case of an investigation related to new technologies, the authorities involved in market surveillance coordinate on a case-by-case basis on how market surveillance activities should be carried out in these areas, which has not occurred often. In the so called "Cayla doll" case, for example, the Ministry of Trade, Industry and Fisheries coordinated the case and decided that the Norwegian Directorate for Civil Protection (DSB) would take the lead in the investigation with the involvement of other market surveillance authorities.

Benchmarks used for assessing the safety of a product (in line with Art 3(3) GPSD) if European standards referenced in the EU Official Journal do not exist

The following benchmarks are used for assessing the safety of a product in Norway if European standards referenced in the EU Official Journal do not exist: Other European standards (not referenced in the EU Official Journal); national standards (not based on European standards); international standards/standards from non-EU/EEA countries; and Commission recommendations setting guidelines on product safety assessment.

4. Administrative measures available, penalties foreseen under Art 7 GPSD, and relevant case law

Administrative measures at the disposal of market surveillance authorities in Norway in case there are consumer product(s) on the market which are found unsafe under the GPSD

[492] Act 11 June 1976 No. 79 Relating to the Control of Products and Consumer Services (*Lov om kontroll med produkter og forbrukertjenester (produktkontrolloven))* https://lovdata.no/dokument/NL/lov/1976-06-11-79/, in English: https://www.regjeringen.no/en/dokumenter/product-control-act/id172150/

[493] National Market Surveillance Programme, 2019, Norway

The authorities have a range of different sanctions at their disposal, ranging from requiring businesses to provide relevant information on the product, on the supply chain and on the distribution of the product; requiring businesses to provide relevant information to ascertain the ownership of websites, where relevant; carrying out unannounced on-site inspections and physical checks of products; acquiring product samples including under a cover identity (mystery shopping); and requiring recalls of products, stopping products being placed on the market, and withdrawal of products.

Penalties foreseen under Art 7 GPSD, according to the national implementation legislation of the GPSD or other relevant provisions (types of penalties, their level/amount)

The penalties foreseen are a temporary ban, sales ban, withdraw and recall, and destruction, as well as economical/general penalties. In some cases, authorities may impose coercive fines. Coercive fines are not considered a criminal penalty or a punishment but are an economic pressure to ensure that the regulations or decisions are complied with.[494]

Recent case law in Norway with respect to or relevant for the GPSD/the national implementation legislation.

No case law was identified in Norway with respect to or relevant for the GPSD or the national implementation legislation.

5. Problems and safety issues encountered, potential improvements of the legislative framework

Practical problems encountered in Norway concerning traceability, definition of safety etc./ Emerging safety issues with particular categories of consumer products not addressed by current safety legislation

No practical problems have been encountered with respect to the application of Art 5 (1) GPSD regarding traceability. However, the definition is considered to be somewhat complex and allowing for different interpretations.

Possible improvements to make the implementation of the GPSD in Norway more effective

The implementation of the legislation could be improved through alignment of the GPSD with the Directives in the harmonised area.

II. Functioning of market surveillance of consumer products

1. Organisation of market surveillance of consumer products and priority setting

Organisation of market surveillance in Norway.

The responsibility at the national level for market surveillance (and product legislation) is divided between the following ten ministries:

- Ministry of Agriculture and Food
- Ministry of Children, Equality and Social Inclusion
- Ministry of Climate and Environment
- Ministry of Health and Care Services
- Ministry of Justice and Public Security
- Ministry of Labour and Social Affairs
- Ministry of Local Government and Modernisation
- Ministry of Petroleum and Energy
- Ministry of Trade, Industry and Fisheries
- Ministry of Transport and Communications

Day-to-day market surveillance is carried out by 14 market surveillance authorities responsible for different sector-

[494] Ibid.

specific legislation (some of the sector-specific legislation falls under the responsibility of more than one authority).[495] The authorities involved in market surveillance specify how market surveillance activities should be carried out in these areas.

Consumers may report potential dangerous consumer products to the market surveillance authorities (according to an online "notice of concern" system). If justified, the market surveillance authorities will follow up on the issue with the economic operator, and make sure that corrective actions are taken when necessary. Information on products presenting a serious risk is published on the website of the responsible authorities (see www.farligeprodukter.no). In extraordinary cases, the market surveillance authorities have alerted consumers via newspapers and other media such as radio or TV.[496]

Plans/programmes in place which define priorities for market surveillance of consumer products

There is a national surveillance plan/programme in place covering all product sectors (consumer and professional products).

The priorities for market surveillance are set on the basis of the following sources of information: Inspection results; RAPEX notifications; coordinated actions on the safety of products organised at EU level; consumer complaints; customs information; and accident reports or injury data.

2. Market surveillance regarding new technologies, online sales and C2C products

Market surveillance activities in Norway with respect to the safety of products containing new technologies (such as Internet of Things, connected devices), products sold online and C2C products

Market surveillance activities with respect to the safety of products containing new technologies (such as the Internet of Things (IoT), connected devices) is conducted only to a limited extent (e.g. "Cayla Doll"). No market surveillance activities are conducted with respect to C2C products.

Market surveillance of products sold online (frequency, sales channels covered, organisation, use of mystery shopping)

The market surveillance authority does not conduct mystery shopping due to legal and other impediments. It is considered difficult to find and to get responsible economical operators to take responsibility (both national operators and in other countries).

3. Market surveillance cooperation with public authorities, including through RAPEX/Safety Gate and cross-border

Functioning of cooperation with other relevant authorities in Norway (except customs) with respect to product safety

With respect to product safety, national market surveillance authorities cooperate on a regular basis through three permanent networks:[497]

The Market Surveillance Council is chaired by the Ministry of Trade, Industry and Fisheries, and has representatives from the ten ministries (mentioned above). The customs authority participates (under the Ministry of Finance) when needed. It meets (normally) twice a year. The RAPEX network and the industrial products network (see below) may also be invited to the meetings. Each ministry is responsible for coordinating the two way flow of information between its own market surveillance authorities and the Council. It also coordinates reporting obligations under Regulations 764/2008 and 765/2008, and the elaboration of national market surveillance programs. Its role is furthermore to contribute to the efficient use of RAPEX and ICSMS.

The RAPEX network is chaired by the DSB, which is also the national contact point of RAPEX. The network meets 2-3 times a year and deals with issues according to the RAPEX Guidelines, i.e. exchange of experiences on how the individual authority is following up on RAPEX notifications and reactions, statistics, training and information, and news from the EU Commission. The following authorities participate in the national RAPEX network:

[495] Ibid.
[496] Ibid.
[497] Ibid.

- Norwegian Directorate for Civil Protection
- Norwegian Environmental Agency
- Norwegian Labour Inspection Authority
- Norwegian Public Road Administration
- Norwegian Food Safety Authority
- Norwegian Directorate for Building Quality
- Norwegian Maritime Authority
- Norwegian Communication Authority
- Norwegian Radiation Protection Authority
- Norwegian Railway Authority
- Norwegian Metrology Service
- Norwegian Medicines Agency
- Norwegian Customs

The network also deals with the exchange of best practices, exchange of results of surveillance activities, enforcement issues, information on Prosafe Joint Actions, on line sales, etc.

The Industry Product network covers areas of the EEA harmonised sector product legislation regarding products used by industry. It comprises representatives from the Directorate for Civil Protection, the Norwegian Metrology Service,[498] the Norwegian Labour Inspection Authority, the Petroleum Safety Authority Norway, and the Norwegian Building Authority as permanent members. When required, other government agencies, industry associations, national employer organisations, unions, etc., are involved.

A national website for dangerous products (www.farligeprodukter.no) was launched in 2019 by the DCP with the involvement of the Norwegian Maritime Authority, the Norwegian Public Road Administration, the Norwegian Labour Inspection Authority, the Norwegian Food Safety Authority and the Norwegian Environmental Agency.

Cooperation with customs authorities in Norway with respect to product safety

The DSB cooperates with customs upon request in various frequencies, on average once a month. Customs authorities have cooperation agreements with most central market surveillance authorities (including the DSB) and perform coordinated border management on behalf of the market surveillance authorities. Cooperation agreements also foresee the establishment of working groups to execute the plans and oversee cooperation. The working groups normally meet biannually, or else when needed.[499]

Customs has also access to and uses the website of RAPEX and the national website for dangerous products.

Cooperation with authorities in other countries (EU/EEA and non-EU/EEA countries) with respect to product safety

Cooperation with other relevant authorities located in EU/EEA countries occurs primarily through RAPEX, the Wiki confluence platform, and through coordinated actions on the safety organised at EU level. Informal cooperation exists e.g. with neighbouring countries (the Nordic Network).

Coordination between RAPEX and national market surveillance systems (in terms of timely notification of dangerous products, non-safety risks notified through RAPEX etc)

All the authorities responsible for market surveillance have full access to the RAPEX application and are responsible for product notifications and reactions. The RAPEX contact point (DSB) provides guidance to the responsible market surveillance authorities and follows up with the notifications. The duration between the detection of a dangerous product and its notification to RAPEX takes more than two weeks on average, although in critical cases it can take a shorter time.

4. Cooperation with stakeholders and awareness raising for product safety

Cooperation of market surveillance authorities with business associations/businesses and consumer organisations

[498] *Justervesenet*
[499] Ibid.

on product safety (regarding businesses: other than for requesting corrective action)

The authority organises seminars and conferences (on average once a year) to create awareness for product safety among businesses, and cooperates with consumer organisations less than once a year (when relevant).

Market surveillance authorities' activities to raise awareness of businesses and consumers with respect to product safety

Information on products presenting a serious risk is published on the website of the responsible authorities. In specific cases, the market surveillance authorities alert consumers via newspapers and other media such as radio or TV.

5. Recalls and other corrective measures

Organisation of recalls and other corrective measures in Norway (including cooperation and information exchange with businesses, existence of codes of good practice on product recalls)

The DSB asks the business to conduct recalls and other corrective measures on either a voluntary or mandatory basis (if needed). In case of a recall or other corrective action, both sides agree on the information channels to use for the recall. Businesses are also required to use all their available customer information for recalls and other corrective measures.

The authority checks and influences the recall strategy and the messages given to consumers. It requires information from the businesses concerning their activities targeted at consumers and at businesses involved in the supply chain. To a limited extent, the DSB requires information on the timeline and the effectiveness of the recall process.

There is also a "National Guideline" on recalls.[500]

Monitoring of effectiveness of product recalls by market surveillance authorities

The effectiveness of the recall process is monitored by the authority to a limited extent by asking for information in terms of the percentage of recalled products that are actually collected, and by conducting spot checks in shops regarding the withdrawal of products.

6. Availability of statistics relevant for market surveillance

Availability of statistics in Norway that is relevant for market surveillance (e.g. concerning dangerous products, related consumer complaints and injuries)

Statistics on dangerous products (other than RAPEX statistics) are available through a national database of dangerous products. Other relevant statistics are notifications/complaints concerning (unsafe) products from consumers, operators and other sources.

There is no common database for accidents and injuries.

7. Problems or impediments to effective market surveillance encountered, potential improvements

Practical problems or impediments to effective market surveillance of consumer products encountered in Norway (incl. regarding market surveillance in general and online, RAPEX, cooperation with stakeholders, recalls)

Problems affecting the functioning of market surveillance are: limited staff resources; lack of statistics to set priorities for market surveillance; lack of awareness by businesses with respect to product safety requirements; and problems to take effective action when the responsible economic operator is another EU/EEA country or located outside the EU/EEA due to legal and practical impediments, specifically in case of rogue traders where there is no information on the identification or location available.

While the RAPEX system is considered overall to function moderately well, several impediments have been encountered by DSB. These are: insufficient human or financial resources (the lack of resources does not allow for following up on all products); difficulties with risk assessment; lack of information from other national authorities

[500] *Veileder om meldeplikt ved farlige produkter*. See https://www.dsb.no/lover/produkter-og-forbrukertjenester/veiledning-til-forskrift/veileder-om-meldeplikt-ved-farlige-produkter/

for notifications; lack of information from businesses; lack of sufficient information to trace notified products.

Areas to make market surveillance of consumer products in Norway/the EU more effective

Regarding RAPEX, the authority sees a need for more training sessions organised by the EC RAPEX team.

In general, the DSB considers that more cooperation is needed with customs. More information from the different EU systems would also need to be provided to national operators and consumers.

III. Overall trends, market surveillance tools and best practices

1. Level of safety of consumer products

Views of the interviewed market surveillance authorities on how the level of safety of consumer products has developed in Norway since 2013

There is no clear trend observable by the authority (the safety level is largely unchanged).

2. Tools for market surveillance and best practices

Views of market surveillance authorities in Norway whether they have the tools at their disposal to address new challenges (e.g. related to e commerce, C2C sales, platform economy, new technologies etc) their market surveillance activities

No information has been provided in this respect.

Views of market surveillance authorities whether approaches in Norway can be considered best practice implementation of the GPSD, which could be of interest to other countries

The DSB does not consider market surveillance approaches in Norway to be best practice implementation of the GPSD.

Annex

A. Number of staff (FTE) working on market surveillance of consumer products (current, or for the last available year).

	Harmonised consumer products (e.g. toys, cosmetics, electrical appliances and equipment under LVD)	**Other (non-harmonised) consumer products under GPSD**	**Total** (all consumer products)
Responsible authority/ies at the national level	*5*	*3*	*8*
Responsible authorities at the sub-national level (regional/provincial/local)	*4*	*n.a.*	*4*
Notes:	*Data for 2019* *In 2018, 13 notifications have been generated by Norwegian authorities. The most represented product and risk categories are cosmetics and chemical risk.* *In 2018, the number of reactions is 80. The most represented product category is motor vehicles.* **No specific resources devoted to market surveillance of online sales*		

B. Number of inspections of consumer products (last available year)

N.a.

C. Number of recalls of consumer goods (last available year)

N.a.

D. Key sources	
Legislation	Act 11 June 1976 No. 79 Relating to the Control of Products and Consumer Services, https://lovdata.no/dokument/NL/lov/1976-06-11-79/, in English: https://www.regjeringen.no/en/dokumenter/product-control-act/id172150/
Studies/reports/articles	Market Surveillance Programme Norway, 2019
Interviews	Filled-in questionnaire of National Market Surveillance Authorities Interview with Directorate for Civic Protection (DSB)