Study to support the preparation of an evaluation of the General Product Safety Directive as well as of an impact assessment on its potential revision

Final report

Part 2: Impact assessment on the potential revision of the General Product Safety Directive

Prepared by Civic Consulting
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Justice and Consumers

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Part 2: Impact assessment on the potential revision of the General Product Safety Directive

Prepared by	Civic Consulting
Reporting	Dr Frank Alleweldt, Dr Senda Kara, Dr Matthias Bauer, Dr Philipp Lamprecht, Dr Vaia Karapanou, Prof. Peter Rott

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LIST OF ACRONYMS

Acronym	Meaning
AI	Artificial Intelligence
ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation AISBL (The European consumer voice in standardisation)
BEUC	Bureau Européen des Unions de Consommateurs (The European Consumer Organisation)
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
DG CONNECT	Directorate General for Communications Networks, Content and Technology
DG ENV	Directorate General for Environment
DG GROW	Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
DG JUST	Directorate General for Justice and Consumers
DG SANTE	Directorate General for Health and Food Safety
DG TAXUD	Directorate General for Taxation and Customs
EEA	European Economic Area
EFTA	European Free Trade Association
EQ	Evaluation question
ESO	European Standardisation Organisation
ETSI	European Telecommunications Standards Institute
EU	European Union
EUR	Euro
GPSD	General Product Safety Directive (2001/95/EC)
IoT	Internet of Things
MSA	Market Surveillance Authority
Safety Gate/ RAPEX	Rapid Alert System for non-food dangerous products
TOR	Terms of reference

Executive summary

This study was conducted by Civic Consulting for the European Commission. Its main objective was to provide the EC with evidence and analysis to allow it to carry out an ex-post evaluation of the General Product Safety Directive (GPSD) and its practical application (see Part 1 of the report) and, in view of the outcome of the evaluation, to carry out an impact assessment for a possible future revision aimed at addressing the shortcomings identified (Part 2 of the report). Key conclusions of Part 2 are:

1. Problem analysis

Based on evidence presented in Part 1, the study identified problems in several areas affecting the protection of EU consumers regarding unsafe non-harmonised products:

Product safety challenges in online sales channels: The increase of e-commerce over the last decade, a higher share of unsafe products in online sales channels as observed by stakeholders, and enforcement problems related to online sales have opened a gap in the system of product safety established by the GPSD. While the importance of B2C cross-border e-commerce with non-EU countries is still limited in absolute terms, this share is increasing. Stakeholders find that sales by third parties on online marketplaces pose specific problems in terms of product safety, which relate to (re-)emergence of recalled and unsafe products, lack of traceability information and lack of effective control of product safety at EU borders. Their view is supported by research conducted by the OECD and in Member States (MS).

Product safety challenges linked to specific product risks, including due to the use of new technologies: A key uncertainty is to what extent software updates and standalone software are considered products under the GPSD. It is also not clear to which extent risks are covered that do not affect directly consumer health and safety, but may do so indirectly (e.g. the issue of cybersecurity of a smart home smoke detector, which may lose its functionality due to interference from hackers). In addition, there is a lack of clarity regarding a product's potential behaviour due to embedded software that applies machine learning and AI. Thus, a product may be, or seem, safe when it is put on the market but then change into a risky product if it is updated or if machine-learning components are re-trained during the use. While there is ongoing work in relevant sectorial legislation to address these issues, it appears important to maintain the safety net role of the GPSD for consumer products also with respect to the use of new technologies. Finally, the GPSD's definition of safety covers environmental risks to the extent that they affect human health and safety, but this may be difficult to prove, especially in areas where no EU legal limits and related scientific reference data exists, and where Member States may use different risk assessment methods.

Challenges related to the rules for market surveillance and standardisation: Market surveillance rules and obligations of businesses in the GPSD lack detail (e.g. in the area of traceability), are not adapted to the online environment, and do not sufficiently specify the powers of market surveillance authorities. This leads to situations where authorities are, for example, not allowed to conduct mystery shopping, limiting the effectiveness of the GPSD. After Regulation (EU) 2019/1020 on market surveillance and compliance of products fully applies from July 2021, there will be major differences in enforcement powers of MSAs, depending on whether market surveillance is conducted regarding harmonised products (e.g. toys) or regarding non-harmonised products (e.g. children's beds). Also, there is no dispute resolution mechanism in case of diverging product safety risk assessment between national authorities, and the process for elaborating European Standards under the GPSD is burdensome and not streamlined.

Insufficient effectiveness of recalls of consumer products: The effectiveness of product recalls from consumers is reportedly low. Reasons include that the GPSD is not fully adapted to ensure adequate traceability, which puts a strain in the implementation of corrective measures, in particular recalls. A second major deficiency regarding recalls concerns the lack of EU-wide general requirements for recall procedure, communication

or the remedies to be offered to consumers. This is a significant shortcoming suggesting that existing GPSD requirements are in themselves currently not sufficient to ensure effective recalls.

Inconsistent application of product safety rules for food-imitating products: While a majority of the MSAs seems to apply the provisions of the Food-Imitating Products Directive only in cases where the risks are serious, there are also countries that consider products in this category as dangerous per se. The legal framework for food-imitating products is therefore applied differently in different countries. There is also limited evidence that would justify a fully separate regime for these products.

Future trends: The identified problems are likely to continue in the future. While the COVID-19 pandemic has led to declines in overall retail sales, e-commerce sales have increased and are expected to increase in the foreseeable future. In the area of new digital technologies, the number of connected IoT devices targeted at consumers is also expected to grow rapidly, likely to be boosted by the roll-out of high speed 5G mobile broadband networks. It is also expected that the relevance of product-related environmental risks will continue to increase in a more circular economy, which involves the re-use and recycling of products. Without changes in legal requirements, it is unlikely that effectiveness of recalls will substantially improve in the future, and country differences in the application of the GPSD and the Food-Imitating Products Directive are likely to continue.

2. Policy options

Initial policy options took into account the results of the GPSD implementation study, which had elaborated key deficiencies of the current legal framework and stakeholder suggestions for improvements. In the course of the current study, these policy options were validated and no further policy options for consideration were identified. The policy options assessed are: Option 0 - 'Status quo': Baseline scenario not involving any new actions; Option 1 - Improved implementation and enforcement of the existing legal framework, without revision of the GPSD; Option 2 - Targeted revision of the GPSD (Directive or Regulation); Option 3 - Full revision of the GPSD and recasting as Regulation; Option 4 - New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020.

3. Baseline

Compliance costs: This study estimates the current costs of EU companies to comply with the GPSD at EUR 1.1 billion per year, of which EUR 343 million accrue to EU manufacturers, EUR 321 million to EU wholesalers and EUR 439 million to EU retailers. SMEs account for 59% of the total of GPSD-related compliance costs. Total EU27 staff costs of Member States for market surveillance of non-harmonised consumer product amount to approximately EUR 122 million per year. EU27 total annual non-staff related costs of market surveillance activities for non-harmonised consumer products are minor, in line with the reported lack of resources for market surveillance (including for testing). They at most accounts for the equivalent of 0.34% of authorities' total staff costs.

Benefits of the GPSD: Authorities and companies/business associations tend to see moderate to significant benefits of the GPSD across the board, with better information on unsafe products/measures taken by authorities provided through Safety Gate/RAPEX, a better functioning internal market and increased consumer trust highest ranked. About nine in ten respondents to our surveys that had an opinion considered the costs due to product safety requirements of the GPSD to be at least "moderately proportionate" to the resulting benefits, close to six in ten respondents found them even to be "largely" or "very proportionate". This largely positive assessment is consistent with the analysis of compliance costs. A large part of costs related EU product safety legislation for consumer products are business-as-usual costs (BAU), i.e. costs that companies would incur anyway (i.e. even in absence of product safety legislation, for example because these costs relate to their due diligence procedures). Compliance costs

that exclude business-as-usual costs are therefore limited, compared to the benefits the Directive brings.

Consumer detriment: Preventable detriment suffered by EU consumers and society due to product-related injuries and accidents can be estimated at EUR 11.5 billion per year (due to data limitations, this figure concerns the total of harmonised and non-harmonised consumer products). Detriment is also suffered by consumers that have (unknowingly) purchased an unsafe product, even if it does not lead (or has not yet led) to concrete harm. In this case, the detriment can be considered to be equal to its purchase price, since the consumers would likely not have bought the product if they knew it was dangerous[1]. The analysis for the baseline year 2019 concludes that the consumer detriment in the EU due to unsafe non-harmonised products estimated on the basis of product value is EUR 3.9 billion for online sales, and EUR 15.4 billion for offline sales channels, for a total of EUR 19.3 billion per year. This detriment is reduced under a baseline scenario of low recall effectiveness by approximately EUR 0.4 billion per year, assuming that consumers are compensated fully for all non-harmonised products they returned to producers in response to a product recall[2]. Due to methodological and data limitations, these estimates have a considerable range of uncertainty. However, they provide an indication of the dimension of detriment suffered by consumer in the EU due to unsafe products.

4. Assessment of policy options

Stakeholder views on options: Authorities and other stakeholders (including consumer organisations) assessed Options 3 and 4 (both involving a full revision of the GPSD) as being most effective, and considered them to well address the challenges. For authorities, this assessment was similar for both options, other stakeholders assessed Option 4 as slightly more effective. In contrast, assessments by companies/business associations do not show a considerable variation between the options, and consider all four options on average to slightly better than 'moderately well' address the challenges. The picture is relatively similar when considering the assessment of the three stakeholder groups regarding the expected benefits that would result from the implementation of each option, compared to the baseline. All stakeholder groups, including businesses, see higher benefits under Options 3 and 4 especially regarding e.g. a better functioning EU internal market, reduced occurrence of products with health and safety risks, greater legal certainty and more level playing field among businesses.

Achievement of objectives: The table below lists the specific policy objectives to address the challenges identified in the problem analysis, and indicates the extent to which the options can be expected to achieve them.

[1] The justification for this assumption is that consumer willingness to pay is close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. For a detailed analysis, see Annexes IV and V.

[2] I.e. it is assumed that a recalled product is repaired or replaced by a good of the same quality, or the value is reimbursed fully.

Specific policy objectives	Option 1	Option 2	Option 3	Option 4
Ensure general safety rules, including for product risks linked to new technologies	neutral / +	+	++	++
Address safety challenges in the online sales channels	neutral	neutral / +	+ / ++	+ / ++
Make product recalls more effective	neutral	neutral / +	++	++
Enhance market surveillance and ensure better alignment of rules	neutral	++	++	++
Address safety issues related to food-imitating products	+	+	+ (++ if ban)	+ (++ if ban)

neutral = no significant difference to baseline situation; + = positive impact; ++ = significant positive impact. An indication of neutral/+ or +/++ indicates an intermediate assessment.

Option 1 (improved implementation of the current GPSD) is unlikely to be adequate to address the problems identified, although uncertainty for businesses and MSAs will be reduced due to EC guidance. Also, Option 2 is likely to be partially adequate to address the identified problems. Gaps will remain regarding the coverage of stand-alone software, and implementation differences in Member States will likely remain. In contrast, Options 3 and 4 are mostly adequate to address the problems identified. Gaps regarding the coverage of stand-alone software will be closed, and implementation differences will be avoided through the choice of a Regulation.

Administrative simplification: The following table summarises the results of the assessment concerning the extent to which the options have the potential to reduce regulatory complexity and uncertainty, thereby reducing administrative burdens.

Area	Option 1	Option 2	Option 3	Option 4
Reduction of regulatory complexity and uncertainty	neutral / +	neutral / +	+	+ / ++

Under Option 1, a slight reduction of regulatory complexity and uncertainty can be expected through the provision of guidance. The picture is relatively similar concerning Option 2, with some reduction of regulatory complexity and uncertainty to be expected. Under Options 3 and 4, the reduction of regulatory complexity and uncertainty is considered to be more significant, as all identified regulatory gaps would be closed. As one single set of rules would apply to harmonised and non-harmonised consumer products, simplification could be expected to be more significant under Option 4. On the other hand, Options 3 and 4 would include some additional administrative requirements for specific types of operators: this includes the requirement for online sellers to provide all safety information online that is also required to be provided with a product in "brick-and-mortar" stores, and several requirements that aim at improving the effectiveness of recalls. These refer e.g. to the possibility to set out further requirements for product registration, the requirement for businesses to register voluntary recalls in an EU public database, the use of a template for recall notices and consumers' right to an effective, cost-free and timely remedy. While these requirements likely lead to related administrative burdens, they would mostly affect those companies that have brought unsafe products on the market and therefore have to recall products from consumers. As currently the limited effectiveness of recalls leads to considerable consumer detriment, these additional measures and the related administrative burdens appear to be proportionate.

Economic impacts: Benefits for businesses are expected to be minor under Option 1, mostly related to reduction of uncertainty due to the provision of guidance. Benefits of Option 2 depend on whether the new legal instrument is a Directive or a Regulation. If a revised GPSD under Option 2 would be recast as a Regulation, implementation differences would be avoided at the legislative level (due to the direct applicability of

the new regulation in Member States). In this case, benefits for businesses would be similar to those under Options 3 and 4, expected to be 59 million EUR annually.

Area	Option 1	Option 2	Option 3	Option 4
Benefits for businesses (EU27)	neutral / +	neutral / + (Benefits of EUR 59 million /year, if Regulation)	+ Benefits of EUR 59 million/year	+ Benefits of EUR 59 million/year
Cost of businesses (EU27)	neutral	Costs increase by < EUR 37 million/year	Costs increase by < EUR 197 million/year	Costs increase by < EUR 332 million/year
Macroeconomic impacts	neutral	neutral / +	+	+

Compliance costs for EU companies are not expected to increase under Option 1, and only to a minor extent under Option 2. Under Option 2, compliance costs are estimated at EUR 36.9 million in the first year (equivalent to 0.004% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products), going down to EUR 29.6 million in subsequent years. Compliance costs are expected to increase under Option 3 to an EU total of EUR 196.6 million in the first year (and EUR 177.8 million in subsequent years), equivalent to 0.02% of turnover. Finally, under Option 4 compliance costs of businesses are expected to increase to an EU total of EUR 331.1 million in the first year (and EUR 296.3 million in subsequent years), equivalent to 0.03% of turnover. A possible explanation for the difference in the assessment of costs provided by businesses in our cost survey regarding Option 3 and Option 4 (which provide identical policy measures) is that businesses tend to provide cautious estimates with regard to additional costs from new regulatory obligations that might arise if one single set of rules would apply to harmonised and non-harmonised products. Some respondents highlighted that changing Regulation (EU) 2019/1020 so quickly could have considerable implications on costs. Under all options, the effects of additional compliance costs (under Option 2 to 4) will have a larger relative cost impact on SMEs than on large companies. Due to their size, SMEs bear a larger relative cost burden resulting from regulatory complexity and uncertainty. At the same time, and for the same reasons, SMEs can generally benefit more from policy measures that aim at a greater level of regulatory harmonisation in the EU. Macroeconomic impacts are expected to be mostly limited, with some (positive) impacts to be expected under Options 3 and 4, as they lead to a more aligned and clearer EU legislative framework as well as reduced legal complexity.

Impact on consumers and households: None of the four options is expected to significantly affect consumer prices or consumer choice, as estimated increases in companies' compliance costs are small compared to baseline costs (see following table).

Area	Option 1	Option 2	Option 3	Option 4
Consumer prices	neutral	neutral	neutral	neutral
Consumer choice	neutral	neutral	neutral	neutral
Consumer safety and vulnerable consumers	neutral	+	++	++

Regarding consumer safety and the protection of vulnerable consumer groups, the four options differ, however. Option 1 is not expected to lead to a reduction of unsafe products in the online sales channels, due to the limited scope of the measures taken. Some reduction of the incidence of unsafe products in online sales channel could be expected with implementation of Option 2. According to the scenario estimates elaborated for this study (see Annexes IV and V), measures taken under this option are expected to reduce consumer detriment in the EU due to unsafe non-harmonised products by EUR 333 million in the first year, increasing to EUR 1 031 million per year in the course of the next decade. The reason for this increase is that overall consumer

detriment is expected to grow in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce. Options 3 and 4 are likely to be more effective to address the challenges for product safety posed by online sales channels, through the introduction of due diligence obligations for platforms, the extension of certain obligations, e.g., for fulfilment service providers and the sanctions and penalties incorporated in the new regulation replacing the GPSD. Benefits under Options 3 and 4 are expected to amount to approximately EUR 1.0 billion in the first year of implementation, increasing to approximately EUR 5.5 billion per year over the next decade. The extent to which these benefits materialise, will however also depend on the continued surveillance of platforms and the enforcement of the platforms' duty of care and other measures that are taken at EU level, including in the new Digital Services Act. An additional benefit is the reduced consumer detriment due to more effective recalls. Measures under Option 1 are not expected to lead to higher recall effectiveness, and therefore are not expected to reduce related detriment. Option 2 could be expected to provide limited improvements in terms of return rates of recalled products, leading to a reduction of consumer detriment of EUR 205 million. Finally, Options 3 and 4 are expected to reduce consumer detriment related to ineffective recalls by EUR 410 million per year.

Impacts on Member States: Benefits for market surveillance authorities are expected to mostly arise from the alignment of the provisions for market surveillance of harmonised and non-harmonised products. This increases efficiency of surveillance. Related savings are estimated at EUR 0.7 million per year across the EU.

Area	Option 1	Option 2	Option 3	Option 4
Benefits for MSAs (EU27)	neutral / +	+ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year
Costs for MSAs (EU27)	neutral	Costs increase by < EUR 7 million/year)	Cost increase by < EUR 7 million/year)	Costs increase by < EUR 4 million/year)
Other effects on MS	neutral	neutral / +	+	+

As all options other than Option 1 would involve greater alignment of the legislative framework for harmonised and non-harmonised products, expected benefits are similar in monetary terms under Options 2, 3 and 4. In addition, streamlined standardisation procedures and an arbitration mechanism that provides clarification regarding risk assessments in case of disputes between Member States' MSAs could lead to additional cost reductions for MSAs over time (under Options 3 and 4) – these could, however, not be quantified. Cost for MSAs are expected to increase slightly under all options, except Option 1. Under the other options, estimates of total additional costs across the EU are between EUR 3.3 million/year (Option 4, which leads to most efficiency gains in terms of market surveillance rules) and EUR 6.6. million/year (Options 2 and 3).

Social impacts, impacts on fundamental rights and environmental impacts: Option 1 is not expected to have significant social impacts, impacts on fundamental rights and environmental impacts, due to the limited scope and voluntary character of the measures foreseen. Measures under Option 2 would be expected to ensure a somewhat higher level of consumer protection (with some positive social impacts with regards to public health and safety possible) and a higher level of environmental protection in line with the Charter of Fundamental Rights of the European Union.

Area	Option 1	Option 2	Option 3	Option 4
Social impacts	neutral	neutral / +	neutral / +	neutral / +
Impacts on fundamental rights	neutral	neutral / +	+	+
Environmental impacts	neutral	neutral / +	+	+

Most impacts are to be expected under Options 3 and 4. The introduction of additional requirements for traceability and product recalls including keeping supply chain records, making registration mandatory for certain products, notifying directly owners of recalled products are expected to improve the effectiveness of recalls. In addition, increased enforcement powers of Member States to impose penalties and sanctions in case of violations of the provisions of a revised GPSD are anticipated to significantly improve market surveillance and enforcement. To the extent that the number of unsafe products on the market is reduced by these measures in the mid- to long term, this potentially could lead to a lower number of injury cases caused by consumer products in need of medical attention or hospitalization, hence lowering public health expenditure for the treatment of product related injuries[3]. Options 3 and 4 are also expected to reduce product-related environmental risks, to the extent that the application of the general safety requirement to products containing environmentally harmful substances is clarified. The implementation of a new regulation replacing the GPSD according to Option 3 or 4 shall hence have a positive impact on consumer protection and environmental protection in line with the Charter of Fundamental Rights of the European Union. At the same time Options 3 and 4 impose additional requirements for businesses. These do not affect the fundamental freedom to conduct a business as they are necessary to pursue the general European Union interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be comparatively low compared to the businesses' turnover. On the other hand, measures also may include a ban of food-imitating products from the EU market (as sub-option). Such a ban would have a negative impact on the freedom to conduct a business, and for this restriction to be proportionate it would need to be justified with the objective of protection of consumers. However, evidence to prove the intended benefits (better protection of children) could not be identified in the framework of the present study.

An overview of the policy measures foreseen under the policy options are presented in Table 10 in section 6.1. A comparative overview of the assessment for all four options is provided in Table 85 in section 8.6. Section 8.7 presents potential complementary measures to increase achievement of objectives and reduce administrative burdens that were identified by the research.

[3] Based on the conservative estimation elaborated for this study, the current cost of health care utilisation for product-related injuries in the EU is approximately EUR 6.7 billion per year, with hospitalization accounting for the larger part of the total health care costs at about EUR 6.1 billion. See Annex I for more details.

1. Introduction

This is Part 2 of the final report of the study to support the preparation of an evaluation of the General Product Safety Directive (GPSD) as well as of an impact assessment on its potential revision, conducted by Civic Consulting. The report presents the result of the study with respect to the impact assessment of a potential revision of the GPSD.

Part 2 is structured as follows:

Section 2 describes the objectives and scope of the overall study, and summarises the methodology applied;

Section 3 describes the background of the study;

Section 4 analyses the problems related to the current implementation of the GPSD in the EU Member States;

Section 5 describes the objectives of a possible EU intervention;

Section 6 presents the policy options assessed in this study;

Section 7 describes the baseline for the assessment;

Section 8 presents the results of the assessment of the options, considering economic impacts on businesses, impacts on consumer and households, impacts on Member States, as well as analysing social impacts, impacts on fundamental rights, and environmental impacts. It also provides a comparison of options and discusses potential complementary measures.

In the Annex we provide the detailed analysis of the consumer detriment due to product-related injuries and fatalities in the EU, supporting materials, detailed analyses of costs and benefits of selected specific measures, as well as the analytical methods used, a list of interviews conducted, and summaries of views of and impacts on SMEs.

For detailed survey results and a list of references, see Annex of Part 1 of this report.

2. Description of the study

2.1. Objectives

According to the TOR, the objective of the overall study is to provide the Commission with evidence and analysis to allow it:

- To carry out an ex-post evaluation of the GPSD and its practical application (Part 1 of the report); and, in view of the outcome of the evaluation
- To carry out an impact assessment for a possible future revision aimed at addressing the shortcomings identified (Part 2 of the report).

For this purpose, the contractor will:

1. Collect data and evidence (incl. stakeholder opinions), as regards, and non-exhaustively, on the impact of the increased digitalisation on consumer product safety; the volume of dangerous products on the EU market and its trends; market surveillance and enforcement and on product safety procedures.
2. Evaluate, also on the basis of the evidence provided, how the GPSD has contributed to its general and specific objectives, in particular against the criteria of effectiveness, efficiency, coherence, relevance and EU added value. The outcome of this evaluation shall feed into the impact assessment.
3. Carry out, on the basis of the evidence collected and of conclusions of the evaluation, an impact assessment of a number of EU policy options concerning consumer product safety.

2.2. Geographical coverage and time period covered

The study covers the EU, with 28 Member States for the ex-post evaluation and 27 Member States for the impact assessment. The TOR also specify that research should cover the current state of the legislation and practice and, to the extent it is relevant and data is available, the situation before the GPSD was adopted.

2.3. Tasks to be performed

The TOR highlight that the research to be conducted will feed into an evaluation of the General Product Safety Directive, and an impact assessment of a possible revision. The Commission expects thus to be able to analyse and assess the different policy options against a background of solid research and an assessment of their strengths and weaknesses, including in terms of cost efficiency and administrative burden. It is also specified that – based on the information gathered during the initial stage of the project – the contractor will produce two, separate and self-standing reports which set out a retrospective analysis (evaluation) as well as a prospective analysis (impact assessment), with the impact assessment study coherently building on the conclusions of the evaluation.

The TOR specify several main tasks and related sub-tasks, which are (the numbering in brackets refers to the relevant headings of the TOR):

- Task 1 – Information gathering, preliminary background analysis and mappings (3.2.)
  - Data on the new digital challenges to the product safety (3.2.1.)
  - Data on the level of product safety and its trends and features on the EU market (3.2.2.)

  - Evidence on enforcement and market surveillance issues (3.2.3.)
  - Data on product safety procedures (3.2.4.)
- Task 2 – Evaluation analysis (3.3.)
  - Intervention logic and background (3.3.1.)
  - Baseline and the implementation state of play (3.3.2.)
  - Evaluation questions (3.3.3.)
  - Conclusions (3.3.4.)
- Task 3 – Impact Assessment (3.4.)
  - Problem definition (3.4.1.)
  - Policy objectives (3.4.2.)
  - Main policy options (3.4.3.)
  - Impacts to analyse (3.4.4.)

All tasks are described in detail in the TOR of the study.

2.4. Impacts to be assessed

The TOR specify that the impact assessment should be based on a comprehensive baseline scenario. For each of the policy options, the contractor will analyse the most significant impacts relative to the baseline scenario, including the following:

- Economic impacts (incl. on SMEs);
- Impacts on Member States;
- Social impacts;
- Impacts on fundamental rights; and
- Environmental impacts.

2.5. Methodology

2.5.1. Literature review

The study takes into account the results of a comprehensive review of relevant documents and academic literature concerning the implementation of the GPSD, market surveillance, Safety Gate/RAPEX, recalls, safety of consumer products and market research with respect to e-commerce and the role of online marketplaces, including their importance in different markets. Also considered were previous impact assessments for related legislation, e.g. market surveillance and value chain due diligence measures. An important source for the problem analysis was the evidence collected for the study for the preparation of an implementation report of the General Product Safety Directive, and the results of the evaluation of the GPSD. A list of references is provided in Part 1 of this report.

2.5.2. Analysis of data from the rapid alert system

Data from Safety Gate/RAPEX was used for the analysis of the baseline situation and the related problem analysis. For this purpose, we retrieved a full dataset covering the years 2005 to 2019 and addressed on this basis relevant research issues specified in the TOR. The dataset consisted of a total of 25 850 notifications that are publicly available. The dataset included 25 051 notifications concerning products with serious

risks, 738 notifications of products with other risk levels, and 61 other types of alerts[4]. This dataset was merged with a second dataset provided by the Commission covering notifications in the period 2011 to 2019, which included complementary (not publicly available) data.

2.5.3. Interviews

Interviews with a total of 60 interviewees were conducted in the framework of the study, covering the following stakeholder groups:

- Commission officials (DG JUST, DG GROW, DG CNCT, DG TAXUD, DG ENV);
- Selected business associations and other stakeholder organisations at EU and MS level;
- Selected companies (producing or distributing relevant non-harmonised products such as childcare articles, clothing and furniture) and online marketplaces that have signed the Product Safety Pledge;
- Officials in market surveillance authorities in the EU and product safety administrations in the US, Canada and Australia;
- Experts working in the area of product safety and product safety-related accidents.

The interviews were aimed at gaining a better understanding of the main issues relevant for different groups of stakeholders and to encourage them to cooperate and contribute to the study. The interviews covered key evaluation questions (relevant for Part 1 of the study) and the impact of the policy options (relevant for Part 2 of this report). The interview process included a total of 20 interviews with companies (including SMEs) and business associations, which also considered in detail potential impacts of the COVID-19 crisis on their operations. In total, 12 companies were interviewed regarding COVID-19. A list of interviewees is provided in Annex VIII.

2.5.4. Surveys

Four interlinked surveys covered key issues of the study, focusing on those questions that were of direct relevance for each group of stakeholders. The surveys targeted market surveillance and customs authorities, businesses and their associations, as well as consumer organisations and other stakeholders, both at the EU level and in Member States. The surveys were implemented on EU Survey. Considerable efforts were made to reach out to stakeholders. This included exploratory interviews with EU business and consumer associations, in which we pointed out the need to involve their members in the study process, to safeguard that views of all stakeholder groups were adequately presented.

To reach a representative sample of stakeholders across the EU, we conducted a mapping of stakeholders during the inception phase and used the Civic Consulting stakeholder database, which was complemented through additional web-based research, to include more companies (and business associations of companies) that produce non-harmonised consumer products such as childcare articles, clothing, and furniture across the EU. The survey questionnaires were widely distributed amongst stakeholders. The surveys were launched on 02 July 2020. Reminders were sent on 8 July 2020 and a second reminder on 24 July 2020. Surveys closed on 9 September 2020. We also conducted phone calls to EU level and national stakeholders for their support in distributing the surveys to their members. In total, 153 survey responses

[4] Note that when using the statistical function on the Safety Gate, the resulting figures may differ, e.g. because notifications are included that are not yet publicly available.

were received, of which 27 responses to the survey of consumer organisations and other general stakeholder; 48 responses to the survey of authorities, 37 responses to the survey of business associations and 41 responses to the survey of companies.

2.5.5. Case studies

A total of four case studies in selected EU Member States (France, Denmark, the Netherlands and Slovakia) complemented the research conducted for the GPSD implementation study, which had covered all Member States and EEA countries in detail. Case studies focused on the following aspects:

- Evidence on unsafe products found online;
- Product Safety Pledge;
- Customs checks;
- Risks posed by new technologies (connected devices, products with AI, Internet of Things).

In addition, three case studies were conducted covering non-EU/EEA countries (Australia, Canada and the US). These case studies focused on:

- Evidence on unsafe products found online;
- Impact of increased number of products connected and based on artificial intelligence on safety of consumer products;
- Injury data related to product safety incidents, and/or any estimates of consumer detriment caused by product safety incidents;
- Product traceability systems.

The case studies informed both the evaluation of the GPSD (Part 1 of this report), and also fed in to the impact assessment (Part 2 of this report). In preparation of the case studies we conducted a review of related literature and reports published on the websites of the case study institutions, which supported the preparation of the interviews, and informed the development of the methodology for the estimation of the product safety-related costs of injuries in the EU (see Annex I).

2.5.6. Economic analyses

For the purpose of this impact assessment, we conducted the following analyses of relevant costs and benefits:

- Estimation of costs of compliance with the GPSD for EU businesses, including SMEs (section 7.1.1);
- Estimation of costs of compliance with the GPSD for Member States (section 7.1.2);
- Estimation of the costs of implementing specific policy options for the potential revision of the GPSD (section 8);
- Estimation of the detriment due to product-related injuries and fatalities in the EU (Annex I);
- Estimation of benefits of measures concerning online sales channels (Annex IV)
- Estimation of benefits of measures in the field of recalls (Annex V);
- Other supporting estimations.

The methodologies applied for these estimations are further elaborated in Annex VII (summary of analytical methods used).

2.5.7. Complementary research and analysis

The methodological tools presented above were complemented by legal research and analysis, as well as the analysis of statistical data (from Eurostat and other sources).

2.6. Acknowledgements

We would like to express our gratitude to all contributors, without whom this study would not have been possible. In particular, we would like to thank all stakeholder organisations, including market surveillance authorities, business associations, consumer organisations and other stakeholders, including product safety experts, who provided valuable input through interviews and who responded to our surveys. We are especially grateful for the authorities and companies that provided cost data for the analysis of compliance costs, and helped us in understanding their perspective. Finally, we wish to thank the representatives of product safety authorities in selected non-EU/EEA countries for their willingness to share their experiences.

Finally, we thank the team of Unit E4 (Product Safety and Rapid Alert System) of the Directorate-General for Justice and Consumers of the European Commission for their continuous support and constructive cooperation throughout the study.

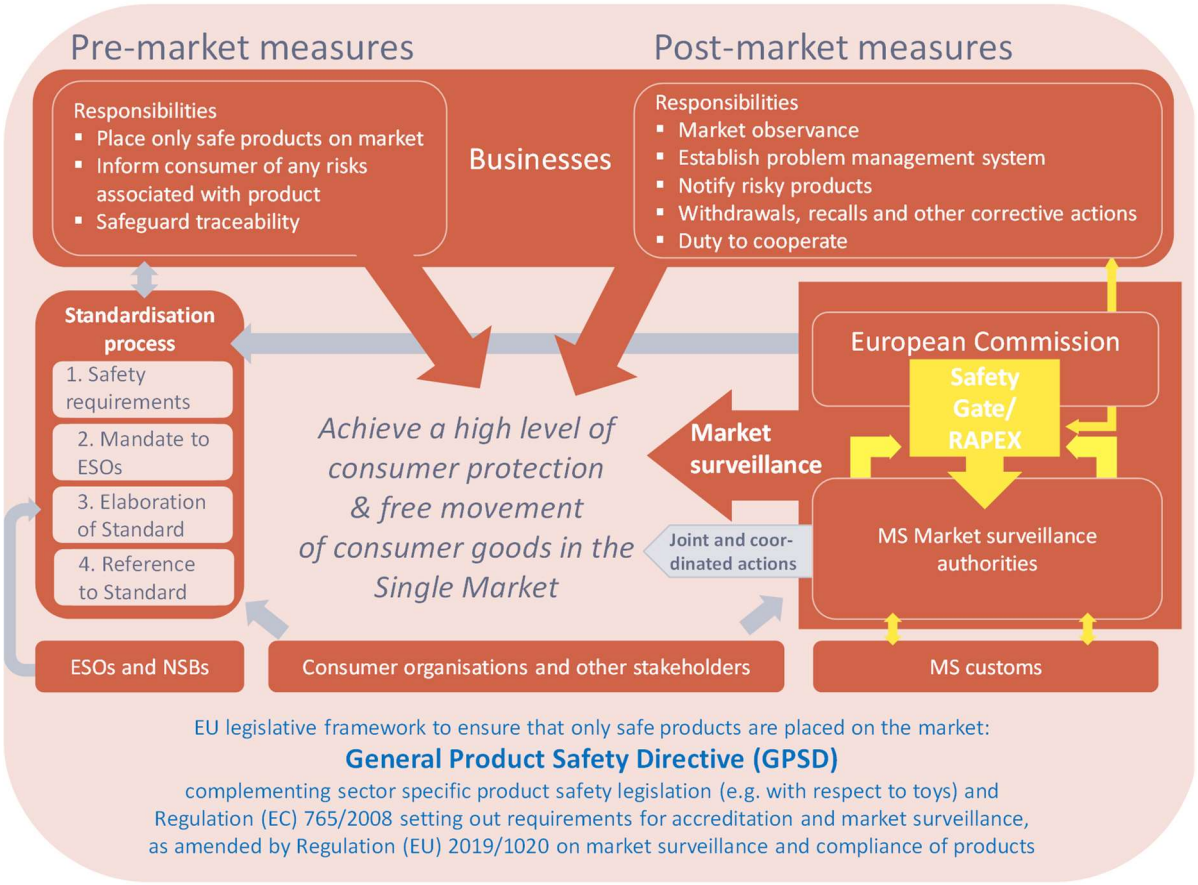
3. Background

Protecting the health and safety of European consumers is a major priority for the EU. In order to ensure that only safe products are placed on the European market, the General Product Safety Directive (2001/95/EC) (GPSD) establishes a general safety requirement for all non-food consumer products and contains provisions for the referencing of standards in the Official Journal of the European Union in support of the general safety requirement. It replaced an earlier General Product Safety Directive dating from 1992. The GPSD is applicable in the whole EU and is also applied in the EEA (European Economic Area) countries: Iceland, Liechtenstein, and Norway. It complements sector specific product safety legislation by applying fully to consumer products falling outside the scope of specific directives, e.g. childcare articles, and by applying partially to consumer products covered by sector legislation, for example toys, for all aspects not covered by the specific harmonized legislation. In 2008, the GPSD and the other product safety legislation was complemented by Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, accompanied by Decision (EC) No 768/2008 on a common framework for the marketing of products. In 2019, a new Regulation on market surveillance and compliance of products (Regulation (EU) 2019/1020) was adopted. Among others, this Regulation consolidates the existing framework for market surveillance activities; requires to have a responsible economic operator in the EU for products placed on the EU market (for certain products under the scope of this Regulation); addresses challenges of international e-commerce and online trade; encourages joint actions by market surveillance authorities from several member states; aims to ensure effective, speedy and accurate exchange of information between authorities and the Commission; and creates a strengthened framework for controls on products entering the single market and for improved cooperation between market surveillance authorities and customs authorities. It also creates a Union Product Compliance Network as a platform for structured coordination and cooperation, including defining priorities for EU-level common market surveillance actions. Moreover, it introduces a peer-review system for national market surveillance authorities.

The consumer product safety system of the GPSD and its accompanying legislation must be seen in context of the free movement of consumer products. The so-called 'New Approach' as introduced in the 1980s, and its follow-on system, the 'New Legislative Framework', was meant to substitute national measures so as to facilitate the cross-border trade and avoid the presence of products that bear a risk for health and safety on the EU market. The manufacturer who puts products into circulation must certify that the products comply with the required safety requirements; and whereas EU law requires a conformity assessment to be carried out by an independent third party (the 'notified body') in some areas, such as medical devices law, this is not the case under the GPSD. Products can circulate freely in the internal market[5]. In order to guarantee the safety of products, the GPSD entails pre-market control as well as post–market control measures. Figure 1 below illustrates the different elements of the system as well as their systemic dimension in contributing to the free movement of consumer goods.

[5] See also ECJ, 19 March 2009, C-489/06 Commission v. Greece, ECLI:EU:C:2009:165. For the relevant point in time, see GC, 26 January 2017, T-474/15 Global Garden Products Italy SpA v. Commission, ECLI:EU:T:2017:36.

Figure 1: The consumer product safety system of the GPSD



Source: Civic Consulting

As the figure illustrates, elements of pre-market control include the standardisation process under the GPSD and legal responsibilities of businesses that place products on the market (including regarding traceability), whereas elements of post-market control include post-marketing responsibilities of businesses, such as market observance and the duty to notify and recall risky products, as well as the responsibility of Member States to conduct market surveillance, facilitated by the Rapid Alert System (Safety Gate/RAPEX).

The pre-market duties of producers are threefold. They have a responsibility to:

- *Place only safe products on the market.* Products have to comply with the general safety requirements as set out above. Products that comply with a harmonized standard are presumed to be safe;
- *Inform consumers of any risks associated with the products they supply.* The aim is 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. This duty is also to be fulfilled when the product is put into circulation. It does not only relate to information on the proper use of the product (as described in user manuals), but also to risks that come, for example, with the age or the wear and tear of a product;
- *Safeguard traceability.* Make sure that any dangerous products present on the market can be traced and swiftly removed if necessary, to avoid putting consumers at risk.

Post-market control is imposed on producers and distributors[6] as well as on the competent authorities of the Member States. Post-market duties of *producers and distributors* are as follows:

- *Market observance.* According to Article 5(1) subparagraph 3 (a), producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to be informed of risks which these products might pose. Thus, they must observe the performance of their products on the market. The GPSD does not specify what exactly producers have to do to comply with this duty.
- *Establishment of a problem management system.* According to the same subparagraph, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to take appropriate action including, if necessary, to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers. Thus, producers must establish a management system that allows them to react speedily in the event of a product turning out to be unsafe. This duty does not only arise once the problem becomes apparent but it is of a preventive nature. The GPSD does not specify the necessary measures further.
- *Notification of risky products.* Producers and distributors are also required to immediately notify respective authorities in EU Member States in case they know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement (Article 5(3) GPSD).
- *Withdrawal from the market, warnings and recalls.* According to Article 5(1) subparagraph 5, producers shall withdraw unsafe products from the market, publish warnings of unsafe products or recall products from consumers on a voluntary basis or at the request of the competent authorities; whereby recalls should be the measure of last resort.
- *General duty to cooperate.* Generally, producers and distributors shall cooperate with the competent authorities on action taken to avoid the risks posed by products which they supply or have supplied. The relevant procedures are to be established at the national level.

These duties on businesses are complemented through a requirement for Member States under the GPSD to establish systematic approaches to perform effective market surveillance. Member States establish or nominate national authorities competent to monitor the compliance with product safety requirements and give necessary powers to these authorities to take appropriate measures under the GPSD. National market surveillance authorities have a responsibility to:

- Check whether products available on the market are safe;
- Ensure product safety legislation and rules are applied by manufacturers and other actors in the supply chain;
- Take appropriate action in case a dangerous product is detected on the market and notify it in Safety Gate/RAPEX (which provides notifications of dangerous harmonised and non-harmonised products).

Most market surveillance authorities in the Member States work on the basis of annual inspection programmes which take into account among others previous experiences and findings, products that are frequently notified through Safety Gate/RAPEX, and consumer complaints. If necessary, all Member States carry out controls and tests which

[6] Distributors are defined as "any professional in the supply chain whose activity does not affect the safety properties of a product" (Art. 2 GPSD).

are not necessarily foreseen in their programming, for example in emergency situations. To provide assistance to the EU Member States' product safety authorities, the Commission has co-funded more than 40 joint and coordinated actions on market surveillance among these authorities since 2007 (since 2018, Coordinated Activities on the Safety of Products or CASP).

4. Problem analysis

In this section we discuss major problems areas related to the current legislative framework, which were identified in the recent GPSD implementation study[7], outlined in the Roadmap/IIA[8] and further researched in the evaluation of the GPSD (see Part 1 of this study). The identified problem areas are as follows:

- Product safety challenges in the online sales channels;
- Product safety challenges linked to specific product risks, including due to the use of new technologies;
- Challenges related to the rules for market surveillance and standardisation;
- Insufficient effectiveness of recalls of consumer products;
- Inconsistent application of product safety rules for food-imitating products.

We first present the available data regarding the size of the problem, namely the occurrence of unsafe products on the EU market in general, as well as injuries and fatalities related to consumer products. We then describe the evidence regarding each problem area, discuss problem drivers, including those related to the current legislative framework, and elaborate on the likely future developments.

4.1. The size of the problem

Several indicators and data sources can be used to assess the size of the problem of unsafe products on the EU market. These include the following indicators/sources:

- Trends in the number of RAPEX notifications;
- Share of unsafe products found during market surveillance inspections;
- Data on product-related injuries;
- Assessment of consumers and stakeholders concerning the level of product safety achieved.

None of these indicators is without limitations, and to obtain an overall picture they have to be considered together.

Trends in the number of RAPEX notifications

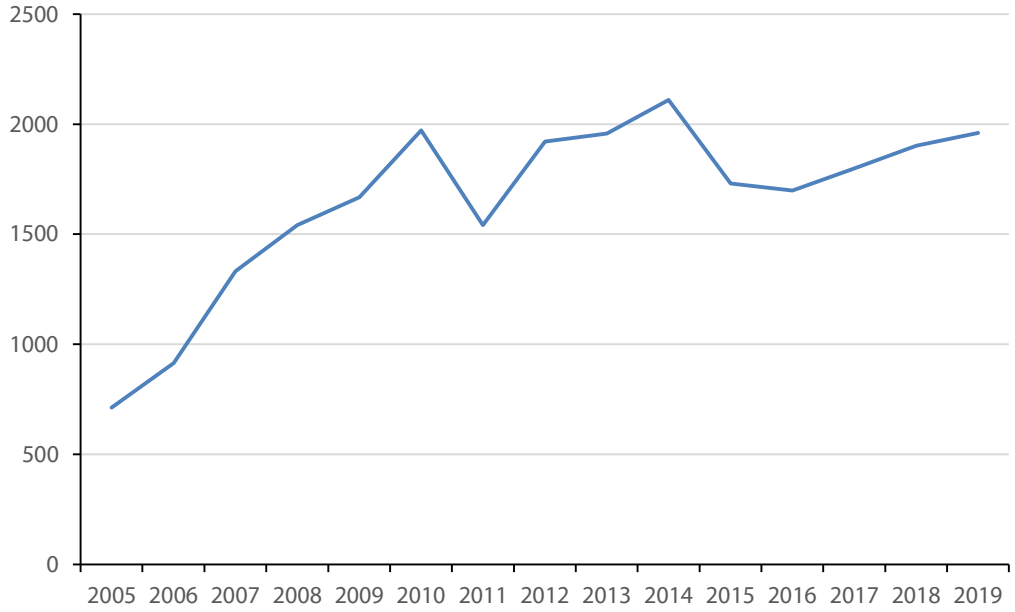
The first indicator is data from the rapid alert system for dangerous non-food products, published on the EU Safety Gate website[9]. The number of Art 12 notifications (products with serious risks) has steadily increased between 2005 (the start of the period for which the Safety Gate provides data) and 2010, and fluctuated thereafter between 1 550 to 2 100 notifications, as shown in Figure 2.

[7] See Civic Consulting 2020, Study for the preparation of an Implementation Report of the General Product Safety Directive, Final report (hereafter GPSD implementation study).

[8] Combined evaluation roadmap/Inception Impact Assessment ('Roadmap/IIA'), see link provided in footnote 156.

[9] The dataset used for the analysis of Safety Gate/RAPEX data covers a total of 25 850 notifications from 2005 to 2019 that are publicly available, downloaded from the EU Safety Gate in 2020. The dataset includes 25 051 notifications concerning products with serious risks, 738 notifications of products with other risk levels, and 61 other types of alerts. A small number of notifications concerning products with serious risks refer to professional products. The following analysis focuses on the 24 769 notifications concerning consumer products with serious risks, if not specified otherwise. Note that when using the statistical function on the Safety Gate, the resulting figures may differ, e.g. because notifications are included that are not yet publicly available.

Figure 2: Number of Safety Gate/RAPEX notifications concerning consumer products with serious risks (2005-2019)



Source: Civic Consulting, based on RAPEX notifications 2005-2019.

Notifications in the rapid alert system may concern products for which specific EU harmonisation legislation exists (harmonised products), and products for this is not the case. 30% of notifications (7 441) relate to product categories for which no harmonisation legislation exists and to which the GPSD therefore applies fully (non-harmonised products). During the last years notifications regarding motor vehicles have grown to account for approximately a quarter of notifications (from less than 200 per year at the beginning of the decade to about 460 annual notifications in 2019). As the total number of notifications has been relatively stable during this period, the number of Safety Gate/RAPEX notifications excluding vehicle recalls has declined since reaching a peak in 2014 (in which the total number of notifications concerning products presenting a serious risk to consumers was 1 926, excluding motor vehicles) to 2019 (in which this figure was 1 500).

Table 1 below presents data regarding the top ten ranked product categories that led to notifications in the period 2005 to 2019 (in total accounting for close to 90% of all notifications). Four of the ten categories refer to non-harmonised products (indicated in bold).

Table 1: Overall number of Safety Gate/RAPEX notifications concerning products presenting a serious risk to consumers, top ten product categories (2005-2019)

Product category	Number of notifications
Toys	6 610
Clothing, textiles and fashion items	**4 586**
Motor vehicles	3 311
Electrical appliances and equipment	2 384
Cosmetics	1 083
Childcare articles and children's equipment	**957**
Lighting equipment	948
Chemical products	574
Lighting chains	**497**
Hobby/sports equipment	**485**
Total	***21 435***

Source: Civic Consulting, based on Safety Gate/RAPEX notifications concerning products presenting a serious risk to consumers 2005-2019. **Bold** = **Non-harmonised** product category. Note that some lighting chains can fall under the scope of the Low Voltage Directive. In contrast, if electrical appliances and equipment do not fall under the Low Voltage Directive, the GPSD also applies fully. a) Includes 3 notifications for which no product category was specified.

Notifications may include information concerning the number of items that are being affected by the measures taken, e.g. the number of items that were rejected at the EU border, or the number of items that were recalled from the market. This information is part of the RAPEX notification that is only accessible for market surveillance authorities. For the purposes of this study, the European Commission provided an extract of this data, covering a twelve-month period from May 2019 to April 2020, and including information for a total of 536 notifications in which more than 1 000 items were affected. These notifications affected some 41.8 million items in total or 77 900 items per notification on average[10]. The largest number of items were registered for harmonised products such as motor vehicles and toys. Notifications that concern clearly non-harmonised product categories account for a total of 477 722 items in this twelve-month period (or about 1.1% of the total number). This comparatively low share of non-harmonised products for which the GPSD fully applies is mostly explained by the overwhelming importance in terms of affected items of a small number of product categories: The top category (motor vehicles) accounts for close to 28 million items (or 67% of total), and the top 5 categories account for a total of more than 40 million items (or 95.6% of total).

Due to data limitations, it is not possible to compare the number of affected items to the total numbers sold in the EU in the same product category, as consistent data regarding the latter is not available. In addition, the number and type of Safety Gate/RAPEX notifications in a given period depends on a variety of factors, such as inspection priorities of market surveillance authorities, differences in efficiency of market surveillance and market developments.

Share of unsafe products found during market surveillance inspections

The second indicator concerns the results of the inspections of consumer products by market surveillance authorities (MSAs) reported from 18 EU Member States. The share of dangerous products found by market surveillance authorities in their inspections

[10] Note that the total of 41.8 million items refers to the 536 notifications in which more than 1 000 items were affected. Notifications in which a lower number of items were affected are not considered. The overall total of items subject to notification in this 12 months period is therefore higher.

during the last year for which data was available (2018 or 2019) was frequently between 2% and 16% of total consumer products inspected, with the median value being 4%[11]. In some countries this share was much higher: from five countries it was reported that the share of dangerous products of total consumer products inspected was close to 20% or higher. However, the data has been reported from various sources according to different criteria, so that these figures have to be interpreted with care. As market surveillance authorities often sample according to risk-based criteria (i.e. focusing on risky products, conducting visual inspections to choose products for testing that can potentially be unsafe), this figure is not representative for the incidence of dangerous consumer products on the market[12]. On the other hand, the data presented above confirms the result of the joint and coordinated market surveillance actions, conducted by Member States' market surveillance authorities, and supported with funding by the European Commission. Most Coordinated Actions resulted in the identification of a significant number of non-compliant and/or dangerous products. While non-compliance rates were often 20% or more, the Coordinated Action reports repeatedly indicate that these high rates of non-compliance were not necessarily representative for the market, as non-random samples were taken[13].

Considerable shares of unsafe products are also observed by stakeholders. In the surveys for this study, we asked market surveillance authorities, companies/business associations and other stakeholders to provide their best estimate of the share of unsafe products on the market in their respective area of activity. Focusing on brick-and-mortar shops, the most frequent answer in all three stakeholder groups was that "unsafe products are relatively common (2% to 5% of products)", with respondents tending to see a higher incidence of unsafe products in the online sales channel (see below for more details).

Data on product-related injuries

The third important indicator for product safety trends is the number of product-related injuries, as collected through the European Injury Database (IDB). According to IDB data, an estimated 11 million non-fatal product-related injuries, in which consumers visited a hospital emergency department due to the injury, occur in the EU each year. In addition, approximately 8 632 fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurred on average in the EU27 outside of work-related locations - and not including transportation accidents - during the period 2013 to 2016 per year[14]. For a detailed discussion of product related injuries and the resulting consumer detriment in the EU, see section 7.3 below.

Assessment of consumers and stakeholders

To some extent, survey data can provide supporting evidence regarding product safety. EU data exists concerning the consumer perception of the level of product safety in the EU. The data derives from the Commission's regular surveys on consumer attitudes toward cross-border trade and consumer protection since 2008 (the last relevant survey was conducted in 2018). The survey results indicate that consumer trust in product safety in the EU has shown a slight increase over time, with the proportion of consumers agreeing that essentially all non-food products in their country are safe (or that only a small number are unsafe) increasing from 65% in 2008 to 78% in 2016, before decreasing again to 70% in 2018. The largest increase (9 percentage points) occurred

[11] The values of 2% to 16% provided above refer to the 1st and 3rd quartile of the data series (between which the middle 50% of the data lie). The median is the middle value, or 2nd quartile (also called 50th percentile).

[12] This risk-based approach also affects the type and number of RAPEX notifications, which may be influenced by changing priorities concerning which risks are considered by MSAs when conducting inspections.

[13] For a more detailed analysis, see GPSD implementation study, section 5.4.

[14] Fatalities are not included in the table. See Annex I for more details.

between the 2014 and 2016 surveys, before returning in 2018 to slightly above the 2014 level[15].

In complementary surveys and interviews conducted for the 2020 GPSD implementation study, market surveillance authorities (MSAs) and general stakeholders were asked to assess at a qualitative level how the level of safety improved in their country since 2013. The largest group of respondents (about 42% of MSAs and 39% of general stakeholders) considered the trend to be positive, i.e. suggested that safety of consumer products improved over this period. Only a small minority saw a negative trend (1%/7%)[16]. Roughly of equal size were the groups of respondents that either saw no clear general trend (level of safety largely unchanged, 15%/20%) or found that the trend depends on the product type or sales channel (16%/26%). Stakeholders that considered the safety trend to depend on product type or sales channel mostly referred to sales from online platforms, products directly sold from third countries and products with new technologies as being more problematic in terms of product safety.

Conclusions regarding the size of the problem

Notifications in Safety Gate/RAPEX, data from market surveillance authorities' regular inspections and the coordinated actions of Member States, as well as stakeholder assessments all confirm that dangerous products continue to enter and be available on the EU market, and can be purchased by consumers in all Member States. The number of notifications in the rapid alert system concerning consumer products with serious risks has fluctuated between 1 550 to 2 200 notifications during the last decade, with millions of items being affected each year. While there are some encouraging signs, such as improvements in product safety perceived by consumers and a plurality of stakeholders, and a slight downward trend in notifications if vehicle recalls are excluded, the available data shows that unsafe products continue to be common. Risk-based and therefore not representative inspections by market surveillance authorities find a median share of 4% of dangerous products on the market, with some countries reporting significantly higher shares (20% or higher)[17]. Dangerous products are found in both harmonised and non-harmonised product categories, with harmonised consumer products such as vehicles, toys, cosmetics and electrical appliances having larger shares in notifications and recalls, in line with their often higher level of complexity (e.g. vehicles), their inherent potential for harming consumers (e.g. electrical tools, cosmetics) and/or relevance for vulnerable consumers groups (e.g. toys). The available data on injuries in the EU shows that a substantial number of injuries of consumers occur that are related to – but not necessarily caused by – products, leading to a large detriment for EU consumers and society. As described in more detail in section 7.3 below, our analysis concluded that the preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at EUR 11.5 billion per year, when health care utilization costs, productivity losses, loss of quality of life for hospitalised cases, and the cost of premature death are considered.

The analysis also illustrates that reliable data on safety trends in terms of product related accidents is scarce. Detailed injury and mortality data used for the analysis is not easily accessible, and not provided in a format that could be used by manufacturers,

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15 See European Commission 2016 and 2018 survey of consumers' attitudes toward cross-border trade and consumer protection. Question text: Thinking about all non-food products currently on the market in (our country), do you think that...? / How strongly do you agree or disagree with each of the following statements. In (our country) … (Essentially all non-food products are safe / A small number of non-food products are unsafe). The percentages indicated in the text provide the proportion of consumers who either "Agree" or "Strongly agree" with these statements.

16 In the sub-category of consumer organisations/NGOs, the assessment was slightly more negative, with 20% of respondents seeing a negative trend. However, the percentage of respondents that saw a positive trend was similar to the overall group (at 40%).

17 This risk-based approach also affects the type and number of RAPEX notifications, which may be influenced by changing priorities concerning which risks are considered by MSAs when conducting inspections. For more details, see Part 1 of this report, EQ1.

market surveillance authorities, and policy makers[18]. Due to gaps and other limitations in the available data, a detailed analysis of products safety related trends on a year-by-year basis is only possible to a limited extent[19], although the available data confirms that the size of the problem is very considerable.

4.2. Product safety challenges in the online sales channels

The way products are sold to consumers have changed considerably over the last two decades, with online sales channels increasing in importance, new online business models emerging, and consumers gaining opportunity and trust to engage in cross-border shopping over the internet. This includes cross-border shopping in the EU, but also with non-EU/EEA countries. The effects of e-commerce, and especially online sales and direct imports by consumers from non-EU/EEA countries on the effectiveness of the GPSD has been a major point of concern by stakeholders and market surveillance authorities. This is in spite of the fact that in line with the broad, horizontal approach of the GPSD, the Directive covers consumer products regardless of the selling method, i.e. it applies equally to brick-and-mortar shops as well as to e-commerce (see EQ3, Part 1 of this report).

Development of e-commerce

In the EU, e-commerce via websites or apps (web sales) have steadily increased over the last decade. In 2019, web-sales accounted for 7% of turnover of EU enterprises. This figure includes sales to other businesses and to consumers carried out via websites or apps. At 3%, the share of turnover of EU enterprises from B2C web sales was slightly less than half of this amount (in 2019, average across all economic activities). In the retail sector (except motor vehicles and motorcycles), the share of B2C web sales was 7%, lower than for accommodation (19%) and information and communication (8%), and similar to transportation and storage (also 7%)[20].

In 2019, the share of B2C web sales in enterprises' turnover in the retail sector was highest in the Netherland (16%), the Czech Republic and UK (both 12%), as well as Denmark and Germany (8%). In absolute terms, the B2C e-commerce turnover in Europe was forecasted by E-commerce Europe (which represents companies selling goods and services online to consumers) to be EUR 621 billion in 2019, close to double the EUR 329 billion estimate for 2014[21]. Depending on the geographical scope and the market definition used, other sources provide lower figures: Statista estimated B2C

[18] For example, mortality data on Eurostat is only publicly available in aggregated format, and while data is grouped according to several public health relevant themes (such as transport accidents), mortality caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) is not one of them.

[19] The limitations of the available data can be illustrated by the following example: In Germany, the most recent mortality data shows that fatalities related to accidents involving electrical current (ICD-10 codes W85 to W87) increased in 2018 to 42 from the all-time low of 34 in 2016. The German VDE (*Verband der Elektrotechnik Elektronik und Informationstechnik e.V.*) presented in a press release its concern in this respect, indicating that a possible explanation is the increasing use of electrical chargers in bathrooms and the increasing direct online purchase of low-cost electrical appliances from outside the EU that do not comply with the applicable electrical safety standards. However, the available data concerning the circumstances of the accidents is very limited, and even the location of the accident (home or other location) was only available for half of the cases. It is also not yet clear whether the increase is indeed a reversal of the long-term decreasing trend (as recently as the year 2000, the number of these fatalities was 100, more than double the 2018 figure), or just a short-term deviation. At EU level, this type of analysis is even more difficult, as granular data according to specific ICD-10 codes is only available to a limited extent, and with several years of delay. See Annex I for more details. The VDE press release from 17.09.2020 is available under https://www.vde.com/de/presse/zahl-der-stromunfaelle-gestiegen

[20] Eurostat, Value of e-commerce sales [isoc_ec_evaln2]. Companies 10 persons employed or more.

[21] Ecommerce Europe, European Ecommerce Report (2019 edition). The geographical definition of Europe used by the report is wider than the EU, and covers the following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom.

e-commerce revenue in Europe (concerning the sale of physical goods via a digital channel to a private end user) for 2019 to be EUR 312 billion, up from EUR 260 billion in 2017[22].

Between 2014 and 2019, the number of internet users who bought or ordered goods or services for private use increased from 63% to 71%, in several EU Member States even to more than 80% (Denmark, Netherlands, Sweden and Germany)[23]. The main product categories bought over the Internet are clothes, household goods (e.g. furniture, toys), books, magazines, newspapers and electronic equipment. This indicates that non-harmonised products (for which the GPSD is fully applicable) such as clothing, sports goods and furniture are among the items most commonly purchased by consumers online, as are some harmonised products such as toys and electronic equipment (e.g. communication and media equipment, electrical appliances falling under the Low Voltage Directive).

As mentioned above, cross-border shopping is getting more relevant in the EU. While the largest group of e-shoppers made online purchases from sellers in their country (87% in 2019), this figure is down by 1 percentage point from 2014. In contrast, an increase can be observed for purchases from sellers in other EU countries (from 29% in 2014 to 35% in 2019) and from sellers outside the EU (from 17% in 2014 to 27% in 2019)[24]. Cross-border shopping is dominated by e-retailers in a relatively small number of countries that attract most consumers that want to shop abroad (hereafter 'e-commerce export countries'). According to a recent survey-based report on E-commerce in Europe 2019, this list of countries was topped in 2019 by China, UK, USA and Germany, with the importance of China increasing considerably over the last decade. Close to two thirds of cross-border shoppers indicated China as country from which they had purchased[25]. A survey conducted a year before came to similar conclusions: It concluded that the number of e-commerce export countries (with focus on B2C e-commerce) is relatively low, while most EU Member States tend to be importers of cross-border e-commerce purchases. In 23 of the 30 surveyed European countries (EU28 plus Norway and Iceland) China was the first ranked country from which the most recent online purchase abroad was ordered. In total, more than one third of e-shoppers (35%) declared that their most recent purchase abroad originated from an e-retailer located in China. The second most important non-EU/EEA country in which European consumers shopped online was the USA with a share of 7%. The main B2C e-commerce export countries in the EU were Germany and the UK (around 30% of e-shoppers' most recent cross-border purchases originated from e-retailers and marketplaces located in these countries)[26]. It is of interest to note that already a 2011

[22] Again, the geographical definition of Europe used by the report is wider than the EU and comprises a total of 44 countries, including the EU Member States, Norway, Iceland and the UK (which are by far the largest markets in the sample). In the Statista definition, the e-commerce market encompasses the sale of physical goods via a digital channel to a private end user (B2C). Incorporated in this definition are purchases via desktop computer (including notebooks and laptops) as well as purchases via mobile devices such as smartphones and tablets. The following are not included in the Statista definition of the e-commerce market: digitally distributed services, digital media downloads or streams, digitally distributed goods in B2B markets nor digital purchase or resale of used, defective or repaired goods (e-commerce and C2C). See https://www.statista.com/outlook/243/102/ecommerce/europe?currency=eur, last accessed on 29.07.2020.

[23] Eurostat (isoc_ec_ibuy)

[24] Eurostat (2020). E-commerce statistics for individuals - Statistics Explained. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=E-commerce_statistics_for_individuals&oldid=417477

[25] PostNord (2019). E-commerce in Europe 2019. Note that the report is based on interviews with a total of about 11 000 consumers in Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Spain, Sweden and the UK, and refers to these countries. PostNord is the name of a holding company owned by the Swedish and Danish state, which combines the two postal companies Posten AB and Post Danmark that were merged in 2009.

[26] WIK (2019). Development of Cross-border E-commerce through Parcel Delivery. https://ec.europa.eu/growth/sectors/postal-services/studies_en, p.49 to 51. The survey was conducted in 2018 and the relevant question covered 8212 consumers.

consumer market study conducted for the European Commission concluded that the same four countries were the main e-commerce export countries. However, the order was then quite different, with two European countries leading the list: Germany (from where 27% of EU cross-border online shoppers had purchased), UK (24%), USA (23%) and China (17%)[27]. The percentage values of the three surveys cannot directly be compared, due to differences in geographical scope and methodology. However, the results clearly show that while B2C e-commerce is becoming increasingly global, the importance of different e-commerce export countries has dramatically shifted over the last decade, with China becoming the undisputed number 1 destination for European e-shoppers when making purchases from abroad.

A key reason for this shift is the growing importance of online marketplaces. Between 56% (Denmark) and 98% (Italy) of surveyed e-shoppers have shopped online from marketplaces in the past year[28]. While several EU players are also among the top ranked online marketplaces (such as Allegro in Poland and Zalando in most covered EU countries), non-EU marketplaces such as Amazon, eBay, Wish, and Alibaba/Aliexpress play a decisive role. In all countries covered by the report, non-EU marketplaces took three of the top four places in terms of frequency of use by the surveyed consumers[29]. These marketplaces are an important tool for small and medium-sized e-retailers to expand internationally particularly not only from Europe but also from countries outside of Europe (including from Asia), as they support payment processes, localise marketing activities and may support logistical processes, including by offering fulfilment services aimed at reducing time of delivery[30]. Particularly traders from China have used this opportunity, also facilitated by the low postal rates for shipping from China[31]. For example, on the Amazon marketplaces based in Europe (Amazon.nl/de/es/fr/it/uk), the share of active sellers that are based in China is reportedly between 37% and 47%, with the share of Chinese sellers in the Top10000 sellers even being higher in some places (up to 57% for Amazon.es). The share of Top Amazon Sellers based in China across all sixteen Amazon marketplaces increased from 23% in January 2017 to 47% in December 2019[32], with the success of businesses from China being enabled by the use of fulfilment services[33].

While increasing, the share of e-commerce purchases of goods originating outside the EU was estimated at 5.6% of total retail e-commerce in the EU in 2015, accounting for

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27 Civic Consulting 2011, Consumer market study on the functioning of e-commerce and Internet marketing and selling techniques in the retail of goods, p. 35.

28 PostNord. (2019). E-commerce in Europe 2019. In this study, the term "marketplaces" referred to Amazon, Wish, eBay, Zalando, Etsy, Alibaba, JD, or Allegro. Also note the limitations in country coverage, see footnote 25.

29 See ibid, p54/55.

30 WIK. (2019). Development of Cross-border E-commerce through Parcel Delivery. P 35/36.

31 International shipments are governed by agreements under the Universal Postal Union (UPU), a UN agency. The UPU international agreements include rules capping the cross-border postal rates (terminal dues) that can be charged to the foreign sending postal company for inbound mail. As shipment prices for domestic e-retailers are not governed (or directly affected) by the UPU rules, the UPU influences the price differential between shipment options available to domestic vs foreign e-retailers. A recent study concluded that "after the necessary adjustments, the average fee for a domestic shipment in Finland is 46 per cent larger than the terminal dues on inbound mail. For Sweden, the differential is +57 per cent". See Copenhagen Economics (2019), International delivery prices: effects on national post an e-commerce - Impact of UPU terminal dues on Finland & Sweden. See also WIK. (2019). Development of Cross-border E-commerce through Parcel Delivery. More details on the agreement are available on the UPU website, www.upu.int.

32 Data from Marketplace Pulse for 2020, see: https://www.marketplacepulse.com/amazon/china-sellers, and https://www.marketplacepulse.com/marketplaces-year-in-review-2019#china, last accessed on 27.07.2020.

33 Fulfillment service providers are entities that provide services to other economic operators. They generally store products and, after receiving the orders, package the products and ship them to customers. They may also deal with returns, see European Commission (2017), Notice on the market surveillance of products sold online.

EUR 11.8 billion[34]. In the same year, the overall turnover of retail trade (except of motor vehicles and motorcycles) in the EU was EUR 2 842.9 billion[35]. This would imply that in 2015, e-commerce purchases of goods originating outside the EU were equivalent to about 0.4% of total retail turnover. This share is likely to have increased since then, in light of relative stable overall retail turnover[36] and increasing e-commerce with non-EU countries (see below).

In 2015, the number of parcels imported to the EU from third countries due to e-commerce purchases of EU consumers that do not exceed the customs threshold of EUR 150[37] was estimated by the European Commission to be 187 million consignments (see Table 2), for a total value of EUR 4.65 billion.

Table 2: Estimated volume and value of parcels imported to the EU from third countries due to B2C e-commerce purchases of EU consumers (2015)

Product category	Volume (million)	Value (billion Euro)
Small value consignments[a)]	144.07	2.97
Parcels between EUR 10-22 and EUR 150[b)]	43.22	1.69
Total	***187.29***	***4.65***

Adapted from European Commission SWD (2017) 466 final Part 3/4, p. 647/648. a) Updated estimate for 2015 by the European Commission, based on 2013 estimates from: EY (2015): Assessment of the application and impact of the VAT exemption for importation of small consignments. The 2013 figure of 115 million consignments has been increased in line with the growth in e-commerce. b) VAT is not due when the total value of all goods in a consignment (value not inclusive of customs duties or transport costs) is less than a threshold. The threshold may vary from EUR 10 to EUR 22. For goods with a value over this threshold, but not exceeding the customs threshold, VAT is due, but not customs duty.

No more recent data on parcels imported to the EU has been identified. While postal statistics on international parcel services is available for most EU countries, this concerns the sum of intra-EU traffic, and traffic with third countries, so that the number of parcels imported into the EU cannot be deducted. The data available for 20 of the EU28 countries shows a growth of 44% between 2015 and 2018 (total number of parcels for all countries)[38]. If this growth rate (which is for both intra EU and extra-EU parcel services) is applied to the figure estimated above for 2015, the resulting rough estimate

[34] This figure includes both B2C and B2B trade. See European Commission SWD(2017) 466 final Part 3/4, p. 644 and SWD(2015)274. Estimate based on the results of the "Consumer surveys identifying the main cross-border obstacles to the Digital Single Market and where they matter most", GfK, 2015, http://ec.europa.eu/consumers/consumer_evidence/market_studies/obstacles_dsm/docs/21.09_dsm_final_report.pdf. In another estimate concerning the same year, the value of e-commerce merchandise (online retail) purchased by European consumers and imported from outside Europe was estimated at EUR 10.8 billion. See Copenhagen Economics 2016, E-commerce imports into Europe: VAT and customs treatment, quoting Forrester (2015), Western European Online Cross-Border Retail Sales Forecast.

[35] See Eurostat, Annual enterprise statistics for special aggregates of activities (NACE Rev. 2) [sbs_na_sca_r2], last accessed on 30.07.2020.

[36] See e.g. SWD(2018) 236 final, Commission staff working document accompanying the Commission communication on a European retail sector fit for the 21st century, p. 10.

[37] The threshold indicates that customs duty is not due for goods, provided directly to the buyer when their value does not exceed 150 euros.

[38] See https://webgate.ec.europa.eu/grow/redisstat/databrowser/view/POST_CUBE1_X$POST_ITR_1/default/time?lang=en&category=GROW_CURRENT, data retrieved on 30.07.2020. The total volume of international inbound parcel services for the 20 EU Member States for which data was available was calculated for 2015 (756 million parcels) and 2018 (1086 million parcels), and the growth rate calculated on this basis. It is notable that the growth rate of 44% for the period 2015 to 2018 is similar to the growth rate of the number of online shoppers that purchased from sellers outside the EU (which increased from 18% to 26% of all online shoppers), see Eurostat, Internet purchases by individuals [isoc_ec_ibuy].

for 2018 would be 269 million parcels imported to the EU from third countries with a value of EUR 150 or less[39].

Implications of e-commerce for product safety

E-commerce poses challenges for market surveillance and enforcement of the GPSD and other product safety legislation in the Member States. In our surveys, a key problem for market surveillance identified by MSAs and general stakeholders concerned online markets, and in this context specifically B2C transactions with operators in non-EU/EEA countries, in which products from those countries are delivered on an individual basis. The lack of effective control of product safety at the borders was emphasised by several MSAs and business and consumer stakeholders, but also issues of jurisdiction and practical difficulties in establishing the identity and the location of a trader in non-EU/EEA countries were considered to be problems[40]. In the following we provide the available evidence concerning the safety of products sold online, including with respect to their traceability.

In light of the growth in B2C e-commerce it is not surprising that the number of Safety Gate/RAPEX notifications of products that are (also) sold online is increasing. Table 3 below provides data on notifications that refer to the online sales channels for the years 2018 and 2019 (for previous years, this information is not available). Almost all notifications concern products with serious risk (94%). Only 29 of the notifications with sales channel online indicated concern products with less-than-serious risk or other types of alerts.

Table 3: Total number of notifications and number of notifications indicating that product has been available online 2018 – 2019

	2018	2019
Number of notifications, total	2 064	2 159
Of which notifications of products with sales channel online indicated	95	210
Share of notifications of products with sales channel online indicated	4.6%	9.7%

Source: Civic Consulting, based on Safety Gate/RAPEX data. Notes: The sales channel online has been indicated since 2018. Provided is the number of alerts in which the description contained the term 'online'. It therefore includes products that were "sold online" or "(also) sold online". The actual share of products (also) sold online is likely higher, as not all MS responsible for a notification provide this information.

The table above shows that approximately 5% of all notifications in 2018 concerned products purchased from an online trader. This figure doubled to almost 10% in 2019. Main categories of notified products that were (also) sold online were toys (33%) and electrical products (24%).

As indicated before, the frequency of Safety Gate/RAPEX notifications is influenced by a variety of factors, and can therefore not indicate whether products in a particular sales channel tend to be more often safe or unsafe than products sold in other sales channels. In the surveys for this study, we therefore asked market surveillance authorities, companies/business associations and other stakeholders to provide their best estimate

[39] An increase of international e-commerce shipments is also experienced in other jurisdictions. The US Consumer Product Safety Commission (CPSC) stated in a recent report that in 2018 an estimated 36 million shipments were e-commerce purchases under its jurisdiction. That number is expected to rise to 60 million in 2023. The estimates do not account for e-commerce that arrives via international mail. U.S. Customs and Border Protection (CBP) estimates that 475 million total mail shipments arrived in the United States in 2018. See United States Consumer Product Safety Commission, Office of Import Surveillance, CPSC e-Commerce Assessment Report, November 2019.

[40] See GPSD implementation study.

of the share of unsafe products on the market in their respective area of activity, both for consumer products sold in brick-and-mortar shops and for consumer product sold online by traders targeting consumers in their country. The average assessment for each stakeholder group is presented in Table 4.

Table 4: In your view, what is the best estimate of the share of unsafe products on the market in your area of activity (i.e. the estimated number of unsafe products per 100 products sold on the market)? – average assessment by stakeholders

Sales channel	Companies/ Business associations	Authorities	Other stakeholders	Average
Brick-and-mortar shops	3%	4%	5%	**4%**
Online	10%	7%	10%	**9%**

Source: Civic Consulting surveys of authorities, businesses, business organisations and other stakeholders. Average assessments by stakeholder group, not considering responses of 'Don't know/no answer'. Each respondent provided an assessment on the following scale: Almost impossible to find unsafe products (0.01% or less of products); Difficult to find unsafe products (0.1% of products); One has to search to find unsafe products (1% of products); Unsafe products are relatively common (2% to 5% of products); Easy to find unsafe products (10% of products); Very easy to find unsafe products (15% or more of products). Assessments were averaged on basis of the mid-point of the percentage ranges provided. An estimated incidence of "0.01% or less" was included with the value of 0.1%, and "15% or more" with the value of 15%, when calculating the average. For detailed results by stakeholder group, see Annex. N=153. Note: The average figures are calculated based on 100 (brick-and-mortar)/105 (online) stakeholders that had an opinion (53/48 indicated Don't know or provided no answer).

The results clearly show that respondents tended to see a higher incidence of unsafe products in the online sales channel[41]. However, authorities and other stakeholders often provided very differentiated answers in the surveys conducted for this study and in complementary interviews during our case studies, which show a more complex picture than the average values would indicate. For example, an interviewee from a market surveillance authority stated that "most of the economic operators have become pretty skilled when it comes to placing products on the market, in particular those who have a valuable brand to protect. The biggest issues are found with the small 'occasional' sellers without a brand name." The Authority conducted a campaign in 2019 concerning Christmas lighting. Here, no significant difference was seen between the conformity level of online and offline traders.

Some authorities have specifically controlled online marketplaces, e.g. in France. The DGCCRF reports that specific control plans on the safety of products sold on Internet marketplaces in 2018 and 2019 have on average found 25% of dangerous products. The level of dangerous products reportedly varied a lot depending on the product category: high rates of dangerous products were found for example in low priced jewellery (74%) and some electrical products (66%), while for toys it was 21% and for leather articles 10%. The situation may also vary greatly considering the marketplace on which the samples were taken (in 2018, ranging for example from 22% to 50% of dangerous products). The authority concluded that it found a significantly higher share of unsafe products on online marketplaces compared to products sampled across all distribution channels. On average, the share of dangerous non-food products found in DGCCRF samples was 13% (average data for 2019).

[41] This is also confirmed by the most frequent assessment chosen for each sales channel: For 'brick-and-mortar' shops the most frequent assessment was 'Unsafe products are relatively common (2% to 5% of products)', which was chosen by 31 of the 100 respondents that had an opinion in this respect. In contrast, for 'online' shops the most frequent assessment was 'Very easy to find unsafe products (15% or more of products)', which was chosen by 49 of the 103 respondents.

Previous research has indicated that products that have been banned by authorities or by economic operators have in some cases continued to be sold by e-retailers. In a follow-up question, we therefore asked whether survey respondents have observed that recalled products continued to be sold or reappeared on the market, again considering both brick-and-mortar shops and online traders. The answers are presented in Table 5:

Table 5: Have you observed that recalled products continued to be sold or reappeared on the market? Please consider both brick-and-mortar shops and online traders – assessment by stakeholders (average of all stakeholder groups)

Answer	In brick-and-mortar shops in your country	Online by traders targeting consumers in your country
Yes	20%	37%
No	34%	17%
Don't know/No answer	46%	46%

Source: Civic Consulting surveys of authorities, businesses, business organisations and other stakeholders. Total of all stakeholder groups. For detailed results by stakeholder group, see Annex. N=153

While a large group of respondents could not provide an assessment, the percentage of respondents having observed recalled products that were continued to be sold or reappeared on the market online (37%) is considerably more frequent than the percentage of those that have made a similar observation regarding brick-and-mortar shops (20%). This assessment was consistent across all stakeholder groups, although other stakeholders and authorities saw a less significant difference between sales channels than businesses.

There has also been research conducted concerning the incidence of recalled products online. In 2015, the OECD conducted a sweep, in which 25 countries including 15 EU Member States[42] undertook a coordinated inspection of 1 709 products sold online[43]. One of the focus points of the exercise was whether banned or recalled products were available online. 693 products were inspected for the purpose of detecting banned and recalled products. In each jurisdiction, a wide variety of banned and recalled products were identified, including small high-powered magnets, sky lanterns and novelty lighters. More than two-thirds (68%) of these products were available for sale in the participating jurisdictions. During the OECD sweep, 136 products were inspected for the purpose of identifying products that do not meet voluntary or mandatory safety standards. Among those products, as much as 76 products were examined online, while 60 additional products were purchased and tested. These included bunk beds and lighters. Among the 136 products, about one-fourth (26%) were assessed as compliant with relevant voluntary or mandatory product safety standards and more than half (54%) were assessed as not complying to such standards. It is notable that the OECD sweep revealed a much higher rate of non-compliance with safety standards at cross-border level (44% at domestic level; and 88% at cross-border level[44]). In contrast, with respect to banned and recalled products, the magnitude of problems encountered was

[42] Austria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungry, Latvia, Malta, Poland, Portugal, Slovenia, Spain, and Sweden.

[43] All results quoted from OECD (2016-11-03), "Online Product Safety: Trends and Challenges", OECD Digital Economy Papers, No. 261, OECD Publishing, Paris. http://dx.doi.org/10.1787/5jlnb5q93jlt-en

[44] Non-compliance rates measured by determining what number of inspected products were assessed as non-compliant or partially compliant.

relatively similar at domestic and cross-border levels (affecting about 70% of inspected products[45]).

More recent research focused specifically on products available from online marketplaces, focusing on product categories where non-compliances are frequent. The Danish Chamber of Commerce (*Dansk Erhverv*) purchased 50 products, mainly toys, from third party sellers on the three large online platforms Wish, Alibaba and Amazon and found that almost none of the selected products complied with EU product safety law, including the Toy Safety Directive[46]. In early 2020, the European consumer organisation BEUC released a press release in which it described the findings of a study for which six consumer groups from the BEUC network tested 250 electrical goods, toys, cosmetics and other products bought from online marketplaces such as Amazon, AliExpress, eBay and Wish. Two thirds of the selected products (66%) did not meet the European safety requirements, according to the press release[47]. The non-compliances included:

- Power banks and chargers that can overheat or cause electric shock.
- Plastic toys with phthalates.
- Children's clothing with long cords or drawstrings.
- Smoke and CO alarms that did not detect deadly concentrations of the gas.
- Teeth whiteners containing excessive amounts of hydrogen peroxide.

These results of both studies support the other evidence provided above. When interpreting the research presented in the previous paragraphs, it is important to recall that all quoted studies are based on risk-based sampling, i.e. they focused on products with a high probability for having non-compliances. While this is a standard approach used by market surveillance authorities, it means that results are not necessarily representative of the overall market, but provide insights into specific problem areas. While these problems clearly seem to exist with the tested product groups sold online, especially by third-party traders on online marketplaces, significant problems have also been reported with specific types of sellers in the 'offline' environment[48].

Tracing of products sold online

Notified products that were sold online are more likely to lack specific information items that are essential to trace them (manufacturer, brand, type/model, batch number/barcode), as Table 6 below with data from Safety Gate/RAPEX illustrates. Table 6 provides data on online sales channels for the years 2018 and 2019 (for previous years, this information is not available). The table shows that while the overall share of notifications in which 'sold online' is indicated is 7% (average 2018/2019), the share of products 'sold online' among products in which one of the four information items was

[45] Non-compliance rates measured by determining what number of suppliers would supply banned and recalled products to the participants.

[46] Dansk Erhverv, memos, provided to the European Commission.

[47] Press release "Two-thirds of 250 products bought from online marketplaces fail safety tests, consumer groups find", can be downloaded from https://www.beuc.eu/publications/two-thirds-250-products-bought-online-marketplaces-fail-safety-tests-consumer-groups/html. The tests were conducted through the International Consumer Research and Testing (ICRT) network, on behalf of a consortium led by Test Achats/Test Aankoop (Belgium) and which includes Altroconsumo (Italy), Consumentenbond (Netherlands), Forbrugerrådet Tænk (Denmark), Stiftung Warentest (Germany) and Which? (United Kingdom). DECO (Portugal) and OCU (Spain) are also publishing the results.

[48] For example, in the GPSD implementation study, it is reported that MSAs from several countries and other stakeholders frequently referred to the problem of rogue traders. According to the Czech authorities, issues related to traceability and emerging safety issues in this country are mainly connected with non-EU/EEA products and dangerous products sold by smaller rogue firms in markets. 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. See GPSD implementation study, p. 33.

missing was between 11% and 17% (depending on the item), i.e. the share of products sold online was roughly twice as high among notified products lacking the information, indicating that such products were more likely to miss a relevant information item essential to trace the product. Interestingly, the share of products 'sold online' was even higher among notifications where all four information items were missing, namely 67% (or 35 of 52 such alerts in the two-year period).

Table 6: Number and share of Safety Gate/RAPEX notifications concerning unsafe consumer products with unknown product information items (by sales channel, 2018-2019)

	Total number of notifications	Number of notifications regarding products not indicating 'online'	Number of notifications regarding products indicating 'online'	Share of notifications regarding products indicating 'online'
Total number of notifications for consumer products 2018-19	3 864	3 590	274	7%
Notifications in which information item is missing:				
- No manufacturer[d)]	1437	1 280	157	11%
- No brand[a)]	800	700	100	13%
- No type/model[c)]	531	451	80	15%
- No batch number/barcode[b)]	805	667	138	17%
- None of the four	52	17	35	67%

Source: Civic Consulting. Based on Safety Gate/RAPEX data, number of alerts concerning consumer products with serious risks (2018-2019). Notes: The sales channel online has been indicated since 2018. The column 'online' contains the number of alerts in which the description contained the term 'online'. It therefore includes products that were "sold online" or "(also) sold online". a) Brand 'unknown' or database field blank b) Batch number/barcode 'unknown' or field blank c) Type/model 'unknown' or field blank. d) Information on manufacturer 'No', N/A or field blank.

A large number of stakeholders and several MSAs again identified particular problems with online marketplaces. For example, in Spain, authorities noted that it is increasingly common to find alerted or potentially unsafe products offered on online marketplaces where an identification of sellers is not always possible, and also from France it was reported that there have been many difficulties concerning traceability with respect to products purchased via online platforms[49]. A related issue for market surveillance authorities noted by the French authorities is that online platforms are often the entities which hold the most relevant information to be able to organise recalls effectively (e.g. customer names and contact details)[50].

Sampling and testing of products sold online

Another problem related to products sold online is the sampling and testing of unsafe products sold online. Traditionally, market surveillance officers have collected products for testing purposes in shops. Today, many products are not sold in stationary shops at all but only online; which makes it more difficult for market surveillance authorities to get hold of samples. The established way of retrieving samples of products would be mystery shopping (i.e. the purchase of products under a cover identity for subsequent testing); which is however subject to legal as well as financial limitations in Member States. In terms of legal limitations, mystery shopping is not an explicit competence of market surveillance authorities that is required by the GPSD, and it is not an explicit

[49] See GPSD implementation study, country reports Spain and France.

[50] See GPSD implementation study, country reports France and Spain.

competence of many market surveillance authorities at the national level[51]. Moreover, mystery shopping entails financial risks. Where samples from shops can usually be seized free of charge, products bought by way of mystery shopping must be paid; which causes problems for market surveillance authorities with low budgets. A related practical problem is the lack of a credit card of the MSA to conduct online purchases. Another practical difficulty for MSAs is to hide their identity when making mystery purchases, for example, by creating a new web or postal address. In some cases, there are also explicit rules that require officials to disclose their identity when conducting inspections; which defeats the very idea of mystery shopping.

Where products are directly sent from third countries to consumers, the only other way to detect unsafe products is at customs. Customs has a key role in safeguarding the safety of consumer products on EU/EEA markets, as a large share of dangerous products notified on Safety Gate/RAPEX originate in non-EU/EEA countries (accounting in 2018 for 76% of notifications)[52]. The capacities of customs authorities are, however, limited, in particular when it comes to small consignments that are typical for the direct delivery to consumers of products from third countries.

Measures taken so far

Multiple measures have been taken with respect to online sales channels by the European Commission and market surveillance authorities, reaching from the clarification of the complex legal situation regarding online market surveillance, specific enforcement actions at national level in some Member States, and measures financed under the EU Consumer Programme. A notable attempt in this respect is also the Product Safety Pledge, where so far seven online marketplaces have voluntarily committed to take action, among other things, in respect to unsafe products notified in Safety Gate/RAPEX or when informed by MSAs. In our interviews, several authorities considered the Pledge to be useful tool, especially as it provided a functioning and clear communication channel with the covered online platforms. In the surveys conducted for this study, all stakeholder groups were asked to assess the Product Safety Pledge in terms of its effectiveness. While market surveillance authorities considered it on average to be moderately effective, companies, business associations and other stakeholders found the Pledge to be clearly less than moderately effective (see Annex of Part 1 of this report with survey results). Reasons include the limited number of platforms covered by the Pledge, and its voluntary nature.

Conclusion on the extent to which e-commerce leads to product safety challenges and likely future trends

The analysis presented in the previous sub-sections shows that e-commerce has rapidly gained importance globally and in the EU. Major shifts have happened over the last decade, with more e-commerce crossing borders, and China emerging as the main destination of EU consumers that purchase goods online from abroad. This shift was facilitated by online platforms and low shipping rates[53], which reduce the transaction costs for e-retailers and their customers. While the importance of cross-border e-commerce with non-EU countries is still limited in absolute terms (accounting for less than one percent of retail turnover[54]), this share is increasing. E-commerce traffic to the EU from third countries due to purchases by EU consumers comprises already now

[51] Reported e.g. from Austria, Bulgaria, Denmark, Iceland. In Poland, the OCCP can 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. In Germany, the power to conduct mystery shopping is not explicitly mentioned in the legal basis (the ProdSG). See relevant country reports in the GPSD implementation study.

[52] See RAPEX annual report 2018.

[53] See footnote 31, above.

[54] Based on 2015 data, e-commerce purchases of goods originating outside the EU were estimated to be equivalent to about 0.4% of total retail turnover. This share is likely to have increased since then, see above for more details.

several hundred million parcels every year (with a rough estimate of 269 million e-commerce parcels imported to the EU from third countries in 2018 with a value of EUR 150 or less elaborated for this study, see above).

Both market surveillance authorities and other stakeholders find that sales by third parties on online marketplaces pose specific problems in terms of product safety and the effectiveness of the GPSD, which relate to the (re-)emergence of recalled and unsafe products, the lack of traceability information and the lack of effective control of product safety at EU borders. Their view is supported by the available research conducted by the OECD and stakeholder organisations, and results of research in Member States[55].

In conclusion, the combination of the increase of online trade generally, the higher share of unsafe products in the online sales channels (as observed by stakeholders) and the specific enforcement problems related to products sold online have opened a gap in the system of product safety established by the GPSD. This is in spite of the multiple measures that have been taken by the European Commission and market surveillance authorities, reaching from the clarification of the complex legal situation regarding online market surveillance, to measures financed under the Consumer Programme and to the voluntary commitments of selected online marketplaces under the Product Safety Pledge. While the Product Safety Pledge is a clear improvement compared to the previous situation, and it could be expected that over the years more online platforms will join the pledge, a key limitation will remain: The Product Safety Pledge is unlikely to cover all online platforms targeting EU consumers, and due to its voluntary nature it cannot provide legal certainty as it is not legally binding.

It is notable that the online environment also brings certain improvements, as it allows a better tracing of customers for recalls (due to availability of customer data in the online environment), and makes it possible to use electronic tools (web-crawlers) for market surveillance. While these improvements and the previously mentioned measures likely had beneficial effects, where they have been applied, they have not been able to change the trajectory described above: Via cross-border e-commerce with non-EU countries, and facilitated by online platforms, a growing flow of consumer products (both those falling under the GPSD and those falling under harmonised legislation) enters the EU market, which is not effectively controlled, includes unsafe and recalled products, with traders and products being often not traceable. While these problems also do occur in the 'offline' environment (e.g. facilitated by rogue traders or businesses that lack knowledge and awareness concerning product safety rules), they are more relevant in the online environment. Also, due to the direct relationship between e-retailers in non-EU countries and EU consumers, no intermediaries are involved that would have responsibilities for ensuring or monitoring product safety and could therefore act as gatekeepers that prevent unsafe products from reaching the market (as is often the role of EU importers and retailers).

In the future, this trend is likely to continue. While the COVID-19 pandemic is expected to lead to declines in overall retail sales, e-commerce sales are expected to increase by 16.9% in 2020 in Western Europe[56]. The boost in new spending is expected to leave e-commerce permanently ahead of its previous pace, with higher sales figures than it otherwise would have through 2023. According to the estimate, retail e-commerce will account for 13.8% of total retail in 2023[57].

Taking into account the growth in cross-border e-commerce over the last years, it appears likely that the number of small consignments entering the EU from abroad will

[55] See GPSD implementation study.

[56] See: https://www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected

[57] Ibid.

continue to grow[58]. While several changes will be implemented in 2021 that will affect the costs of cross-border e-commerce (such as the change in the VAT regime, as well as expected changes in postal rates for shipping from China[59]), it is unlikely that this will change the long-term trajectory. In a recent survey conducted by the International Post Corporation, respondents who had bought online from China in the past year were asked what they would do if the cost of their purchases from China increased due to higher taxation by EUR 10 per item. The report on the survey elaborates that this new question was asked in anticipation of European Union changes to VAT and customs legislation for low-cost items coming from China, and was also reflecting possible higher postal delivery costs for future Chinese purchases. Only about a third of respondents indicated that they would stop buying from China altogether (36%), while 41% would buy slightly less, and 13% would have no change to their purchase activity (10% did not know)[60]. A particular effect of the COVID-19 crises, the decline in global air cargo capacity[61] and the related increase in international air freight costs, are also unlikely to change the trend in the mid-to long term. This is due to the expected rebound of international passenger air travel (which is essential for air cargo capacity) after the end of the pandemic and also because other modes of transport continue to be developed, including train transport from Asia[62].

4.3. Product safety challenges linked to specific product risks, including due to the use of new technologies

Since the GPSD was adopted in 2001, new types of products have entered the market, or are about to enter the market, which have changed our understanding of what products are and how they function, blurring in some cases the borderline between goods and services. While the GPSD is technology-neutral, i.e. the general safety requirement applies independent from which technology is used in a consumer product, in practice the effects of new technologies on GPSD effectiveness can be manifold. This is because the coverage of the GPSD depends on the interpretation of key notions, such as "safety" and "product", which may be ambiguous for certain new technologies, and therefore create difficulties for the application of the GPSD and market surveillance, as elaborated below. At the same time, product safety was traditionally understood to be

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58 See GPSD implementation study. Note, however, that a recent study by the Committee for the Coordination of Statistical Activities (CCSA), which is situated at the United Nations Statistics Division, on the consequences of the COVID-19 crisis concluded that "overall, even if domestically the demand for deliveries and online sales has surged, international mail has been decreasing. Estimates gathered from high-frequency data indicate that the drop of international mail due to the emergence of the pandemic is 23%. This is just one of the symptoms of the extent to which COVID-19 has impacted international economic flows". See CCSA 2020, How COVID-19 is changing the world: a statistical perspective. However, it appears unlikely that this drop of the volume of international mail will affect the long-term trend, which is clearly the increase in cross-border shopping.

59 See footnote 31. Note that this situation is changing, as new VAT rules will apply due to the VAT e-commerce package. Wheras previously VAT was only levied on shipments from outside the EU with a value above EUR 22, as from July 1, 2021, the VAT amount needs to be applied as from EUR 0. Also, the Universal Postal Union (UPU) will change the applicable rules by implementing a new system, known as "Option V". Under the new rules, within 5 years, postal operators within the UPU can increase gradually the rates applying for intercontinental postal shipments. See https://ec.europa.eu/taxation_customs/business/vat/modernising-vat-cross-border-ecommerce_en, and https://www.upu.int/en/Publications/Factsheets-backgrounders/5-things-to-know-about-Option-V

60 2019 IPC Cross-Border E-Commerce Shopper Survey, p12. See https://www.ipc.be/sector-data/e-commerce/cross-border-e-commerce-shopper-survey

61 See e.g. https://www.accenture.com/us-en/insights/travel/coronavirus-air-cargo-capacity and

62 According to Chinadaily, the eastern Chinese city of Yiwu handled 1.47 million consignments of cross-border parcels in April 2020, up 867 percent year-on-year. The China-Europe freight train service, which was launched in Yiwu in 2014, has provided a new channel for the transportation of international mail amid the COVID-19 pandemic. After the epidemic broke out, due to the falling number of international cargo flights, many cross-border e-commerce sellers chose to transfer some goods to Yiwu and transport them to Europe via freight trains. The Article quotes a customs official that the number of parcels exported each day rose from 10 000 to 20 000 consignments of parcels to more than 50 000 amid the pandemic. See www.chinadaily.com.cn/a/202005/08/WS5eb4e881a310a8b2411543b1.html

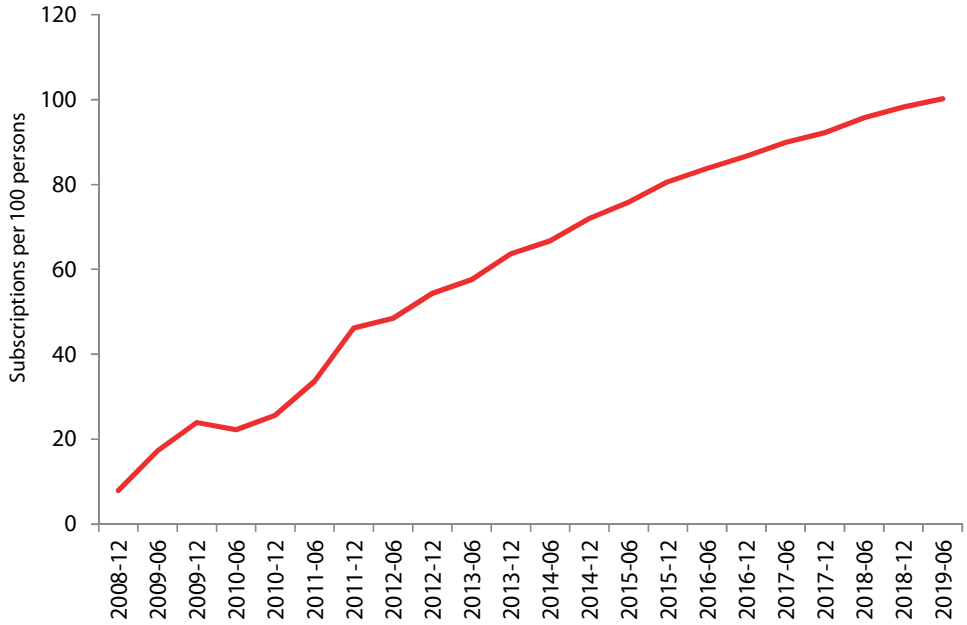
related to physical health and safety. This continues to be a highly relevant category, and certainly the most relevant. Recent societal and technological developments have, however, added, or may in the near future add new risks of products that could be considered under product safety law. In addition, a number of risks would seem to be currently covered by the GPSD only where they can, indirectly, result in damage for health and safety. This includes certain risks related to new technologies (e.g. cybersecurity risks) as well as environmental risks.

The implications of new technologies for product safety

While 'new technologies' is a very broad concept, the term is here used for referring to digital technologies, such as Internet of Things (IoT), autonomous vehicles/drones, artificial intelligence (AI)/machine learning, robotics, 3D-printing, augmented reality (AR)/virtual reality (VR) etc. These technologies are often interrelated, in that several of the listed technologies are used at the same time. For example, an autonomous vehicle will typically be linked to the internet (so be part of the Internet of Things), and may use pattern recognition algorithms that apply or are based on artificial intelligence/machine learning.

Consumer products that are connected to the internet and use or potentially use artificial intelligence are ubiquitous in the form of mobile phones, tablets and computers that are connected to the internet, most of which also use software-based AI systems such as voice assistants, image analysis software, search engines, speech and face recognition. Due to the broad application of software-based AI systems in mobile devices that are connected to the internet, mobile broadband take-up can be used as an indicator for this development. According to the Digital Economy and Society Index 2020, there are 100.2 active mobile broadband SIM cards per 100 people in the EU.

Figure 3: Mobile broadband penetration in the EU (subscriptions per 100 people), 2008 to 2019



Source: COCOM, European Commission, Digital Economy and Society Index (DESI) 2020. Data retrieved from https://digital-agenda-data.eu/datasets/digital_agenda_scoreboard_key_indicators/visualizations

The mobile broadband penetration rate more than doubled over the last 7 years (from 48% in mid-2012), and increased fivefold over the last 10 years (from less than 20% in mid-2009). In some countries (Poland, the Nordic countries, Estonia, Latvia and Luxembourg) there are already more than 120 subscriptions per 100 people, while in Hungary the take-up rate is the lowest, with 70 subscriptions per 100 people. Most mobile broadband subscriptions are used on smartphones rather than on tablets or notebooks[63]. Considering only connected IoT devices, the increase since 2014 is also considerable. These devices include connected cars, machines, meters, sensors, point-of-sale terminals, consumer electronics and wearables. There were around 1.5 billion IoT devices with cellular connections worldwide at the end of 2019, up from 245 million in 2014[64].

The increase in IoT devices and the use of artificial intelligence has led to challenges to product safety[65]:

- **Connectivity** is challenging the traditional concept of safety, as connectivity may directly compromise the safety of the product and indirectly when it can be hacked leading to security threats and affecting the safety of users;

- A certain degree of **autonomy** in the execution of tasks is one of the features of many AI applications. AI based unintended outcomes could cause harm to the users and exposed persons;

- **Data dependency** is considered an essential characteristic of AI-based products and systems. Data **accuracy** and **relevance** is essential to ensure that AI based systems and products take the decisions as intended by the producer;

- **Opacity** may result from the fact that for some of the AI based products and systems, the rules governing the functions of the product or system are not explicitly programmed, but generated by automated means. This may lead to a decision-making process of the system difficult to trace ('black box-effect');

- **Complexity** of the products and systems may impact safety, as various components, devices and products can be integrated and have influence on each other's functioning (e.g. products that are part of a smart home ecosystem).

Complex systems often involve software, which when updated could substantially modify the product in which it is downloaded.

While these are clearly identifiable challenges, the number of practical cases in which these new technologies are relevant in a consumer safety perspective appear to be limited so far, according to the evidence collected for this study. Only two relevant Safety Gate/RAPEX notifications have been identified – a smart watch for children (lacking a minimum level of security), and a passenger car in which the radio in the vehicle may have certain software security gaps allowing unauthorised third-party access to the interconnected control systems in the vehicle (RAPEX notifications A12/0157/19 and A12/1671/15). During the interviews conducted with non-EU/EEA market surveillance authorities, few additional examples could be identified so far: One concerned an internet connected sensor for carbon monoxide, which malfunctioned (but not due to the fact that is was connected to the internet), and a mobile phone which would not properly call the emergency phone number (and was recalled for this reason).

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63 European Commission, Digital Economy and Society Index (DESI) 2020, Connectivity, p18/19.

64 Ericsson Mobility Report, June 2020.

65 This summary is to a large extent based on the report by the European Commission, Report on safety and liability implications of AI, the Internet of Things and Robotics, COM(2020) 64 final, pp 5-11.

Other examples for safety and/or security concerns related to digital technologies, and in particular regarding connected consumer products that are documented include:

- The doll 'My Friend Cayla', a connected toy using speech recognition technology. The doll was removed from the market in countries such as Germany due to security concerns[66]. It was argued that the child's security was placed at risk due to a security breach, as a stranger could speak to the child through a Bluetooth connection;
- Several consumer groups asked ethical hackers to test smart home appliances, and frequently found flaws. In one case the hackers managed to install a malicious app on a children's tablet in less than a minute. This allowed them to monitor the images of the tablet's camera, eavesdrop through its microphone and control its Internet browser function. Another example concerned wireless cameras that hackers were able to manoeuvre, allowing them to monitor activity in the house[67].

When considering the effects of new technologies, several aspects are relevant. These are:

- Coverage of software as product under the GPSD;
- Definition of safety in the GPSD;
- Effects of AI use, including machine learning after placing of products on the market;
- Market surveillance of products containing new technologies.

These aspects are elaborated in more detail in the following paragraphs.

As software is at the core of new digital technologies, a key uncertainty is to what extent software updates and standalone software are considered products under the GPSD. The GPSD only applies to "products", and the extent to which this includes software is currently not fully clear. While it is obvious that products with embedded software lie within the scope of application of the GPSD, the leading interpretation for most Member States of the current regime is that stand-alone software is not covered by the GPSD[68]. Stand-alone software includes updates for software that is embedded in a product. The general opinion appears to be that safety problems related to subsequently embedded software are thus neither attributed to the software producer nor to the producer of the product that is later upgraded[69]. Only in a few Member States, the malfunctioning of non-embedded software in a product (e.g. downloadable as application) appears to be covered by the national legislation implementing the GPSD[70]. This certainly leaves a gap, as not only smart products become ever more frequent on the market but also the separation between the producer of the "hardware" and the provider of related software.

Art. 2(b) of the GPSD provides that "safe product" shall mean "any product which, under normal or reasonably foreseeable conditions of use including duration and, where

66 See e.g. www.bbc.com/news/world-europe-39002142.

67 BEUC, FACTSHEET, How the EU can make smart products consumer-proof, 2018.

68 In Germany, there is some academic debate as to whether standalone software is a product in the terms of the GSDP. 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. In practice, anyway, the market surveillance does not deal with software "as such".

69 See also the Commission Report on safety and liability implications of AI, the Internet of Things and Robotics, COM(2020) 64 final, at 10 f.

70 See GPSD implementation study.

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". Of course, the malfunctioning of embedded software can affect the safety and health of persons, for example, if it leads to overheating and therefore inflammation of a product, or if it stops an emergency mechanism from exercising its very function. These cases are clearly covered by the definition of safety of the GPSD.

Legal uncertainty is mainly reported in relation to cybersecurity risks and to the type of potential damage that shall be avoided by the GPSD. The main issue is to what extent cybersecurity risks are related to the protection of the "safety and health of persons", Article 2(b) GPSD. Indeed, cybersecurity risks related to consumer products can affect consumers in many different ways. They can affect their privacy when personal data of a private, internet-connected video camera are illegitimately accessed. They can affect their economic interest and wellbeing when, for example, hackers get access to their bank accounts or credit card data, or when a smart front door is unsafe and allows third parties to enter the house. They can, however, also directly affect their health and safety when, for example, hackers can manipulate a smart car from the outside, thereby causing an accident[71]. For this reason, in the area of harmonised product legislation, there is relevant work ongoing in relation to the Radio Equipment Directive, the Machinery Directive, and the Low Voltage Directive.

A special problem relates to the fact that software and therefore the feature of products with embedded software may be changed over time through updates or certain types of machine learning, where a machine learning application would be automatically re-trained while it is in use. Currently, such systems are used in virtual environments (e.g. in online learning for content recommendation or for targeting advertisements) or in controlled experimental environments. Thus, a product may be, or seem, safe when it is put on the market but then change into a risky product[72]. In addition, software that is based on machine learning might be safe in certain contexts, but not in others. Risks might emerge when the environment in which the software is used does not correspond to the environment reflected in the training data that was used to create the software.

At the same time, "safety" in the terms of the GPSD means that a product is designed in such a way that it is not only safe on day one or in a limited set of environments and conditions.

Currently, systems that "learn" while in use are a very small minority, such as in the case of online learning for recommender systems for video streaming services, where the labels for new training data are generated automatically based on the viewing actions of users, or such as reinforcement learning, which has few use cases outside the realm of simulations or controlled experimental environments. For the large majority of AI systems that make use of machine learning techniques, the training, validation and deployment phases are separated and the machine learning model does not change during the use phase until it is updated by the developers.

The producer must make sure that a product remains safe during its expected lifetime. This also applies to products with embedded machine-learning software; which means that the producer must ensure that the software does not learn features that render the product unsafe. Thus, the software must be designed in such a way that it cannot

[71] See ibid., at 5.

[72] A process so called 'product hazardisation', and discussed specifically in the context of IoT See e.g. Recap of the International Consumer Product Health and Safety Organization (ICPHSO) 2019 International Symposium: Trinity College, Dublin 24 – 25 October 2019. https://icphso.org/resource/resmgr/intl_2019newfolder/intl_recap.pdf

become unsafe if it is used as intended, and even in the case of foreseeable misuse[73]. Only characteristics that are learned through unforeseeable misuse cannot be attributed to the producer[74].

The problem is, again, of a practical nature. The very idea of machine-learning systems is that the development cannot be predicted entirely at the outset, which makes appropriate tests necessary. Market surveillance authorities do not have the expertise to assess the safety of a machine learning / AI system proactively. Even if a product with embedded machine-learning software causes harm, it may be difficult to establish what exactly caused the problem. Was it the original product or some other software it interacted with? And if so, was the interaction and the problem resulting thereof foreseeable and the original product and/or the software embedded therein therefore unsafe? From the perspective of market supervision, effective control is only possible if the producers of the product and of the software are subject to relevant documentation obligations as well as subject to the obligation to (be able to) explain the changes that the software has undergone after the product was placed on the market[75].

New technologies are considered by many market surveillance authorities to be comprehensive problem areas in need of more attention. However, related market surveillance activities pose specific difficulties: Some authorities consider that no adequate legal basis is available, and therefore the right to conduct control activities in this field is not considered to be sufficiently certain. From several countries it was reported that products containing new technologies required clarifications of responsibilities between the market surveillance authorities in a country. As products containing new technologies may pose different types of risks (e.g. related to safety, data protection, privacy and cybersecurity), clarity is required as to whether a particular modern technology product would then need to be monitored by one or more authorities[76]. Problems at the institutional level can specifically arise in Member States where the competences for market surveillance under the GPSD and market surveillance under the Radio Equipment Directive lie with different authorities. The example was given of a refrigerator which fell under different regulators depending on whether it used WIFI[77].

The coverage of environmental risks

Environmental risks are covered in sector-specific legislation. In particular, the horizontal legislation on chemicals – Regulation (EC) No 1907/2006 (REACH) explicitly has the purpose, according to its Article 1, "to ensure a high level of protection of human health and the environment". However, the definition of safety in the GPSD only covers environmental risks to the extent that they also affect human health and safety (e.g. heavy metals such as lead and cadmium, phthalates etc.). A broader scope of risks to be considered in addition to those related to the health and safety of consumers, such as security and environmental risks, was only introduced with Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. Since then, Safety Gate/RAPEX applies to measures which prevent, restrict or impose specific conditions on the marketing and use of products posing a serious risk to the health and safety of consumers or, in the case of products covered by Regulation (EC) 765/2008, to measures which prevent, restrict or impose specific conditions on the marketing and use of products posing a serious risk to the health, safety or other relevant public interests (for example, security or the

[73] See also Rott, Gutachten, at 34; Pieper, Die Vernetzung autonomer Systeme im Kontext von Vertrag und Haftung, Zeitschrift zum Innovations- und Technikrecht (InTer) 2016, 188, at 193.

[74] See also Wendt and Oberländer, Produkt- und Produzentenhaftung bei selbständig veränderlichen Systemen, InTer 2016, 58.

[75] Note that in this area there is also relevant work ongoing in relation to the Machinery Directive, and the new horizontal instrument on AI.

[76] See GPSD implementation study, country report Poland.

[77] See GPSD implementation study, country report Netherlands.

environment) of the end-users[78]. Safety Gate/RAPEX notifications therefore can be based on environmental risks without necessarily implying a health impact. However, the above-mentioned limitation in the definition of safety of the GPSD remains, and the assessment of the risk for health and safety concerning environmental pollutants has caused difficulties in the past. The revised RAPEX guidelines clarify that in certain cases, the Commission may validate notifications that are submitted without a detailed and individual risk assessment, if a product contains a chemical substance either banned or in a concentration above the limit established by European legislation (see Part 1 of this study, EQ 19, for more details). Relevant references are to be found, for example, in the:

- RoHS 2 Directive (RoHS=Restriction of Hazardous Substances in Electrical and Electronic Equipment)[79], which is only applicable to electrical waste and equipment;
- Mercury Regulation[80];
- Battery Directive[81];
- Regulation on persistent organic pollutants (POP Regulation)[82];
- REACH, which also provides restrictions concerning several substances with the exclusion of substances already covered by the ROHS or by the Batteries Directive.

Where legislative references for risk assessment and/or restrictions to the use of substances are not available in EU legislation, this is considered to lead to gaps regarding chemicals with environmental impact, and reduce possibilities for referring to legal limits and related scientific reference data. Specific difficulties were also noted related to endocrine disruptors and mixtures of toxicities where several chemicals are involved.

In absence of limits established by EU legislation, the situation is more complicated, as it is more difficult for a market surveillance authority not only to demonstrate an environmental risk but also its indirect risk for human health and safety. As Member States often use different methods of risk assessment for this purpose, and may have also different national threshold limits in place, this leads to a number of issues. Thus,

78 Commission Implementing Decision (EU) 2019/417 of 8 November 2018 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 (hereafter referred to as 'RAPEX guidelines'.)

79 EU legislation restricting the use of hazardous substances in electrical and electronic equipment (EEE) and promoting the collection and recycling of such equipment has been in force since February 2003. The objective of these schemes is to increase the recycling and/or re-use of such products. The legislation also requires certain hazardous substances (heavy metals such as lead, mercury, cadmium, and hexavalent chromium and flame retardants such as polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) to be substituted by safer alternatives. Waste EEE poses environmental and health risks if inadequately treated. The RoHS and WEEE directives on electrical and electronic equipment were recast in 2011 and 2012 to tackle the fast-increasing waste stream of such products. https://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

80 Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008

81 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Text with EEA relevance)

82 Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

the lack of clarity in the coverage of environmental risks also poses specific problems for enforcement of the GPSD[83].

Implementation differences in Member States

In line with its nature as a Directive the GPSD has been implemented into national legislation in the Member States and EEA countries. This process often leads to certain implementation differences, which may or may not affect the functioning of the overall legal framework. In the case of the GPSD, these implementation differences have been aggravated by the Directive's lack of precision in certain key concepts, which led to uncertainty on part of MSAs and of businesses (and thereby reduced the Directive's effectiveness, see Part 1 of this report). This is especially obvious in the case of new technologies, and refers to the scope of application of the Directive (e.g. the coverage of stand-alone software or cyber-risks, see above), the notion of "safety" in general as well as to the notion of "serious risk" for the purposes of Safety Gate/RAPEX. Legal uncertainty due to vague concepts and implementation differences has two negative effects. First, it may prevent MSAs from taking action for perceived lack of competence or perceived lack of the fulfilment of relevant requirements for taking action, in particular the lack of safety of a product; which may lead to a lack of enforcement of the GPSD (as implemented in national law). Second, it may lead to an uneven application of the GPSD by MSAs of different Member States, or even within a Member State where enforcement is decentralised; which does not only impact on the level of consumer protection but also on the free movement of goods within the internal market.

Conclusion on the extent to which specific risks – including those related to new technologies - lead to product safety challenges, and likely future trends

The example of consumer products using new technologies illustrates both the strengths and the weaknesses of the general safety requirement of the GPSD. It confirms the advantage of a general requirement that products are safe independent from the technology used, i.e. of the safety requirement being technology-neutral. However, it also has shown its weakness in that certain key definitions, such as "safety" and "product", which need to be broad and unspecific to apply in all situations, can be ambiguous in the context of new technologies, and therefore create practical difficulties for the application of the GPSD, which reduce its effectiveness. These difficulties relate to several areas.

As software is at the core of new digital technologies, a key uncertainty is to what extent software updates and standalone software are considered products under the GPSD. Currently, only a few Member States explicitly include software that is only subsequently embedded in a product in the scope of application of their national legislation implementing the GPSD, whereas other Member States do not apply product safety law to such software. This certainly creates legal uncertainty, as not only smart products become ever more frequent on the market but also the separation between the producer of the "hardware" and the provider of related software. This also creates a new uneven level of protection between Member States as regards such software, or the products in which it is embedded.

A second uncertainty relates to the definition of safety, as it is not clear to which extent risks are covered that not directly affect consumer health and safety, but may do so indirectly (e.g. the issue of cybersecurity of a smart home smoke detector, which may lose its functionality due to interference from hackers), or that may affect other aspects

[83] It is notable in this context that for this reason EU consumer organisations call for the possibility to adopt legally binding chemical safety criteria for product categories which are not covered by specific EU product legislation, such as clothing and textiles, construction materials/products, furniture, childcare articles and sports and playground equipment and surfaces (Join statement ANEC, BEUC: Achieving a higher level of consumer safety through a revision of the General Product Safety Directive). A similar suggestion was made by a market surveillance authority.

of well-being (including mental health, as elaborated in the recent Commission Report on safety and liability implications of AI, the Internet of Things and Robotics[84]).

A third area is a lack of clarity regarding a product's potential behaviour due to embedded software that applies machine learning and AI. Thus, a product may be, or seem, safe when it is put on the market but then change into a risky product if it is updated or if machine-learning components are re-trained during the use. This process of a potential 'product hazardisation' in the context of smart devices and IoT is frequently discussed and potentially relevant for consumer safety, although examples outside the area of self-driving vehicles so far seem to be rare[85]. While there is ongoing work in relevant sectorial legislation to address these issues, it appears important to maintain the safety net role of the GPSD for consumer products also with respect to the use of new technologies.

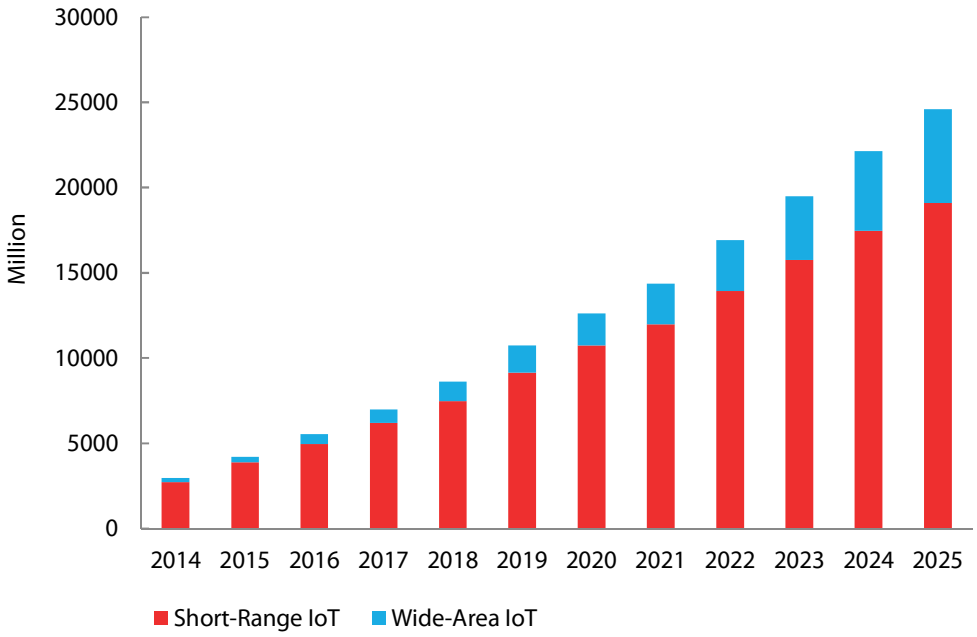
Finally, the definition of safety in the GPSD covers environmental risks to the extent that they also affect human health and safety, but this is in some cases difficult to prove, especially in areas where no EU legal limits and related scientific reference data exists, and where Member States may use different methods of risk assessment.

The mentioned uncertainties are expected to remain relevant for the foreseeable future, and increase in importance. In the area of new digital technologies, the number of connected products is expected to rapidly increase, as illustrated in Figure 4. In 2025, the number of IoT devices with cellular connections is expected to reach 5.2 billion.

84 COM(2020) 64 final.

85 In the area of self-driving vehicles or vehicles using advanced autopilot systems several relevant accidents are documented, see e.g. https://www.nytimes.com/2020/02/25/business/tesla-autopilot-ntsb.html, and https://towardsdatascience.com/another-self-driving-car-accident-another-ai-development-lesson-b2ce3dbb4444. Note that these examples may also concern systems that were updated by developers, not systems that were set up to re-train during use.

Figure 4: Connected IoT devices (worldwide, in million)



Source: Ericsson Mobility Report, June 2020. Data retrieved through Ericsson Mobility Visualizer, www.ericsson.com/en/mobility-report/mobility-visualizer

In total, about 25 billion connections will be related to the IoT by 2025, including both wide-area IoT and short range IoT. The wide-area segment consists of devices using cellular connections, as well as unlicensed low-power technologies. In contrast, short-range IoT concerns devices connected by radio technologies with a typical range of up to 100 meters, such as Wi-Fi and Bluetooth[86]. These forecasts show that the number of connected IoT devices targeted at consumers is expected to grow rapidly, likely to be boosted by the roll-out of high speed 5G mobile broadband networks in Europe, reinforcing the issues described above.

Regarding environmental risks, it is expected that their relevance will continue to increase in the future through changes related to the overall goal of achieving a sustainable and circular economy[87]. Products will be required to be easier to upgrade, to repurpose and to be recycled. Closing the loop will imply that when products are recycled that contain specific chemicals, contamination of new products may occur, implying increasing challenges for manufacturers and market surveillance authorities to safeguard product safety. In other words: In a circular economy a product will need to be safe throughout its lifecycle: at the time of placing on the market, in its use phase, and after refurbishment. The GPSD as key element of the current legislative framework for product safety is not sufficiently adapted to this challenge.

4.4. Challenges related to the rules for market surveillance and standardisation

The GPSD provides a requirement for Member States to establish systematic approaches to perform effective market surveillance. Member States establish or nominate national authorities competent to monitor the compliance with product safety requirements and

[86] Ericsson Mobility Report, June 2020.

[87] See also COM(2019) 640 final, Communication from the Commission, The European Green Deal.

give necessary powers to these authorities to take appropriate measures. National market surveillance authorities have a responsibility to:

- Ensure that producers and other actors in the supply chain comply with their obligations from the GPSD (as implemented by the Member States);
- Ensure effective market surveillance;
- Take appropriate action in case a dangerous product is detected on the market and notify it in the rapid alert system (the rapid alert system contains notifications of dangerous harmonised and non-harmonised products).

The GPSD is complemented by other legislation concerning market surveillance, such as Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. New legislation applicable to market surveillance and compliance of products subject to EU harmonised legislation has been adopted (Regulation (EU) 2019/1020) and will become fully applicable as from 16 July 2021.

The organisation of market surveillance at the national level and the competences of the national authorities differ significantly between Member States. The following matrix provides an overview of the market surveillance systems for consumer products at the national level, by categorising the systems according to the degree to which market surveillance is conducted by MSAs with broader or narrower sectoral responsibility, and whether responsibility for market surveillance is (partly) delegated to or is the competence of sub-national administrations, in line with the administrative structure of the country.

Table 7: Organisation of market surveillance of consumer products in EU Member States, according to sectoral distributions of responsibilities and involvement of sub-national administrations

	Responsibility for market surveillance is centralised (no sub-national administrations involved)	**Responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country**
One Market Surveillance Authority for all non-food products	Malta	-
A main Market Surveillance Authority for consumer products, complemented by a small number of other MSAs in specific sectors (e.g. telecommunications, chemicals)	Belgium, Cyprus, Denmark, Estonia, Ireland, Netherlands, Finland, Latvia, Luxembourg, Sweden	France, Croatia, Greece, Lithuania, Poland
Several MSAs with sectoral responsibilities for consumer products	Bulgaria, Slovenia, Slovakia	Austria, Czech Republic, Germany, Hungary, Italy, Portugal, Romania, Spain

Source: GPSD implementation study. Notes: At an institutional level, market surveillance is typically not conducted separately for harmonised and non-harmonised products, and separating both aspects is often not possible. Considered in this overview are therefore market surveillance authorities for harmonised and non-harmonised consumer products, not including medicinal products. For more information see GPSD implementation study.

Table 7 above shows the large variation in the organisation of market surveillance for consumer products in EU Member States. In a small market such as Malta a single market surveillance authority can have the responsibility for market surveillance of all non-food products (except medicinal products). In a second group of countries a main market surveillance authority at national level has broad responsibilities for consumer products, and is complemented by a small number of other MSAs in specific sectors (e.g. telecommunications, chemicals). Some (often larger) countries that have a main market surveillance authority for consumer products also rely on sub-national

administrations or regional networks for enforcement, in line with their overall administrative structure. Finally, there are countries where several MSAs have sectoral responsibilities, without an organisation having a general or broad competence for consumer products. While in several countries this organisational approach only involves MSAs at the national level, in other countries following this approach responsibility for market surveillance is also (partly) delegated to or is the competence of sub-national administrations.

As varied as the institutional model of market surveillance is the amount of staff resources available for market inspections, and the number of inspections conducted. For the analysis of baseline costs of MSAs for enforcing the GPSD, we have calculated the number of market surveillance staff dedicated to non-harmonised consumer products only (see section 7 below). We estimated that the median[88] number of FTEs (Full Time Equivalents) per million population working on non-harmonised consumer products is 3.5 in those Member States where responsibility for market surveillance is centralised (no sub-national administrations involved, see second column of Table 7, above), and 4.6 in Member States where responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country (see third column of Table 7).

The total number of inspections (concerning all consumer products) conducted in the EU/EEA also varies considerably between countries, with a range of 102 to 1 152 inspections per million population (considering the first and third quartile percentile of the distribution), and a median of 407 inspections per year and million population. Compared to the large number of consumer products on the market (which counts in the millions), the number of inspections conducted is therefore low. There is general agreement among market surveillance authorities and other stakeholders that two out of the three top problems affecting the functioning of market surveillance relate to a lack of resources: limited staff resources of market surveillance authorities in general, and in addition, specifically a lack of financial resources for product testing (the third most often listed problem is the control of products from non-EU/EEA countries directly reaching consumers)[89]. In our research, several market surveillance authorities noted that the lack of personnel impacted the workload and thus the capacity of the existing staff to effectively monitor the safety of all product groups, with the result that not all consumer product types could be controlled, no attention to emerging issues related to new technologies could be paid, and specific activities such as online market surveillance or mystery shopping could not be conducted[90]. It is therefore likely that the effectiveness of the GPSD has been affected by this lack of resources allocated to market surveillance.

The second most important cluster of problems for market surveillance concerns online markets, and in this context specifically B2C transactions with operators in non-EU/EEA countries, in which products from those countries are delivered on an individual basis. These problems relate to issues of jurisdiction and practical difficulties in establishing the identity and the location of a trader in non-EU/EEA countries (see above, section 4.2).

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88 The median is the middle value, or 2nd quartile (also called 50th percentile).

89 See GPSD implementation study.

90 Ibid. The GPSD Implementation study therefore recommended to improve resources for market surveillance. It stated: "Proposed improvements regarding the lack of staff and financial resources of MSAs mostly revolve around the provision of more staff, more budget, more training, more powers, more spot checks and better controls in certain areas. Potential sources of funding that were suggested included EU funds/projects for market surveillance, but also the allocation of funds originating from sanctions imposed by MSAs. It was suggested that the European Commission should enforce Member States' obligations when it comes to market surveillance, including by developing comparable ways to measure the resources used in the Member States for this purpose, or by specifying the intensity of sampling."

In light of the large number of authorities involved in market surveillance, coordination and information exchange are crucial, both between authorities inside a country, and with authorities in other Member States. The main channel for market surveillance authorities when communicating and cooperating with other relevant authorities in the EU/EEA is the rapid alert system (Safety Gate/RAPEX), complemented by two other IT tools that are used by MSAs in nearly all countries, namely ICSMS and Wiki confluence platform[91].

The role of the rapid alert system

The EU Rapid Alert System for dangerous non-food products was established in 2003 in accordance with Article 12 GPSD. Related IT tools include the RAPEX application for indicating notifications and reactions, and the Risk Assessment Guidelines (RAG) application, which assists authorities in applying the risk assessment guidelines for non-food consumer products. In the period 2005 to 2019, a total of 25 560 notifications concerning consumer products were submitted through the rapid alert system (or close to 5 on average per day during this period). This illustrates that the system fulfils its function, and detailed analysis of the data also shows that all Member States have to different degrees submitted notifications during this period. On average, each EU Member State (EU28 as of 2019) submitted 60 notifications concerning consumer product per year, with the numbers differing widely between countries.

Despite a general satisfaction of most authorities and stakeholders with the functioning of the rapid alert system (see Part 1 of this report, EQ2), there are also issues that impede its operation. The lack of sufficient information to trace notified products was one of the highest-ranking problems. Many authorities and stakeholders experienced that notifications sometimes do not contain enough information to identify the products, for example, no information about the brand, manufacturer/importer/distributor, type/model, batch number, sales channel are indicated, pictures of products are sometimes missing or of poor quality[92]. It also appears that at present, the GPSD provisions are not sufficiently explicit to guarantee that complete information on supply chains and distribution of the product is gathered. Initially because the GPSD does not contain detailed traceability requirements[93] and secondly because some issues pertaining to the present-day trade conditions e.g. regarding online marketplaces, could

[91] The ICSMS (Information and Communication System on Market Surveillance) aims at facilitating communication between market surveillance bodies in the different countries, including for information sharing on non-compliant products (which is a broader concept than 'dangerous products', as there are many non-compliant products that are not necessarily dangerous). The Wiki confluence platform (or Confluence Wiki) is a collaborative online platform made available by the Commission, to make accessible practical information, such as documentation that are relevant for MSAs, and to facilitate communication. In certain areas, e.g. with respect to chemicals, other EU IT tools are also relevant. For example, the European Chemicals Agency (ECHA) provides enforcement authorities with the Portal Dashboard for National Enforcement Authorities (PD-NEA) that allows them to access the subset of REACH and CLP data submitted by the industry to ECHA.

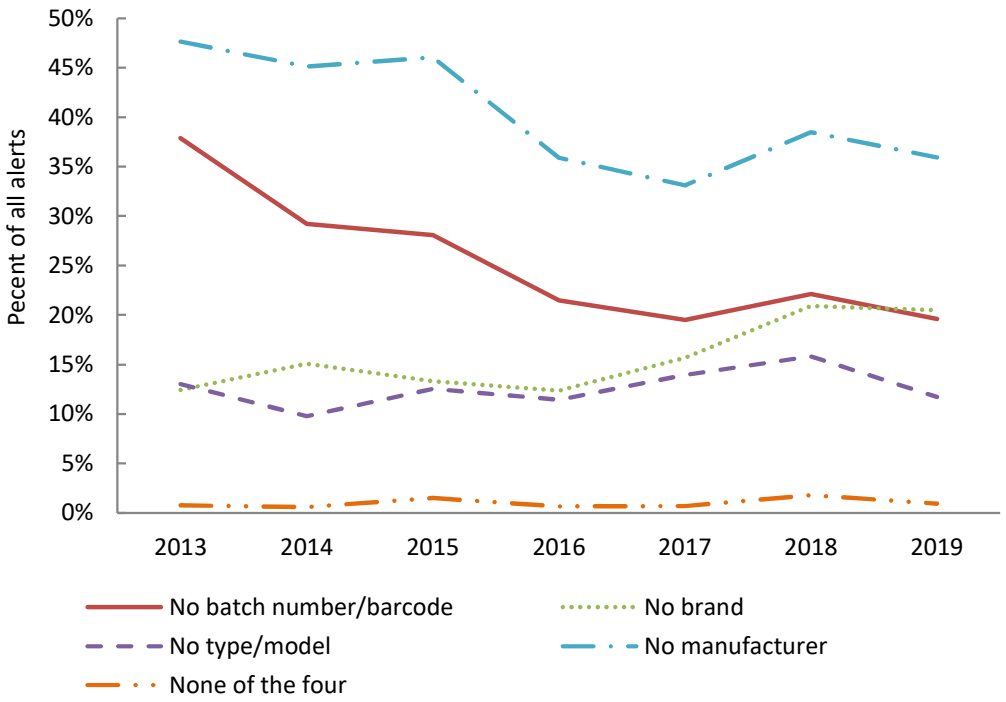
[92] The analysis of RAPEX data confirmed that information regarding brand, type/number of model, batch number or barcode is often not available (see EQ 6 below).

[93] The GPSD does not contain detailed traceability requirements, but rather a general obligation for producers to provide the necessary information for tracing a product, without asking for specific or minimum identification information. According to Article 5(1) of the GPSD, this information may for example include "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". Apart from producers, distributors are also required to keep and provide documentation necessary for tracing the origin of the products (article 5(2) GPSD). Given the lack of specific product information requirements in GPSD, it is up to the Member States to adopt concrete measures to implement the traceability obligation. This has resulted in Member States taking different approaches with regards to traceability of products falling within the scope of GPSD, i.e. non-harmonised consumer products and harmonised products for which EU legislation does not provide specific traceability requirements. Consequently, producers' obligations with regards to traceability can differ from one Member State to another. Most common traceability requirements, in line with GPSD, are the indication on the product or its packaging of the name and contact details of the producer and a product reference or the batch of products. Despite similarity of requirements, their application is not uniform across EU/EEA countries.

not have been anticipated in 2001 when the GPSD entered into force and are therefore not specifically addressed in the GPSD. A third shortcoming of the GPSD relates to the downstream tracing of products to distributors and sellers up to the final consumer. It is often difficult to keep track of the supply chain and locate or identify buyers of unsafe products, as was reported by several MSAs[94]. Often, the majority of affected consumers are not aware that they own e.g. a recalled product. Not only (in particular in the case of offline purchases) it is difficult to identify the owners of recalled products but even in situations where such data is available (e.g. due to loyalty schemes or online purchases), economic operators are not required to use it for recall purposes. As a consequence, companies may decide to not use customer data at their disposal for recall notifications due to data protection concerns, which affects the effectiveness of recalls (see also next section).

The extent to which these requirements based on the GPSD achieve adequate product traceability, can be demonstrated through the data available in Safety Gate/RAPEX. From 2013 to 2019 a significant share of the alerts that were submitted for dangerous consumer products, involved products with unknown product information items. In 2019 for instance, 36% of alerts for dangerous consumer products did not include information on the manufacturer, 20% did not include information on brand or batch number/barcode, and 12% did not provide type or model information. Figure 5 below based on alerts registered in the EU Safety Gate shows that, only the provision of information on manufacturer and batch number/barcode shows an improvement in recent years (i.e. a decrease of the number of alerts that did not provide such information). For the rest of the traceability information there is no clear trend of improvement over time.

Figure 5: Share of RAPEX alerts with unknown product information items (2013-2019)



Note: Indicated is the share of alerts with unknown brand, unknown type/number of product, and unknown batch number/barcode as percentage of total alerts. Source: Civic Consulting, based on Safety Gate/RAPEX data (number of

[94] See GPSD implementation study, e.g. country reports Spain, Netherlands.

alerts concerning consumer products with serious risks 2013-2019). Note that this information was not consistently available for previous years.

The same data also reveal that missing product information is more typical for specific types of products such as laser pointers, lighters, jewellery, decorative articles, etc. What these products have in common is that they all fall within the scope of GPSD and are not subject to sector-specific harmonisation rules. It follows that product categories under the GPSD are more likely to lack relevant information items that are essential to trace them in case they are notified on Safety Gate[95].

Another major shortcoming that concern the rapid alert system refers to the risk assessment underlying notifications. Market surveillance authorities of different Member States may come to different conclusions in relation to the safety of a particular product. In this regard, the two aims of the GPSD of fostering the free movement of products within the internal market and of promoting health and safety are connected, as the GPSD only aims to foster the free movement of *safe* products. This means that major differences in the assessment of safety risks and related market surveillance and testing approaches between Member States must be avoided for the achievement of both aims. In some cases disputes on risk assessments are therefore discussed within the RAPEX network. Over recent years, the number of such disputes to better align the risk assessments by different Member States' authorities has been relatively stable, as indicated in Table 8 below. The number of notifications that were subject to disputes has been on average less than 30 per year[96].

Table 8: Number of disputes on risk assessments that needed to be discussed within the RAPEX network

Year	Number of notifications that were subject to disputes	Number of follow up disputes
2013	19	21
2014	39	41
2015	33	39
2016	19	24
2017	24	28
2018	26	27
2019	30	30
Total	***190***	***210***

Source: Civic Consulting, based on data provided by European Commission.

In this regard, it is important that over the years, the European Commission has issued a number of guidance documents that support the uniform application of the GPSD in the Member States, including:

- Commission Notice on the market surveillance of products sold online;

[95] See GPSD implementation study, p 32.

[96] The number of actual disputes was slightly higher, as in some cases more than one Member State provided a different risk assessment in a follow-up notification (or "reaction" as it was named previously) that needed to be settled with the risk assessment by the Member State that submitted the original notification.

- Commission Decision 2004/905/EC laying down guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors;
- Commission Implementing Decision (EU) 2019/417 of 8 November 2018 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.

Moreover, there is evidence that the training programmes that the European Commission organised for the national market surveillance authorities[97] and the financing of joint market surveillance activities of EU Member States contribute to the uniform application of the GPSD in the Member States. However, the problem has so far not sufficiently been resolved, and is considered especially an issue in the context of chemical and environmental risks (see previous section).

The role of standards

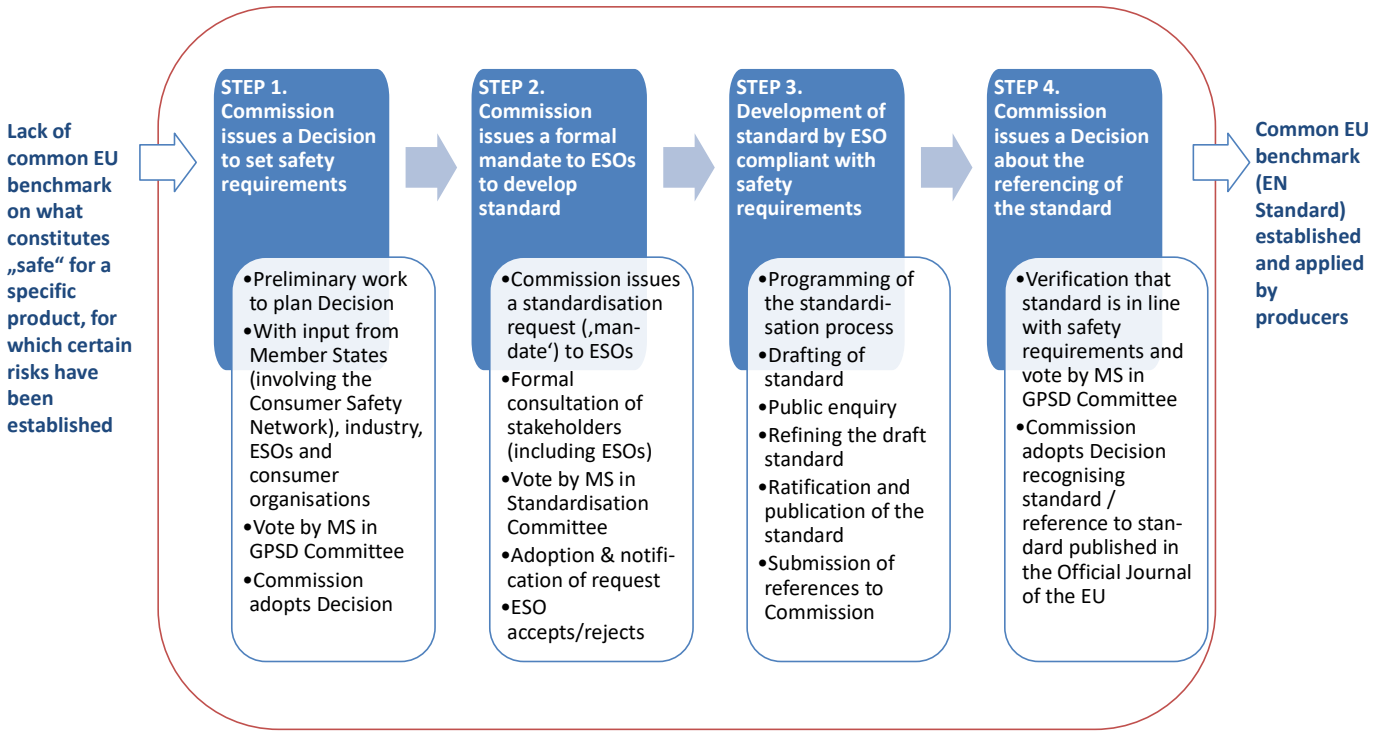
Standards play an important role in EU product safety law. In the framework of the GPSD, they serve a double purpose: they facilitate market access and they ensure the safety of products. According to Article 3(2) of the GPSD, a product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the EU in accordance with Article 4 of the GPSD. In that sense, standards contribute to the uniform application of the GPSD in the Member States. This would imply that the greater the number of standards is the more does the GPSD contribute to the uniform application of product safety law in the Member States. Since its adoption, a total of 80 standards were referenced under the GPSD by the European Commission, which indicate the effectiveness of the Directive in this respect[98]. This issue is further explored in Part 1 of this report, EQ5.

The current procedure regarding standardisation as laid down in Article 4 of the GPSD consists of four steps (see Figure 6). The figure describes the process in detail, also indicating the intended outcome of the process, namely a European standard which serves as benchmark, and is intended to lead to a reduction of the identified risks to the minimum compatible with the product's use.

[97] For a detailed overview, see Civic Consulting, Ex-post evaluation of the Consumer Programme 2007-2013 and mid-term evaluation of the Consumer Programme 2014-2020.

[98] As of 31.10.2019. Some of the standards have been withdrawn in the meantime, see full list in the Annex. Note, however, that the existence of relevant standards does not necessarily imply that all companies use them, as significant fees have to be paid to access them. This was also reported from some MSAs.

Figure 6. Steps of the standardisation process established under the GPSD



Source: Civic Consulting. Note: simplified overview.

The long duration of the standardisation process is an often commented-upon weakness (see Part 1 of this report, EQ5). As shown in Figure 6 above, GPSD standardisation involves four steps, and whilst delay may occur within any or all of the four steps, the fact that there is a multi-stage procedure inevitably risks building up delays. An important difference between the standardisation process under the GPSD and standardisation in harmonised areas is that the harmonisation directives contain essential safety requirements on which the standards can be based. There is therefore no need for the first step required under the GPSD procedure of establishing a Commission Decision to set safety requirements. However, due to the wide range of products for which no harmonisation legislation exists and that fall therefore under the GPSD – reaching from jewellery and furniture to ladders and bicycles – concretisation of essential safety requirements (as required in Article 4 of the GPSD) is needed as guidance for the standardisation process. The GPSD also brings into play a parallel EU committee regime. The GPSD Committee is involved in the front and back end of the process establishing the safety requirements in a Decision (Step 1) and ensuring that the standard formulated complies with the Decision (Step 4). The Standardisation Committee is, however, the one that needs to approve the Commission's proposal for the standardisation request to ESOs before the Commission can adopt a decision on this. This means that two separate EU committees are involved in the process and that requires time for both committees to become familiar with and work through the issues, as often different people work in the committees, which reduces the efficiency of the process.

Conclusion on the extent to which the rules for market surveillance and standardisation have led to challenges, and likely future trends

Market surveillance rules and obligations of business operators in the GPSD sometimes lack detail (e.g. in the area of traceability), are not adapted to the online environment, and do not sufficiently specify the powers of market surveillance authorities. This leads to situations where authorities are, for example, not allowed to shop online to obtain

samples or conduct mystery shopping at all. This limits the effectiveness of the GPSD, and may lead to higher occurrence of dangerous products on the market and may affect consumers' trust. The legal framework on market surveillance is complex and even for experts sometimes difficult to understand in its intricacies, with a main difference being the lack of alignment between the framework for harmonised products, and for non-harmonised consumer products under the GPSD. As elaborated in detail in the 2020 GPSD implementation study, there are also major discrepancies in the GPSD implementation across Member States.

At a more general level, the market surveillance system under the GPSD (consisting of market surveillance activities by authorities in the Member States, information exchange through Safety Gate/RAPEX and coordination and support measures) appears to be operating under considerable resource constraints. It is widely acknowledged that the staff and financial resources of market surveillance authorities are often insufficient, with fragmentation of responsibilities leading to inefficiencies due to a lack of economies of scale in some cases, and contradictory measures and approaches for risk assessment between authorities in others. Also, the number of inspections is low, with a median of roughly 400 inspections of consumer products per year and million population in the EU, based on data from those Member States that provided such information. While the framework set by the GPSD, Safety Gate/RAPEX and the related coordination measures at EU level contribute to better and more coordinated market surveillance, fragmentation of responsibilities as well as resource constraints limit the effectiveness of the overall system. This emphasises the importance of the rapid alert system, which is the backbone of the current system of market surveillance in the EU. While market surveillance authorities and other stakeholders therefore consider Safety Gate/RAPEX mostly to be well functioning and effective, certain issues currently impede its operation, such as delays between the detection of a dangerous product in a Member State and its notification to Safety Gate/RAPEX, or differences in risk assessment between Member States in certain cases. Currently, there is no dispute resolution mechanism in case of diverging product safety risk assessment between national authorities. In addition, the process for elaborating European Standards under the GPSD is burdensome and could be streamlined.

With respect to the future trends in this area, the recent adoption of Regulation (EU) 2019/1020 on market surveillance and compliance of products, which covers products under EU harmonised rules will further increase differences in obligations for the different actors based on whether they are dealing with products subject to such rules or not. The Regulation will fully apply from 16 July 2021, and bring a modernisation of requirements for certain harmonised consumer products (e.g. the obligation for an EU representative), and also a catalogue of enforcement powers as elaborated in Chapter V of Regulation (EU) 2019/1020. In the absence of legislative action to increase the coherence of the EU legislative framework for market surveillance, there will be major differences in the enforcement powers of MSAs after this time, depending on whether market surveillance is conducted regarding harmonised consumer products (e.g. toys) or regarding non-harmonised consumer products (e.g. children's beds).

4.5. Insufficient effectiveness of recalls of consumer products

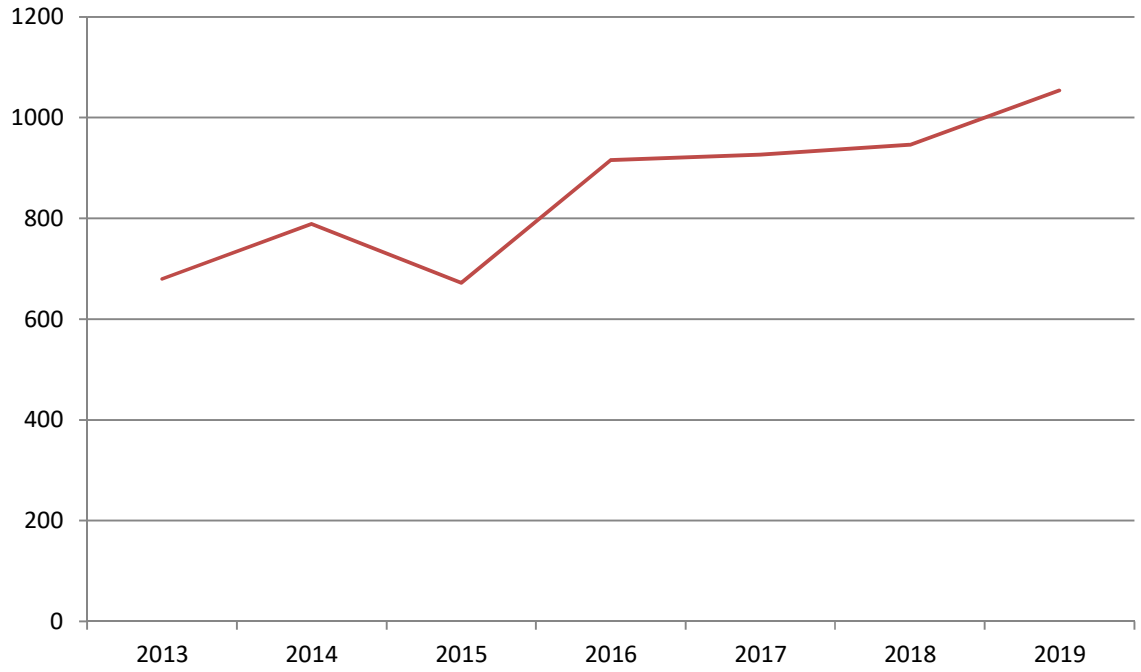
A fundamental obligation that derives from the GPSD is the obligation of producers and distributors to notify the authorities and take the necessary actions for consumer protection, once one of the products that they have placed on the market is identified as dangerous[99]. Corrective measures to be taken by producers may include withdrawing products from the supply chain, adequately and effectively warning consumers and, as a measure of last resort, recalling products that have already been supplied to

[99] GPSD Art 5 (3).

consumers[100]. Distributors have to act "with due care" and must not supply products which they know are unsafe. They also have to pass on information on product risks and cooperate in the action taken by producers and competent authorities to avoid the risks[101]. In parallel, the GPSD requires Member States to ensure that the appropriate corrective measures are being taken and inform the Commission without delay through Safety Gate/RAPEX (Articles 8 and 11(1) GPSD).

According to the data retrieved from Safety Gate/RAPEX, a total of 5 983 recalls took place from 2013 to 2019, taking into account notifications concerning products of serious risks and other risk levels. During this period an overall increase of recalls of approximately 35% occurred, with the annual number of recalls being highly variable but increasing on average by more than 8 % (see Figure 7). These figures may well be an underestimation, as not all recalls in a country are necessarily notified at EU level[102].

Figure 7: Number of recalls registered in the EU Safety Gate 2013-2019 (total, by year)



Note: Safety Gate/RAPEX data for the period 2013 to 2019. Considered are all notifications concerning products with serious risks and products with other risk levels, where at least one of the measures included a recall.

The increasing trend can to a large extent be attributed to the increase in the number of recalls concerning motor vehicles, which grew by a factor of more than 3 from 159 recalls in 2013 to 507 in 2019. Apart from motor vehicles, the five more frequently recalled product categories according to Safety Gate/RAPEX alerts were toys, clothing and textiles, electrical appliances and equipment, lighting equipment, childcare articles and children equipment, of which toys, electrical appliances and lighting equipment are

[100] See GPSD Art 5 (1), (b) of the third subparagraph, and last paragraph.

[101] GPSD Art 5 (2).

[102] See Part 1 of this report, EQ2. As indicated, Member States are required to notify corrective measures in cases where the effects of the product risk can go beyond the territory of the Member State, implying that not all recalls in a country are necessarily notified at EU level. In addition, as regards products posing a less than serious risk, notification is encouraged but not mandatory in the case of voluntary measures taken against products covered by the GPSD and in the case of both voluntary and compulsory measures taken against products subject to EU harmonised legislation.

subject to sector-specific harmonisation rules, while the rest are non-harmonised consumer products.

The GPSD does not contain any specific rules for recall procedures and timelines, communication or the remedies to be offered to consumers. Producers undertake voluntary action to organise recalls but authorities can also order a recall on the basis of notifications of dangerous products from other countries or the results of their own market surveillance activities or if producers' actions are deemed insufficient. Each Member State follows its own approach with regards to recalls, with some common elements, but also diverging practices. Product recalls can be organised both on a voluntary basis and on a mandatory basis after an order of the competent authorities. Country research showed that the most common type of product recalls is voluntary, which is in line with the results of previous studies[103]. Collaboration of the economic operators is crucial ito ensure the effectiveness of both voluntary and mandatory recalls[104].

A recall, whether conducted by the producer or the authorities, generally aims at locating all already sold unsafe products and removing them from the possession of consumers by providing comprehensible information to the public, with regards to the product flaw, the related risk(s), the way to participate in the recall and the remedy offered[105].

However, given that GPSD does not specify how recalls should be carried out, differences are observed between Member States approaches with regard to the involvement of different actors (e.g. authorities' collaboration with businesses or the involvement of online marketplaces in the recall process), the choice of information channels[106] and content of recall information for consumers.

An important difference between the national provisions on recalls and recall practices of Member States involves the remedies provided in case of a recall. In Slovenia for instance, while the economic operator decides how consumers shall be compensated, the Consumer Protection Act stipulates that the consumer has the right to decide for a product refund[107]. In the Czech Republic the Product Safety Act does not provide for the possibility of a product replacement as it is considered that consumers have sufficient alternatives in the market to choose a different product. In Luxembourg, although the national consumer code stipulates that consumers can choose between different remedies including receiving a refund or keeping the product and be partially compensated, if the supplier replaces or repairs the product within one month, the supplier has no obligation for providing further remedy[108].

The increase in the number of product recalls over time and the fact that most recalls take place voluntarily, seem to indicate that producers have become more proactive with regards to monitoring and safeguarding their products' safety in line with their obligations under the GPSD. On the other hand, the lack of minimum requirements and agreed and generally used up to date guidance on recalls, for example regarding the level of involvement of national authorities, how to inform consumers or what remedies

[103] See e.g. OECD, Enhancing Product Recall Effectiveness Globally, 17 December 2018.

[104] See GPSD implementation study, country report Spain.

[105] US Consumer Product Safety Commission (2012), 'Recall Handbook', p. 18, available online at: https://www.cpsc.gov/s3fs-public/8002.pdf.

[106] For example, in a response to the consultation on the GPSD roadmap it was highlighted that some countries still demand printed advertising as part of the recall process. In other countries, this is reportedly not the case.

[107] See questionnaire answered by MSAs in Consumer Safety Network Exchange.

[108] Ibid.

consumers are entitled to, creates uncertainty as to what is required to conduct an effective recall. No updated guidance at EU level is available in this respect[109].

Customer traceability and recalls

Being able to identify and contact buyers of unsafe products has been reported by MSAs as a challenging task[110], which is however crucial for achieving high return rates by consumers following the launch of a product recall. The GPSD does not contain any specific rules on the traceability of end product users/owners. Depending on the case, businesses operating in the European Union may have access to some sources of customer data, which enable reaching up to the final consumer.

In particular, product registration allows to easily identify the owners of recalled products and, hence, improving registration figures could considerably increase recall effectiveness[111]. Yet, apart from motor vehicles (whose registration with public authorities is mandatory), most consumer products are not registered. Registration schemes are only available for few higher-value product categories like domestic electronic appliances and communication devices, and even in these sectors actual registration rates tend to be rather low. In a recent consumer survey, declared registration rates ranged from 37% for communication devices, 33% for domestic electrical appliances and 24% for childcare articles to 8% for toys[112].

One factor explaining low registration rates is that many consumers do not make a link between product registration and safety[113]. In a European Commission survey on consumer behaviour only 40% of EU consumers indicated they are aware of the possibility to register their products for safety reasons[114]. In a more recent survey, 42% of participants who did not register their products in the past, indicated as the main reason for not doing so, the fact that they did not know registration was possible and a quarter indicated that they did not see the benefit of registration[115]. In consumer focus groups, participants associated product registration with warranty or after-sales support but did not make a link between registration and safety[116]. At the same time, research on existing registration schemes indicated that even when companies do envisage the use of registration data for safety notifications in their privacy notices, they very rarely say so in the invitation to register[117].

Consumers' personal data concerns is another factor that has been reported to prevent product registration as consumers worry about how their data will be used[118]. For instance, in a US survey, 59% of respondents were concerned about unwanted

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109 For an overview of guidance in use, see Part 1 of this report, EQ6.

110 See GPSD implementation study, e.g. country reports Spain, Netherlands.

111 European Commission, Notes from EU Workshop on strategies to maximise the effectiveness of product recalls, 23rd October 2019.

112 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

113 European Commission (2019), EU Workshop on strategies to maximize the effectiveness of product recalls, Background document, p. 1-5. European Commission, Notes from EU Workshop on strategies to maximize the effectiveness of product recalls, 23rd October 2019, p. 3.

114 European Commission, 2019a, Survey on consumer behaviour and product recalls effectiveness. Final Report https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf

115 European Commission (2021), Behavioural study on strategies to improve the effectiveness of product recalls.

116 Ibid.

117 Ibid.

118 European Commission (2019), EU Workshop on strategies to maximize the effectiveness of product recalls, Background document, p. 1-5. European Commission, Notes from EU Workshop on strategies to maximize the effectiveness of product recalls, 23rd October 2019, p. 3.

communication from the company after registering a product and 79% said they would be more likely to register products if companies were prohibited from contacting consumers for non-safety-related issues[119]. A similar result emerges from the EU focus groups: a key reason participants provided for not registering their products was that they felt uncomfortable about providing personal data, which they feared would be used for targeted advertising (profiling) and other marketing purposes[120].

The effort required to complete a product registration has been suggested as another deterrent factor. It has therefore been recommended to keep registration as simple as possible, while innovations such as making a QR code available that could be scanned with a mobile phone to allow instant registration of the product, has been proposed as a way to facilitate the registration process for consumers[121]. The timing of registration has been identified as another important factor, the point of sale being the key moment during which consumers can be prompted to register their products[122]. In the online experiment carried out by the European Commission, considerably more respondents clicked on the invitation to register a product when they saw it at the check-out (45%) than when they saw it after completing the purchase, either as part of the packaging (14%) or as a general registration campaign (10%)[123].

While customarily intended for marketing promotion, loyalty programmes and other data (e.g. delivery address) held by retailers can also enable identification of consumers in case of product recalls. A third source of consumer data for recall purposes is the consumer information provided in the context of online purchases. Purchasing a product directly from the online seller implies that registration is performed automatically and the online seller can hence easily use the information provided in the event of a product recall. The situation changes when the purchase takes place through an online marketplace. The data held by online marketplaces could be used either to notify consumers directly or to be forwarded to the sellers in the event of a recall campaign[124]. Similarly, the data held by payment card providers could also be used to inform consumers about relevant recalls.

There is general agreement both in research literature and stemming from actual recall data that direct communication with consumers (e.g. via email, telephone, SMS or connected devices) is more effective not only for reaching affected consumers but also for encouraging consumer response compared to indirect methods such as e.g. press releases, product recall notices published on webpages etc[125]. In this respect, the US Consumer Product Safety Commission found that direct recall alerts have a return rate of 50% compared to media releases which have a consumer return rate of 6%[126]. This has been corroborated by consumer groups, who indicated direct contact as their preferred communication method[127], as well as by an online experiment in which 72% of respondents that were presented with a direct recall notification, wished to act on it,

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119 Schoettle, B., Sivak, M. (2015). Consumer Preferences Regarding Product Registration. (Report No. UMTRI-2015-26), available at: http://deepblue.lib.umich.edu/bitstream/handle/2027.42/116020/103219.pdf?sequence=1&isAllowed=y

120 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

121 European Commission, Notes from EU Workshop on strategies to maximize the effectiveness of product recalls, 23rd October 2019, p. 3. European Commission, 2020, Study on recalls, p. 80.

122 Ibid.

123 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

124 European Commission, 2020, Study on recalls, p. 65.

125 European Commission, 2020, Study on recalls, p. 65.

126 CPSC (2017), CPSC Defect Recall Data Carol Cave Deputy Director, Office of Compliance and Field Operations July 25, 2017, available at: https://www.slideshare.net/USCPSC/cpsc-recall-effectiveness-workshop-recall-data.

127 Ibid.

while the equivalent percentage of respondents that were presented with a generic notification was 31%[128].

If indirect communication methods need to be used to notify consumers, using a multitude of communication channels is recommended by most MSAs to increase the visibility of the recall message and appeal to different consumer categories[129]. These channels may include the businesses' websites, press announcements in TV, radio, newspapers as well as social media. Traditional channels such as newspaper or TV announcements are expected to be more effective for elder consumer groups[130] while younger consumers seem to be indifferent between traditional and new communication channels[131]. In any case, social media are increasingly emerging as an effective way to inform consumers and in a recent study interviewed stakeholders proposed using them as a way to increase recall awareness[132]. In light of the above, scientific literature suggests that a combined use of new channels (internet advertising, social media) with more traditional channels (radio, newspapers etc.) shall enhance communication with consumers and improve its effectiveness[133].

In addition to the above channels, a number of government agencies have engaged in sharing information about recall campaigns on their websites and social media. Central national recall databases which serve as information centres for consumers regarding recall notices do not exist in all EU/EEA countries[134].

Factors affecting consumers' response to a recall

The extent to which a product recall will be successful and will achieve the recovery of a high proportion of unsafe products, depends on whether consumers will respond once they become aware of a recall procedure for a product they own. A recent survey on recall effectiveness by the European Commission found that "over a third of consumers (35%) did not react to a recall that was relevant to them; 31% continued using the product with extra caution, while 3.9% took no action whatsoever"[135]. Lack of consumer responsiveness was also pointed out by several MSAs, according to which, even when consumers are aware that a product they have is unsafe and is recalled, they still do not return it[136]. The high percentage of no reaction to recalls is concerning as it means that too many dangerous products still remain in the hands of consumers. Similar findings were reported in a recent OECD report, according to which the effectiveness of product recalls from consumers is low since products that have been recalled in the past, remain in the possession of consumers[137].

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128 European Commission, 2020, Study on recalls, p. 50.

129 European Commission (2019), EU Workshop on strategies to maximize the effectiveness of product recalls, Background document, p. 7.

130 Jones Day (2019), 'How to conduct a product recall in Australia', p. 6, available at: https://www.jonesday.com/en/insights/2019/04/how-to-conduct-a-product-recall.

131 European Commission, 2020, Study on recalls, p. 48.

132 European Commission, 2020, Study on recalls, p. 45. See also CPSC (25th July 2017), Recall effectiveness workshop meeting minutes, p. 24.

133 Bond, C., Ferraro, C., Luxton, S., & Sands, S. (2010). Social media advertising: An investigation of consumer perceptions, attitudes, and preferences for engagement. In P. Ballantine, & J. Finsterwalder (Eds.), *Proceedings of the Australian and New Zealand Marketing Academy (ANZMAC) Conference 2010 -'Doing More with Less'* (pp. 1 - 7). University of Canterbury.

134 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

135 European Commission (2019). Survey on consumer behavior and product recalls effectiveness, p. 20, available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

136 See e.g. GPSD implementation study, country report Portugal.

137 See OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 5.

One factor behind consumers' motivation to respond or not to a product recall, pertains to the attractiveness and timelines of remedies offered to consumers. Tardy or insufficient remedies have been reported to reduce consumers' propensity to act upon a product recall[138]. The Sale of Goods Directive (EU) 2019/771 provides consumers with contractual remedies (repair, replacement, price reduction, full refund) for a lack of conformity of goods that existed at the time of delivery and became apparent within two years. However, many recalls take place after a longer period.

Complex and unclear recall information and other costs associated with recall participation may also lead to a lack of consumer responsiveness. These costs may include financial costs (e.g. of shipping back the product), opportunity costs/loss of time, loss of product use, required effort etc. which may prevent consumer response if they outbalance perceived benefits. It has therefore been suggested to make the recall procedure as simple as possible in order to encourage consumer response. Likewise, standardising key elements to be included in a recall notice has been suggested as a way to increase consumer understanding and engagement in recalls[139].

A study by US CSPC has indicated that consumers' perception of the risk or severity of an injury that can potentially be caused by a product, is another important factor influencing consumers participation in recalls[140]. Yet, the majority of recall notices in the EU have been found to use terms that could minimise consumers' perception of risk, such as "voluntary/precautionary recall", "in rare/specific cases", "in rare cases"/"in specific conditions", or emphasised the lack of reported injuries[141].

Several other factors have been pointed out by MSAs to affect consumers with respect to recall participation. In Portugal, for instance, a large proportion of consumers do not return recalled products, due to either a lack of information or of due diligence[142]. So, many products that are considered unsafe stay on the market, with the obvious risks that this situation entails. Behavioural research suggests that cognitive biases and heuristics may also influence consumers to take suboptimal decisions regarding how to respond to product recalls and may lead them not to take action. For example, information overload and framing effects mean that if recall notices are lengthy and unclear, consumers may ignore them, especially if they are acting under time constraints. Over-optimism may result in consumers underweighting the risk posed by a recalled product, while inertia and endowment effect relate to the fact that consumers have an inherent preference for status-quo, which in the case of recalls means keeping the product.

Conclusion on the extent to which effectiveness of recalls of consumer products is ineffective, and likely future trends

Evidence collected through surveys of MSAs and general stakeholders as well as from other studies indicates that the effectiveness of product recalls from consumers is relatively low[143]. Reasons include that the GPSD is not fully adapted to ensure adequate

[138] European Commission (2019), EU Workshop on strategies to maximize the effectiveness of product recalls, Background document, p.1-5. OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 21.

[139] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

[140] CPSC, XL Associates and Heiden Associates (2003), 'Recall effectiveness research: a review and summary of the literature on consumer motivation and behavior', p. 17 ff, available at: https://www.cpsc.gov/s3fs-public/RecallEffectiveness.pdf.

[141] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

[142] See GPSD implementation study, country report Portugal.

[143] See Part 1 of this report, EQ6.

traceability[144], which puts a strain in the implementation of corrective measures, in particular recalls.

A second major deficiency regarding recalls concerns the lack of EU wide general requirements for recall procedure, communication or the remedies to be offered to consumers. This is a significant shortcoming suggesting that existing GPSD requirements are in themselves currently not sufficient to ensure effective recalls.

The limited effectiveness of recalls may negatively affect consumer safety and the degree to which there is a level playing field for businesses in the internal market, affecting therefore the extent to which the objectives of the GPSD are achieved in practice. Without any changes in legal requirements, it is unlikely that the effectiveness of recalls will substantially improve in the future, although the increasing share of online transactions could in principle lead to improved customer traceability, if this information is used for recalls.

4.6. Inconsistent application of product safety rules for food-imitating products

Council Directive 87/357/EEC (the Food-imitating Products Directive) has been adopted to address the lack of harmonisation amongst national measures trying to ensure product safety of products 'appearing to be other than they are'. These products, pursuant to Article 1(2) Food-imitating Product Directive should have a 'form, odour, colour, appearance, packaging, labelling, volume or size' that consumers, especially children, could confuse with foodstuffs, and should endanger health of safety of consumers, pursuant to its Article 1(1). The fact that these products imitate foodstuffs could then lead to consumers putting such products in their mouths, sucking or ingesting them, which could be dangerous. This led the European legislator to prohibit the marketing and introduction of such products on the market[145] through the above-mentioned Directive. The justification for the adoption of this measure was twofold: to improve consumer protection, especially protection of children, as well as to ensure fair competition on the Internal Market of such products[146]. The latter goal aimed at eliminating barriers to the free movement of goods that could imitate other products, but which would not create serious risks to consumer protection.

While most Member States have implemented the Food-imitating Products Directive into national legislation as in the Directive, without additional provisions[147], there are differences in interpretation. Some MSAs perceive products in this category as dangerous per se[148], whilst others are of the opinion that any serious risks need to be proven through an appropriate risk assessment procedure[149]. The European Commission has previously emphasised that the restrictions on food-imitating consumer products are only applicable when the products are not only imitating foodstuffs, but also cause serious risks and when a risk is chemical, a chemical analysis report is required for the RAPEX notification[150]. This requirement for food-imitating products to cause serious or high risk might not have been sufficiently emphasised in the Directive itself[151]. This had

144 See Part 1 of this report, EQ2 for more details.

145 Article 2 Food-imitating Directive.

146 See recitals to Directive 87/357/EEC as well as PROSAFE, 'Five Consumer Products. Final Implementation Report' (June 2013), at 26.

147 See results of MSA survey, Annex Part 1 of the report.

148 See e.g. responses of the MSAs from Romania, Belgium.

149 See e.g. responses of the MSAs from Malta, Slovak Republic. See also e.g. Dutch case, Rb. Rotterdam 24-11-2016, ECLI:NL:RBROT:2016:9046 drawing attention to the need to harmonise the risk assessment.

150 PROSAFE, 'Five Consumer Products. Final Implementation Report' (June 2013), at 26 and 35.

151 Ibid, at 41.

then led to differences in the national assessment whether a particular food-imitating product should be prohibited from the market. However, the number of Safety Gate/RAPEX notifications of food-imitating products is small[152]. Between 2013 and 2019, a total of 114 notifications that relate to food-imitating products[153]. Table 9 shows the product categories for these notifications in the period 2013 to 2019.

Table 9: Number of notifications of food-imitating products, 2013 – 2019

Product category	Year							Total
	2013	2014	2015	2016	2017	2018	2019	
Cosmetics				3	1	28	1	33
Decorative articles	1			1		4	17	23
Food-imitating products	26	12	8					46
Other							2	2
Stationery							2	2
Toys		1				4	3	8
Total	***27***	***13***	***8***	***4***	***1***	***36***	***25***	***114***

Source: Civic Consulting, based on RAPEX notifications 2013-2019.

The table shows that the number of notifications of food-imitating products is fairly small – up to 36 notifications out of the approximately 2 000 notifications annually. The number has varied significantly in the years, from 1 to 36 notifications annually.

The table shows that the product category "Food-imitating products" was only used up to 2015. Afterwards, the products have been categorised according to their use (cosmetics, clothing, etc.). This seems to indicate that a change of practice has occurred in the Member States to remove the overlap between the category "food-imitating products" and other product categories. Most of these notifications makes reference to the Food-imitating Products Directive in the description of the risk and include a statement like "The product does not comply with the Food-imitating Products Directive." Apparently, it is easier for many MSAs to ban a food-imitating product because the Food-imitating Products Directive directly bans such products without the need for a risk assessment.

The vast majority of the notifications related to food-imitating products (87%) mentions or includes choking in the description of the risk associated with the product, presumably because the product is or contains small parts. The second-most common risk type is "chemical" (12%).

There is little evidence available regarding the adverse effect of food-imitating products. A 2011 opinion by the Scientific Committee on Consumer Safety concluded that "Few cases of accidental ingestion of food-resembling or child-appealing products are reported. This may be due to the lack of sufficient registered information to discriminate these types of products. Data from poison centres and scientific literature on accidental ingestion of cosmetics or liquid household products suggest that the majority of such

[152] It has been suggested that the number of notifications have decreased over the years due to the Joint Action having been undertaken in this area, which led to the development of a specific risk assessment procedure allowing to better identify when such products cause serious risks, see ibid, at 39.

[153] These are identified in different ways, and some cases meet several of the criteria at the same time: The parameter "Category" includes "Food-imitating products" (46 notifications); The parameter "Product" includes the text "imitat" (6 notifications); The parameter "Description" contains the text "imitat" (46 notifications); The parameter "Risk" contains the text "imitat" (57 notifications). Cases that were identified using the filtering term "imitat" have subsequently been reviewed manually to remove cases that did not refer to food (e.g. notifications related to "leather imitation", "imitation of gun", etc.)

ingestions result in mild gastrointestinal effects. […] The weight of evidence from accidental ingestion of cosmetics suggests that there is a low risk of acute poisoning in either children or the elderly. For household products, there is a slight increase of a more serious outcome" [154]. From the opinion, which focused on chemical consumer products resembling food and/or having child-appealing properties, it appears that these food-imitating products rarely represent serious or high risks. However, the opinion also concludes that "there is a lack of specific data on accidental ingestion from consumer products resembling food and/or having child-appealing properties".

Conclusion on the extent to which the application of product safety rules for food-imitating products is inconsistent, and likely future trends

While a majority of the MSAs seems to apply the provisions of the Food-imitating Products Directive only in cases where the risks are serious[155], there are also countries that consider products in this category as dangerous per se. In other words, the legal framework for food-imitating products is applied differently in different countries. There appears also to be limited evidence that would justify a fully separate regime for these products. Without legal clarification, country differences in the application of the Food-imitating Products Directive are likely to continue.

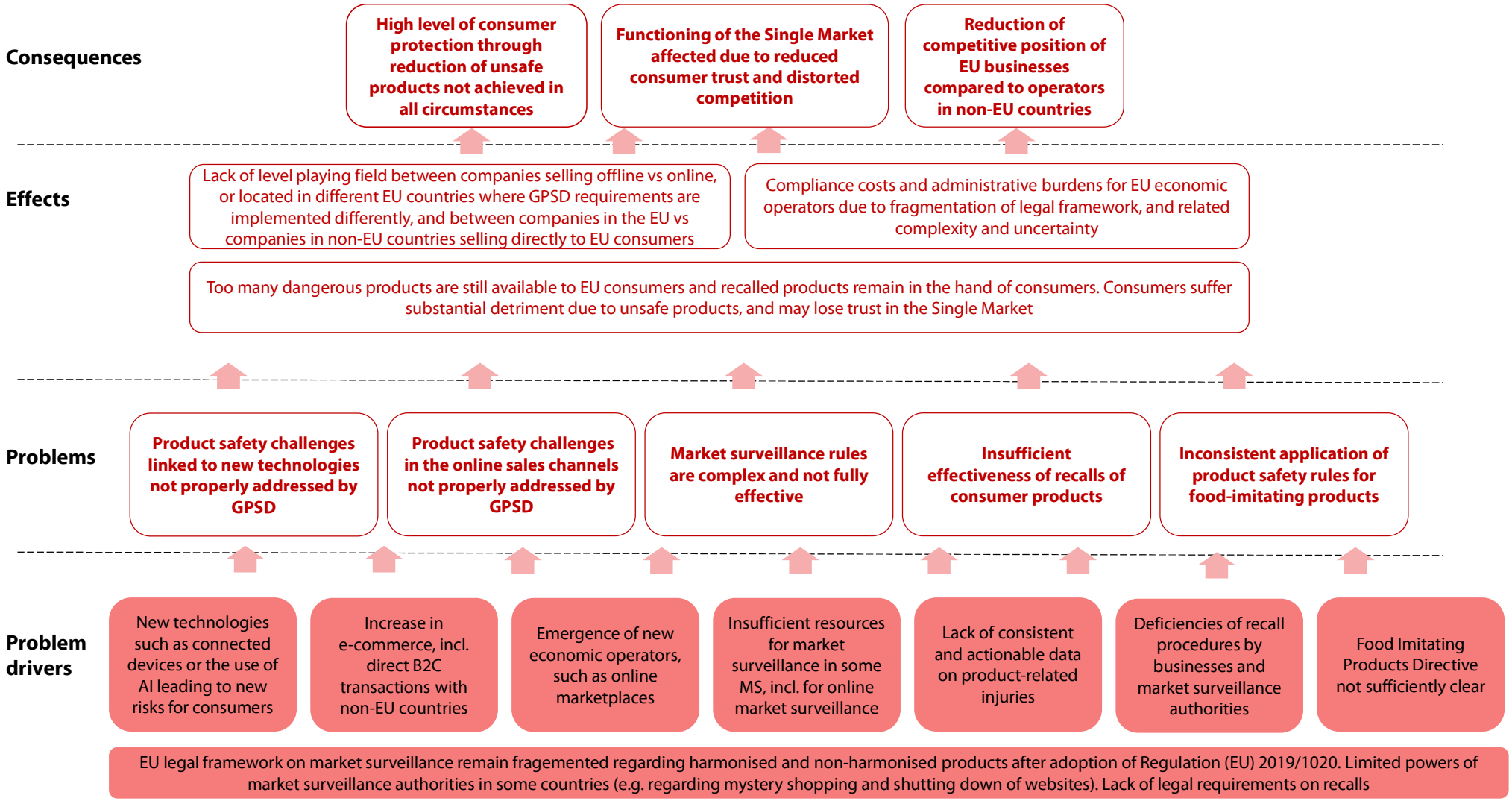
4.7. Overview of problems identified and their drivers

Figure 8 on the next page summarises the problems and drivers identified in the previous sub-sections.

[154] See Scientific Committee on Consumer Safety (SCCS), 'Opinion on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties' (22 March 2011) <https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_056.pdf>, at 8-9.

[155] See PROSAFE, 'Five Consumer Products. Final Implementation Report' (June 2013), at 39.

Figure 8: Problem analysis



5. Objectives of a possible EU intervention

5.1. Objectives of a possible EU intervention

In June 2020, the European Commission published a combined evaluation roadmap/Inception Impact Assessment[156] ('Roadmap/IIA'), which presented initial policy objectives for a possible EU intervention. These were refined on basis of the results of the research and consultation conducted for this study. The following paragraphs present the proposed main objectives of a possible future EU intervention, and related specific objectives.

Proposed main objectives of a possible future EU intervention:

- To ensure the safety of non-food consumer products on the EU market
- To contribute to the functioning of the Single Market and ensure a level playing field for businesses

Proposed specific objectives of a possible future EU intervention:

(1) Ensure that the EU legal framework provides for general safety rules for all consumer products and risks, including product risks linked to new technologies;

(2) Address product safety challenges in the online sales channels;

(3) Make product recalls more effective and efficient to keep unsafe products away from consumers;

(4) Enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products; and

(5) Address safety issues related to food-imitating products[157].

These proposed general and specific objectives of a possible future EU intervention also take into account the results of the recent GPSD implementation study[158], the consultations conducted for this study and the findings of the evaluation of the GPSD (see Part 1 of this report).

5.2. Intervention logic of a possible EU intervention

Based on the problem analysis and the definition of objectives it is possible to elaborate the intervention logic of a possible future EU initiative. It considers the underlying "theory" of the intervention (how it would be expected to work), as derived from the analysis of the study. Figure 9 below presents the proposed intervention logic and shows how the identified problems and needs relate to the proposed main and specific

[156] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12466-Review-of-the-general-product-safety-directive

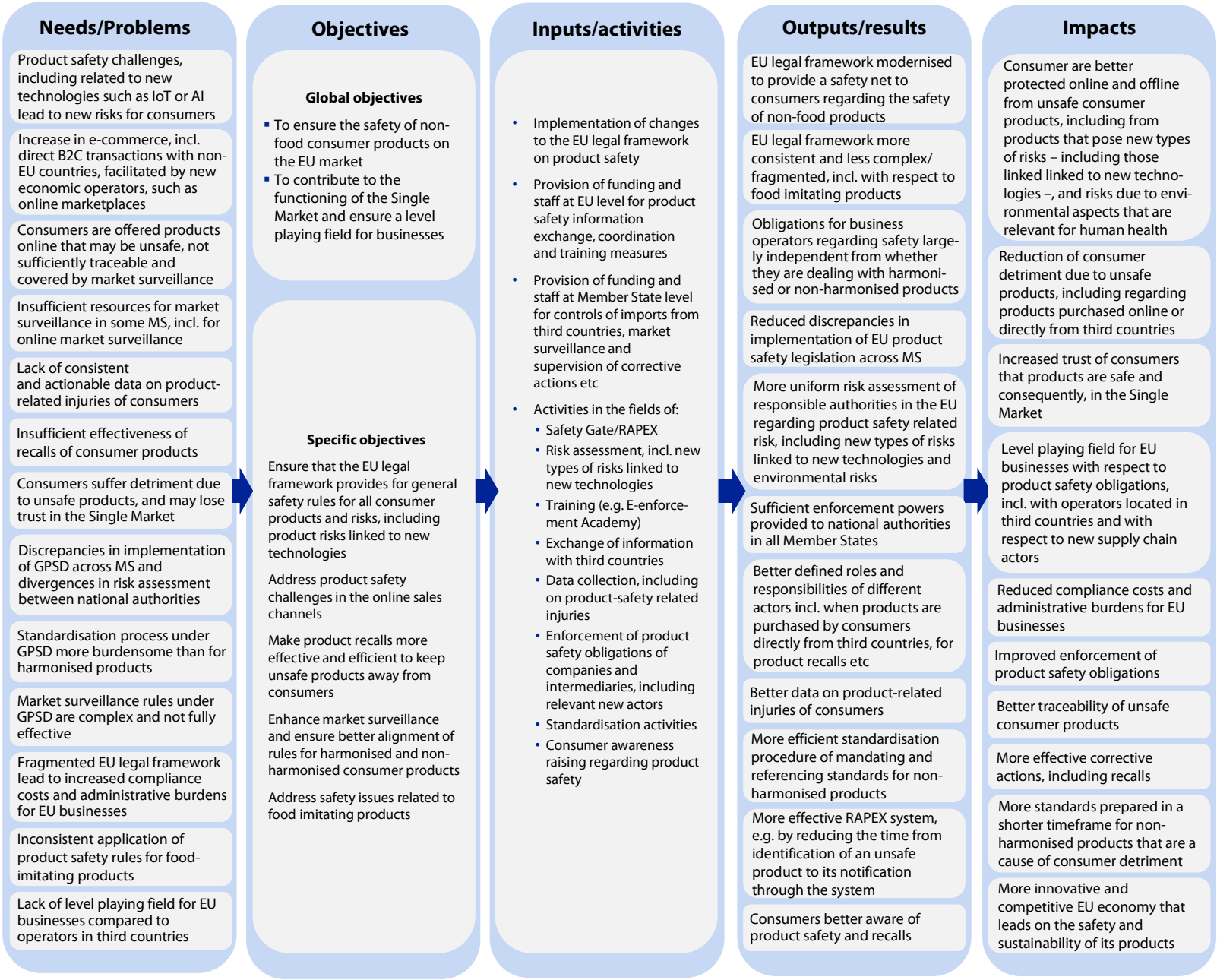
[157] The Food-imitating Directive (87/357/EEC) concerns products that may be confused with real food by children or other vulnerable persons. Examples are food-shaped shampoos or bath gels. The Directive creates a separate regime for these specific products, which differs from the GPSD in key aspects.

[158] Civic Consulting (2020), Study for the preparation of an Implementation Report of the General Product Safety Directive, Final report.

objectives, as well as to the expected inputs/activities, the intended outputs and results, as well as the wider impacts.

Note that the intervention logic focuses on a comprehensive EU initiative, in line with Options 3 and 4 presented below. If another option would be preferred, the intervention logic would need to be adapted accordingly. For example, if no legal measures would be taken (Option 1), potential impacts with respect to a reduced fragmentation of the legal framework could not be expected and would have to be removed from the intervention logic.

Figure 9: Intervention logic of a possible EU intervention



6. Policy options

In this section, we first present an overview of the policy options for a possible EU intervention considered in this study. Further details of each option are provided in the subsequent section.

6.1. Overview of policy options

As the combined evaluation roadmap/Inception Impact Assessment[159] ('Roadmap/IIA') emphasises, the GPSD is nearly 20 years old and as such does not reflect recent developments in products and markets, as analysed in section 4 above. The Roadmap/IIA presented a preliminary set of policy options to simplify, make more coherent and update the EU legal framework for consumer product safety. These are: The status quo option (baseline) and four options involving varying degrees of policy changes to address the above challenges. The policy options are set out in Table 10 below, which also specifies for which stakeholder group (consumers, businesses, market surveillance authorities etc.) each policy change would be primarily relevant.

Initial policy options presented in the Roadmap/IIA took into account the results of the GPSD implementation study, which – based on a broad consultation process – had elaborated key deficiencies of the current legal framework and stakeholder suggestions for improvements. In the course of the current study, the completeness of these policy options was validated and no further policy options for consideration were identified[160].

[159] See link provided in footnote 156.

[160] Note, however, that several potential complementary measures to increase achievement of objectives and reduce administrative burdens were identified, which are presented in Section 8.7.

Table 10: Overview of policy objectives and related policy options for a possible revision of the GPSD

Specific policy objectives	Option 0. 'Status quo': No new actions	Option 1. Improved implementation and enforcement, without revision of the GPSD	Option 2. Targeted revision of the GPSD (in form of Directive or Regulation)	Option 3. Full revision of the GPSD and recasting as Regulation	Option 4. New Regulation merging market surveillance provisions of GPSD and Reg. 2019/1020	Most directly relevant for …
Ensure general safety rules, including for product risks linked to new technologies	No change	Guidance for businesses that cybersecurity threats and other risks of new technologies affecting physical or mental health are covered. Exploring use of European Standards for new risks	New risks (see Option 1) explicitly covered through revision of GPSD, without extending the definition of product to standalone software	The new Regulation would explicitly cover new risks (as in Option 2), and extend the definition of product to standalone software	This option would provide for a new legal instrument including all elements described under Option 3 and also merging the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products, so that one single set of rules would apply to harmonised and non-harmonised consumer products.	Businesses (for consumer products incorporating new technologies) and MSAs
Address safety challenges in the online sales channels	No change	Update of the Product Safety Pledge, its promotion in order to expand it to further signatory marketplaces	Legal revision making most provisions of the Product Safety Pledge legally binding	As in Option 2. Additional obligations for online marketplaces beyond the provisions of the Product Safety Pledge, as well as to businesses selling online to consumers to provide all safety information online that are also required 'offline' and marketplaces required to make sure that third party sellers provide this information		Online marketplaces, businesses selling online to consumers, and MSAs
Make product recalls more effective	No change	Guidance on product recalls for market surveillance authorities and economic operators	Clarify/create legal basis for economic operators to use available customer contact details to notify the owners of recalled products. Mandatory key elements defined that are to be included in recall notice and prohibition to use the terms decreasing the perception of risk	As in Option 2. Additional requirements include possibility to set out further requirements for product registration; use of a template for recall notices; consumers' right to an effective, cost-free and timely remedy; and requirements for businesses to register voluntary recalls in an EU database		Businesses (harmonised and non-harmonised consumer products), MSAs
Enhance market surveillance and ensure better alignment of rules	No change	Increased funding of joint market surveillance activities among Member States, including joint testing of consumer products	Align GPSD with market surveillance rules in Regulation (EU) 2019/1020, to have more uniform framework for harmonised and non-harmonised consumer products while keeping different legal instruments. Aligning the traceability requirements to those for harmonised products. Simplifying standardisation procedures	Aligned market surveillance framework for harmonised and non-harmonised consumer products while keeping different legal instruments. Aligning the traceability requirements to those for harmonised products. Simplifying standardisation procedures (as Option 2). Enforcement powers are further strengthened (e.g. on penalties and sanctions). Arbitration mechanism (Member States and/or Commission) in case Member States have diverging product safety risk assessments		MSAs and businesses (in particular businesses of non-harmonised consumer products)
Address safety issues related to food-imitating products	No change	Revision of the Food-imitating Products Directive, clarifying the way to assess level of risk of these products without integrating into GPSD	Incorporation of food-imitating products into the GPSD general framework	Incorporating provisions on food-imitating products into the new Regulation, and consider banning their marketing and sale in the EU market		Producers of food-imitating products and MSAs

6.2. Detailed description of policy options

As indicated in Table 10 above, the policy options identified are briefly as follows:

- Option 0. 'Status quo': Baseline scenario not involving any new actions;
- Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD;
- Option 2. Targeted revision of the GPSD (Directive or Regulation);
- Option 3. Full revision of the GPSD and recasting as Regulation;
- Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

The options are explained in detail in the following sub-sections.

6.2.1. Option 0. 'Status quo': Baseline scenario not involving any new actions

This option would entail no changes at all in the EU legislative framework for consumer product safety, other than those that have been already adopted (notably Regulation (EU) 2019/1020). Non-legislative measures are also not foreseen.

6.2.2. Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD

This option would not require a legal revision of the GPSD, and would include:

a) *Development of guidance on the safety of new technologies and exploring the use of European standards to address new risks.* The general safety requirement of the GPSD already encompasses protection against all kinds of risks arising from the product to the safety and health of persons. The guidance would clarify how this includes not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons[161], and other risks related to new technologies that potentially affect physical or mental health[162]. The European Commission would also explore the use of the procedure of Art 4 GPSD to elaborate European Standards that address safety requirements for consumer products concerning certain new risks.

b) *More support and promotion of the Product Safety Pledge.* In the Product Safety Pledge[163], first signed in 2018, seven online marketplaces have so far voluntarily committed to take action in respect to unsafe products notified in RAPEX or when informed by Member States' authorities and to other activities with the aim to ensure safety of products they are listing. The Pledge would be updated and promoted through awareness campaigns, and other online marketplaces would be encouraged to sign the Pledge.

c) *Development of guidance on product recalls.* The guidance would address current deficiencies concerning the effectiveness and efficiency of recall procedures by economic operators and market surveillance authorities, relying on the current legislation. The guidance would concern e.g. the provision of more transparent information to consumers regarding the safety risk that led to the recall, the use of customer data for direct notifications and cooperation between different actors in the recall process.

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[161] E.g. a smart watch for children, which does not causes a direct harm to the child wearing it, but lacks a minimum level of security, so that it can be easily used as a tool to have access to the child. Another example would be a car that may have certain software security gaps allowing unauthorised third party access to the interconnected control systems in the vehicle.

[162] Mental health risks for consumers deriving, for example, from their collaboration with humanoid AI systems.

[163] https://ec.europa.eu/info/files/product-safety-pledge_en.

d) *Increased funding for joint market surveillance activities among Member States*, so that more coordinated actions of authorities across EU Member States could be conducted, including the joint testing of consumer products.

e) *Revision of the Food-imitating Products Directive* (87/357/EEC)[164] *to clarify its scope.* Currently, the Directive is applied differently across EU countries, as authorities in Member States can take action on products such as food-shaped shampoos or bath gels, even though no specific risk evaluation has been made (interpretation of the Directive as a *per se* prohibition of food-imitating products). A revision would better detail the requirements of the Food-imitating Directive and require an evaluation of the risks posed by the specific food-imitating product, as it is done for other consumer products.

6.2.3. Option 2. Targeted revision of the GPSD (Directive or Regulation)

Option 2 would require a legal revision of the GPSD, which would remain a Directive or become a Regulation. In case the new instrument is also a Directive, changes to the GPSD would need to be transposed by Member States into national legislation. The changes to the legal framework would include:

a) *Making explicit how the scope of the legal framework and its definitions apply to risks posed by new technologies but without applying it to standalone software.* The definition of safety in the GPSD would be revised to clarify that the covered risks arising from the product to the safety and physical/mental health of persons include not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect health (similar to the guidance that would be provided under Option 1). The definition of product in the GPSD would not be changed, so that safety risks stemming from software are only covered if the software is integrated in a product at the time of its placing on the market (as is currently the case). There will be not specific provisions on or references to software updates, and also standalone software would not fall under the safety requirements of the GPSD, even if the software can interact with a product[165].

b) *Adding requirements for online marketplaces by making most provisions of the voluntary Product Safety Pledge legally binding*. The Product Safety Pledge includes commitments of marketplaces with respect to the safety of non-food consumer products sold online by third party sellers on their platform. The commitments include to consult information on recalled/dangerous products available on RAPEX and also from other sources; to take appropriate action in respect to recalled/dangerous products, when they can be identified; to provide single contact points for EU Member State authorities and to cooperate with them; to have an internal mechanism for notice and take-down procedure for dangerous products and other requirements. These provisions would become legally binding for all online marketplaces targeting EU consumers[166].

c) *Adding requirements for enhancing the effectiveness of product recalls*. Clarify/create legal basis for economic operators to use any available customer contact details at their disposal (e.g. obtained through loyalty schemes) to directly notify the owners of recalled products (without the need of consumer consent). The use of customer registration systems for the purpose of product safety would be encouraged (without making them binding). Mandatory key elements would be defined that are to be included in every recall notice (product description with a photograph, description of risk, instructions on what to do, link to a recall website and free phone number or online service for queries). Prohibition to use terms decreasing the perception of risk in recall notices (e.g. 'voluntary/precautionary recall' or "overheating" instead of fire). In case not all affected

[164] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al21189.

[165] An example would be a third party operating system uploaded on a product after its placing on the market which affects the performance and/or features of a product in terms of safety. Under Option 2, this would continue to not be covered by the GPSD.

[166] All commitments under the Pledge would become legally binding, except most probably commitment 7 (training to sellers on compliance with EU product safety legislation, etc.) and 12 (Exploring new technologies and innovation to improve the detection of unsafe products).

consumers can be contacted directly, businesses would need to disseminate recall announcements on their website/social media and other appropriate channels to ensure the widest possible reach.

d) *Ensuring alignment with harmonised market surveillance rules while keeping different legal instruments and simplifying standardisation procedures*. The market surveillance rules provided in the GPSD would be aligned with the provisions in Regulation (EU) 2019/1020 on market surveillance and compliance of products[167]. Requirements for businesses would reflect the current obligations under the GPSD, and include complementary requirements in Regulation (EU) 2019/1020 (notably regarding the requirement of an EU responsible economic operator)[168] and other harmonisation legislation[169]. As a result, general requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products. Also, standardisation procedures at the Commission level under the GPSD would be simplified.[170].

e) *Integrating the provisions of the Food-imitating Products Directive into the risk assessment related provisions of the GPSD.* The provisions of the Food-imitating Products Directive would be integrated in the GPSD and similar to Option 1, the revised provisions would better detail the requirements for food-imitating products and require the evaluation of the risks posed by the specific food-imitating product, similarly to the requirements under the GPSD for other consumer products.

6.2.4. Option 3. Full revision of the GPSD and recasting as Regulation

Option 3 would repeal the Directive and ensure even application of its implementation through the choice of a Regulation (i.e. it will be directly applicable in Member States). This option would include all elements of Option 2 and, **in addition**:

a) *Extend the definition of products to standalone software*. In addition to changing the definition of safety as in Option 2, this option would also change the definition of product of the GPSD to include standalone software. Software updates after a product is placed on the market that affect the safety of the product would be covered, and standalone software would also fall under the general safety requirement[171].

b) *Making legally binding most provisions of the voluntary Product Safety Pledge for online marketplaces (as in Option 2) and include new provisions for actors across the online supply chain.* These new provisions for actors across the online supply chain would require them to provide all safety information online that is also required to be provided with a product in 'brick-and-mortar' stores. Online marketplaces would have a duty of care and they will be required to make sure that third party sellers on their platform

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167 I.e. the provisions of Chapters IV and VI in Regulation (EU) 2019/1020.

168 Regulation (EU) 2019/1020 requires in Article 4 an economic operator established in the Union to be responsible for key tasks in relation to the safety of products. This might be a manufacturer, importer, authorised representative, or a fulfilment service provider. It also requires that the name and contact details of the responsible operator will have to be displayed on the product or on its packaging, the parcel or an accompanying document. Traceability requirements would include the requirement to keep supply chain records (to allow for one-up one-down traceability, i.e. the identification of suppliers and clients, except final consumers).

169 See also 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 provides reference provisions, definitions and general obligations for economic operators.

170 Changes would concern the involvement of MS committees at various stages of the process. The elaboration of the European Standards by the European Standardisation Organisations would not be affected.

171 Possible scenarios where this extension of the definition of product for standalone software would be relevant are: software that can interact with a product and affects is safety, e.g. a third party operating system uploaded on a product after its placing on the market which affects the performance and/or features of a product in terms of safety; electronic games with highly addictive potential, or electronic games that cause dangerous behaviour of people, especially vulnerable groups such as children (e.g. in the context of augmented reality games in public spaces or dangerous 'real-world' challenges posed by a game).

provide this information together with the product offer (without being required to check the accuracy of the safety information provided).

c) *Establish mandatory requirements for product recalls and registration.* In addition to all the elements of Option 2, the following would be introduced:
- Economic operators who offer product registration systems (e.g. for warranty or technical support) should offer consumers the possibility to register their contact details specifically to receive possible safety notifications (personal information collected for the purpose of product safety should be limited to the necessary minimum and must not be used for marketing purposes);
- Possibility to set out further requirements for product registration and determine categories of products subject to mandatory supply-side registration through implementing act;
- Binding requirement for economic operators to use a template for recall notices (annex of the Regulation);
- Consumers' right to an effective, cost-free and timely remedy would also be set out;
There would be binding requirements for businesses to register voluntary recalls in an EU public database and to monitor recall effectiveness; In case of voluntary recalls of products posing a serious risk, MSAs would have the possibility to pre-approve proposed remedies and communication strategy before the recall goes public. They would also have the possibility to request monitoring data on the effectiveness of a product recall from economic operators and decide if the case can be closed.

d) *Give stronger enforcement powers to Member State authorities (for example on penalties and sanctions) and establish arbitration mechanism in case Member States have diverging product safety risk assessments.* Building on Option 2, general requirements for businesses and responsibilities of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products. However, under Option 3 stronger enforcement rules would be incorporated (e.g. on penalties and sanctions). In case Member States have diverging assessments of the risk posed by a notified product, a mechanism could be triggered where either a group of Member States or the Commission are called to arbitrate.

e) *Consider a ban on the marketing and sale of all food-imitating products in the EU market.* As in Option 2, the provisions of the Food-imitating Products Directive would be integrated in the new Regulation. However, such products (e.g. food-shaped shampoos or bath gels) that could be confused with real food by vulnerable consumer groups such as children), could be banned throughout the Union *per se*.

6.2.5. Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

This option would provide for a new legal instrument including all elements described under Option 3 and also merging the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products, so that one single set of rules would apply to harmonised and non-harmonised products.

7. Description of baseline

The baseline scenario is the "no policy change" option. This option would therefore entail no changes at all in the EU legislative framework for consumer product safety, other than those that are already adopted (notably Regulation (EU) 2019/1020 on market surveillance and compliance of products, which will apply from 2021 onwards). Non-legislative measures are not foreseen.

The problems and problem drivers related to the current legislative framework, as well as the likely future developments over the next decade are described in section 4. This section therefore focuses on the current costs and benefits of the GPSD, estimates current product-related detriment to consumers in the EU and explores possible impacts of the COVID-19 crisis on the baseline situation.

7.1. Costs of the GPSD

The current costs of compliance with the GPSD (or baseline costs) are directly accruing to businesses (hereafter interchangeably used with the term 'companies') and market surveillance authorities, and only indirectly to consumers in the form of costs of consumer goods (which may be influenced by product safety legislation) and taxes (of which a very small part are used for market surveillance). The following section focuses on the costs of businesses, with baseline costs accruing to other actors being elaborated in the subsequent sub-sections.

7.1.1. Businesses

Assessing the costs of compliance of businesses with the GPSD is challenging due to a number of factors:

- As mentioned before, the GPSD applies fully to consumer products for which no specific EU harmonised legislation exists (non-harmonised products such as childcare articles, furniture, clothing etc.). It does not apply to industrial/ professional products. While the GPSD is also applicable to harmonised consumer products (such as toys) to the extent that there are no specific provisions with the same safety objective in the EU harmonised legislation (for example type of risk), the significance of this 'residual effect' of the GPSD depends on several factors, most notably on the extent to which EU harmonised legislation reflects the same level of protection. In practice, the residual effect of the GPSD for harmonised products is not possible to separate from the effects of the harmonised legislation itself. As the residual effects of the GPSD on manufacturing and distribution of harmonised products are in any case expected to be very minor compared to the effects in the area of non-harmonised products, this assessment focuses on the latter. In other words, the following assessment considers the current costs of compliance with the GPSD for manufacturers and distributors of non-harmonised consumer products. This focus of the cost assessment is illustrated in the following matrix (left quadrant, marked in green).

Table 11: Area of application of the GPSD with focus on cost assessment (marked in green)

	Consumer products	Industrial/professional products
Non-harmonised products	**GPSD fully applies**	GPSD does not apply
Harmonised products	Residual effect of the GPSD	GPSD does not apply

Source: Civic Consulting.

- Companies often manufacture or distribute both harmonised and non-harmonised products. Our research established early on that it is not feasible for companies to differentiate their compliance costs for product safety legislation in the harmonised area vs those in the non-harmonised area. The reason is that the workflow to safeguard product safety is not differentiated according to this criterion, and often embedded in the broader framework of regulatory compliance. The following assessment therefore considers company costs to safeguard the safety of consumer products manufactured, imported or sold/distributed by the surveyed companies. Respondents to the cost survey were asked to consider all costs for ensuring product safety of both harmonised and non-harmonised consumer products (excluding pharmaceuticals, medical devices or food). Costs for product design and development were excluded, as well as costs for tasks related to the compliance with other regulation, such as environmental legislation. These costs were then allocated according to turnover due to harmonised vs. non-harmonised products at a sector level, based on the share of harmonised products circulating within the European Single Market provided in the 2017 impact assessment for the new Market Surveillance Regulation[172]. This allowed us to subtract the costs accruing due to manufacture or distribution of harmonised products from those costs that are relevant for non-harmonised products (see below for further details).
- To extrapolate data collected at the company level through our cost survey, there is a need to have data on overall turnover and/or number of companies for the relevant sectors of the EU economy. This is not trivial: Eurostat data does not differentiate between industrial/professional products and consumer products on the one hand, and harmonised and non-harmonised products on the other hand (and also does not provide the number of companies according to these criteria). As GPSD compliance costs may accrue throughout the supply chain, our assessment considers the costs for manufacturers, wholesalers and retailers in those areas where the GPSD fully applies (see matrix above). For the estimation of relevant sector data, we have applied an innovative approach, which combines data from national accounts (consumption expenditure for non-food products) with data from turnover of EU companies manufacturing/selling consumer products, by company size class.

Our methodological approach and the results derived are explained in the following sub-section. We first focus on the estimation of the baseline market size, i.e. the total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer

[172] SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

products in the EU[173], before presenting the company level compliance cost data, and extrapolating it to EU level, based on the estimated baseline market size.

7.1.1.1. Estimation of total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer products in the EU

The estimation of the baseline market size, i.e. the total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer products in the EU, is based on the following three steps:

Step 1: Estimation of EU companies' total annual turnover from the production and/or sales of non-harmonised consumer products in the EU

In this step, we take into consideration manufacturing sectors (NACE Rev. 2, B-E), wholesale services sectors and retail sectors (NACE Rev. 2, G) in which both harmonised and non-harmonised products are either produced or sold. Based on NACE industry codes and sector descriptions, we identified those sectors in which consumer products are produced and/or sold, i.e. we excluded sectors that clearly focus on the production and sales of industrial products. Note that sectors related to motor vehicles have been excluded, in line with the focus on non-harmonised consumer products.

On basis of a review of the relevant NACE definitions, we have identified the following sectors as being relevant:

Table 12: Relevant manufacturing sectors (NACE Rev. 2, B-E), wholesale services sectors and retail sectors (NACE Rev. 2, G)

Manufacturing sectors	Wholesale services sectors and retail sectors
• Manufacture of textiles • Manufacture of wearing apparel • Manufacture of leather and related products • Manufacture of products of wood, cork, straw and plaiting materials • Manufacture of articles of paper and paperboard • Manufacture of paints, varnishes and similar coatings, printing ink and mastics • Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations • Manufacture of rubber and plastic products • Manufacture of glass and glass products • Manufacture of other porcelain and ceramic products • Manufacture of cutlery, tools and general hardware • Manufacture of other fabricated metal products • Manufacture of computer, electronic and optical products • Manufacture of electrical equipment • Manufacture of other general-purpose machinery	• Wholesale on a fee or contract basis • Wholesale of household goods • Wholesale of information and communication equipment • Retail sale in non-specialised stores[174] • Retail sale of information and communication equipment in specialised stores • Retail sale of other household equipment in specialised stores • Retail sale of cultural and recreation goods in specialised stores • Retail sale of other goods in specialised stores • Retail sale via stalls and markets • Retail trade not in stores, stalls or markets

[173] All estimates in this section refer to the EU27 as of 2020.

[174] In sector "G47.1 Retail sale in non-specialised stores", sales of food, beverages or tobacco is predominating. Activities mainly include activities of general stores that have, apart from their main sales of food products, beverages or tobacco, several other lines of merchandise such as wearing apparel, furniture, appliances, hardware, cosmetics etc. Precise numbers for the share of food and non-food items in this category are not available. Given that this category is best described by the above activities, we have assumed that 10% of the turnover in G47.1 is related to non-food consumer products.

• Manufacture of metal forming machinery and machine tools • Manufacture of transport equipment n.e.c. • Manufacture of furniture • Manufacture of jewellery, bijouterie and related articles • Manufacture of musical instruments • Manufacture of sports goods • Manufacture of games and toys • Manufacturing n.e.c.	

While retail sale can be assumed to be largely related to consumer products (although retailers may also sell to professional users, and may sell services), the wholesale and manufacturing in the listed areas clearly also contain industrial/professional products, an issue that will be considered in Step 3 below.

To arrive at the share of non-harmonised products produced and/or sold in these sectors, we apply the estimate provided in the 2017 EU impact assessment for the new Market Surveillance Regulation, which estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products[175]. It should be noted that the share of non-harmonised products may have declined in recent years due to greater product coverage of harmonised legislation. Still the above estimate is broadly in line with the estimates provided by two large EU online business operators which both indicated in their response to our company survey relative shares of 60% for harmonised products and 40% for non-harmonised products offered by them.

Based on this approach, the total EU turnover from non-harmonised products in the selected sectors amounts to EUR 773 billion for EU manufacturers, EUR 750 billion for EU wholesalers and EUR 581 billion for EU retailers (see Table 13).

[175] SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

Table 13: Annual turnover of EU companies manufacturing, wholesale and retail of products, by company size class, in million EUR, based on 2017 values

	Total of harmonised and non-harmonised products[a)]			Non-harmonised products only[b)]			
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	*From 0 to 49*	*50 – 249*	*250 or more*	***Total***
Total of manufacturing	362 944	493 730	824 523	166 954	227 116	379 280	**773 351**
Total of wholesale	603 713	425 061	602 593	277 708	195 528	277 193	**750 429**
Total of retail	673 651	129 742	458 904	309 879	59 681	211 096	**580 657**
Total	***1 640 308***	***1 048 533***	***1 886 020***	***754 542***	***482 325***	***867 569***	***2 104 436***

Source: Civic Consulting, based on most recent Eurostat data. a) In sectors in which consumer products are produced and/or sold (see Annex tables). b) Based on estimate that 46% of harmonised products circulating within the European Single Market are non-harmonised (in value terms). Note that this estimate also includes industrial/professional products, see SWD(2017) 466 final PART 2/4, p166.

A detailed overview of relevant manufacturing, wholesale and retail sectors and annual turnover by company size class is provided in the Annex.

Step 2: Deduction of extra-EU export

A part of the turnover estimated in Step 1 is generated through export to non-EU countries. We exclude this share, as we are interested in estimating the costs of the GPSD for products sold on the EU market. Also, exported consumer products have to comply with the laws of the destination countries, which may or may not be similar to EU requirements. Accordingly, we reduce the annual turnover derived in Step 1 by export sales to non-EU countries (extra-EU exports). It should be noted that imports from non-EU countries represent costs, which are reflected in companies' turnover data, so that imports do not have to be specifically considered.

To calculate the net turnover for non-harmonised consumer products that are only sold in the EU, we therefore deducted the share of extra-EU exports from the total turnover of EU companies. The calculation is based on an approximation of sector-specific export shares. The extra-EU trade by enterprise characteristics data provided by Eurostat do not exactly match the sector classification of turnover data by enterprise size class[176]. We therefore approximated the extra-EU export shares of manufacturing, wholesale and retail sectors on the basis of those sectors for which we found full concordance in the two datasets[177]. Based on this approximation, we arrive at the extra-EU export share estimates outlined in Table 14 below.

[176] In the Annex, we provided detailed trade volumes of extra-EU exports by NACE Rev. 2 activity and enterprise size class.

[177] These sectors are: "Manufacture of textiles, Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials", "Manufacture of paper and paper products", "Manufacture of computer, electronic and optical products", "Manufacture of electrical equipment", "Manufacture of furniture", "Wholesale trade, except of motor vehicles and motorcycles", and "Retail trade, except of motor vehicles and motorcycles". In the Annex, we provide shares of extra-EU exports in key consumer products sectors broken-down by enterprise size class.

Table 14: Estimated extra-EU export shares of manufacturing, wholesale and retail sectors

	From 0 to 49 employees	50 – 249 employees	250 or more employees
Estimated export shares applied for manufacturing sectors	10.0%	15.2%	17.7%
Estimated export shares applied for wholesale and retail sectors	6.6%	8.3%	3.4%

Source: Own estimation, based on Eurostat data.

These estimated extra-EU export shares of manufacturing, wholesale and retail sectors are subtracted from the annual turnover of EU companies with non-harmonised products in the selected sectors (calculated above). The resulting estimates excluding exports are presented below.

Table 15: Annual turnover of EU companies manufacturing, wholesale and retail of non-harmonised products, by company size class, excluding exports, in million EUR, based on 2017 values

	Turnover by company size			Total turnover
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	**All size categories**
Total of manufacturing	150 335	192 666	311 959	**654 960**
Total of wholesale	259 516	179 372	267 706	**706 595**
Total of retail	289 580	54 750	203 871	**548 202**
Total	***699 431***	***426 789***	***783 536***	***1 909 757***

Source: Own calculation, based on Eurostat data.

We therefore estimate an annual EU turnover related to non-harmonised products of EUR 655 billion for EU manufacturers, EUR 707 billion EUR for EU wholesalers and approx. EUR 548 billion EUR for EU retailers (see Table 15). Detailed annual extra-EU export-adjusted turnover data are provided in the Annex.

Step 3: Deduction of industrial and professional products

As indicated before, the EU turnover data for non-harmonised products in the selected sectors include turnover from industrial products and professional products sold in business-to-business (B2B) markets. We therefore corrected the EU turnover derived in Step 2 by the percentage shares of turnover that can be attributed to the production and/or sales of consumer products in manufacturing, wholesale and retail sectors.

For this purpose, we draw on a different dataset, namely the final consumption expenditure of households by consumption purpose[178]. We again correct for the share of harmonised products, so that we arrive at an estimate for total household consumption of non-harmonised products.

[178] Eurostat, Final consumption expenditure of households by consumption purpose (COICOP 3 digit) [nama_10_co3_p3].

Table 16: Estimated household consumption in the EU, in million Euro (2018)

	Total consumption
Total EU27 household consumption	7 115 852
Total EU27 household consumption of services	4 344 391
Total EU27 household consumption of non-food goods, ex medical products, ex vehicles (harmonised and non-harmonised consumer products)	931 878
Total EU27 household consumption of non-food goods, ex medical products, ex vehicles (non-harmonised consumer products only) [a)]	**428 664**

Source: Civic Consulting, based on most recent Eurostat data. Notes: a) Based on estimate that 46% of harmonised products circulating within the European Single Market are non-harmonised (in value terms). Note that this estimate also includes industrial/professional products, see SWD(2017) 466 final PART 2/4, p166.

As indicated in Table 16 above, EU27 households spend approximately EUR 932 billion annually on non-food, non-services consumer products, both harmonised and non-harmonised. Applying the same approach as above, we calculate that the estimated consumption of non-harmonised consumer products for which the GPSD fully applies is approximately EUR 429 billion. For the following analysis we assume that this consumption of non-harmonised consumer products is equivalent to the total turnover from non-harmonised consumer products sold by EU retailers. The estimated retail turnover from non-harmonised products indicated before was adjusted accordingly, and the amount of EUR 429 billion was allocated between the three enterprise size classes (see Table 17 below).

Due to data limitations, the same methodology cannot be applied for manufacturing and wholesale sectors[179]. For manufacturing and wholesale sectors, we estimated the share of turnover that can be attributed to consumer products on the basis of the share of "consumer-oriented" wholesale services in total wholesale services (for an overview of consumer-oriented wholesale services, see Annex)[180]. Based on the list of consumer-oriented wholesale services, we estimate that 44.3% of the total turnover across all wholesale services that distribute consumer as well as professional/industrial products can be attributed to the sales of consumer products[181]. It is assumed that the same share reflects the portion of consumer products produced and/or sold by manufacturers. Based on this approach, EU companies' annual EU turnover from non-harmonised consumer products amounts to EUR 290 billion for manufacturing sectors and EUR 313 billion for wholesale sectors.

[179] Eurostat data do not allow to extract "pure" consumer products for manufacturing and wholesale sectors, i.e. final products that are consumed by households.

[180] For a similar breakdown of consumer-oriented wholesale services, see AIT-IS-Report (2016), EU wholesale trade: Analysis of the sector and value chains, vol. 128, June 2016.

[181] For "wholesale of computers, computer peripheral equipment and software", which includes many professional ICT products sold to businesses and the public sector, we approximated the share of products sold to consumers on the basis of EU27 household spending on "audio-visual, photographic and information processing equipment), which accounts for 10.2% of total consumer products spending (excl. audio-visual, photographic and information processing equipment). Accordingly, the share of 10.2% was applied on the total of such consumer-oriented wholesale services, resulting in "wholesale of computers, computer peripheral equipment and software" that can be attributed to consumers of approx. EUR 63 billion.

Table 17: Annual turnover of EU companies manufacturing, wholesale and retail of non-harmonised consumer products, by company size class, excluding exports, in million EUR, based on 2017 values

	Turnover by company size			Total turnover
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	**All size categories**
Total of manufacturing[a)]	66 650	85 417	138 305	**290 373**
Total of wholesale[a)]	115 055	79 524	118 686	**313 265**
Total of retail[b)]	226 436	42 812	159 416	**428 664**
Total	***408 141***	***207 753***	***416 407***	***1 032 301***

Source: Own calculation, based on Eurostat data. a) Manufacturers' and wholesalers' annual turnover that can be attributed to consumer products (approx. 44.3%, estimate based on share of consumer-oriented wholesale services in total wholesale services) b) Retailers' turnover that can be attributed to consumer products (approx. 45% of total retail turnover, calculated on basis of household consumption for consumer goods).

As a result, the total annual EU turnover of EU companies from non-harmonised consumer products is estimated at EUR 1032 billion EUR. This figure includes sales along the consumer products value chain, i.e. manufacturing, wholesale and retail services (including imports)[182]. In other words, this figure does not equal the size of the EU's consumer product market that is often represented by retail sales numbers.

7.1.1.2. Estimation of compliance costs, based on firm level data

The estimation of compliance costs and their extrapolation to the EU is again discussed step-by-step as follows:

Step 4: Derivation of empirical estimates for companies' product safety-related costs on the basis of survey responses

In our company costs survey and the complementary interviews conducted with selected companies, businesses were asked to indicate staff time used for the following activities to comply with safety requirements for (harmonised and non-harmonised) consumer products[183]:

- *Managing product safety* (e.g. checking that only safe consumer products are marketed/distributed, checking of Safety Gate/RAPEX, removing/taking down notified products, addressing product safety related consumer complaints, preparing safety instructions, safeguarding traceability and keeping related documentation)
- *Testing for product safety* (e.g. testing safety of materials and samples of marketed consumer products regarding safety, preparing product safety certifications etc.)
- *Recalls* (including withdrawal of unsafe consumer products from the market, warnings and recalls)
- *Other consumer product safety related activities* (e.g. staff training on product safety, communicating with authorities, consumers, or sellers/suppliers etc.)

As mentioned above, we asked respondents to consider all costs for ensuring product safety of both harmonised and non-harmonised consumer products (excluding

[182] Note that direct imports by consumers from traders in non-EU countries are not included.

[183] Business stakeholders were asked to provide estimates expressed in person-days per month.

pharmaceuticals, medical devices or food), as the identification of costs for non-harmonised products only was not considered to be feasible. In addition to staff requirements, companies were asked to provide estimates for other costs to comply with safety requirements for consumer products (e.g. costs for external legal advice, costs for external safety testing, costs for certification of safety of products etc.)[184]. The cost estimates provided by the respondents also include business-as-usual costs, which would incur even in absence of product safety regulation (see Step 6).

A total of 36 companies provided quantitative estimates for staff time used (in person-days per month) and other costs (in EUR). These estimates were used to estimate companies' annual regulatory compliance costs in Euro terms. The calculation of Euro-denominated costs for staff is based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour[185]. To account for overhead costs, a 25% mark-up was added to staff-related costs. Subsequently, the costs for each company were related to the EU turnover for consumer products, i.e. we expressed companies' annual cost resulting from activities to comply with safety requirements for (harmonised and non-harmonised) consumer products as a share of the related turnover.

We then analysed the full sample data by company size and by the type of respondent (manufacturer vs retailer/wholesaler). The results were as follows:

- The sample data suggest a negative correlation between companies' relative compliance costs and companies' size, both for annual turnover and the number of employees. In other words, companies' product safety compliance costs in percent of annual turnover from producing and/or selling consumer products in the EU tend to decrease with increasing company size (see below for more details).
- The data also suggest that retailers and wholesalers indicated relatively lower compliance costs compared to companies that were (also) involved in manufacturing.

With respect to the first result, which is plausible due to scale effects, it should be noted that only five companies with less than 50 employees participated in the consultation and only six companies that had between 50 to 249 employees. At the same time, the cost estimates provided by some of these respondents should be treated with caution, as the estimates were partly unrealistically high (see maximum values in Table 18).

Due to a larger and more representative sample size for each group, we therefore chose to extrapolate companies' product safety-related compliance cost on the basis of the empirical median value for two groups of companies: distributors (importers[186], wholesalers, retailers including online retail, excluding online marketplaces) and manufacturer/producers (including manufacturers that also import). This approach allows us to capture distinct differences in the relative compliance cost between manufacturers (0.59% of annual EU turnover from consumer products in the EU), on the one hand, and wholesale and retail services (0.14% of annual EU turnover from consumer products in the EU) on the other. A shortcoming of this approach is that we may underestimate the product safety-related cost incurred by small companies (in our analysis: companies with 0 to 49 persons employees), which due to economies of scale effects tend to show higher relative costs for every unit of turnover. The sample statistics concerning the cost data provided by the responding companies is provided in

[184] Business stakeholders were asked to estimates average costs per month in EUR.

[185] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

[186] Note that according to Art 2 GPSD, the term 'producer' includes importers, if there is no representative of the manufacturer established in the Community. However, here we have included importers into the distributor categories, in line with the methodological approach chosen for the extrapolation.

Table 18. The estimated level of compliance costs is broadly in line with the findings of impact assessments of similar policy measures[187].

Table 18: Sample statistics for product safety-related compliance cost of companies, as percent of turnover related to consumer products

	Distributors (import, wholesale, retail)[a)]	Manufacturer/ producer [b)]
Number of responses	11	25
Min	0.00%	0.00%
Max	132.00%	14.14%
Average	12.44%	2.13%
Q1	0.07%	0.10%
Q2 (median)	**0.14%**	**0.59%**
Q3	0.44%	1.96%
Q1 to Q3 (middle 50% of values)	0.07% - 0.44%	0.10% - 1.96%

Source: Civic Consulting, based on company survey. Notes: Detailed sample statistics are provided in the Annex. a) Distribution including online retail, excluding online marketplaces. b) Manufacturers/producers may also be involved in wholesale and retail.

Step 5: Extrapolation of EU companies' annual costs related to the GPSD incl. business-as-usual costs that occur also in absence of regulation

For each enterprise size class, we multiplied the empirical median values for companies' relative product safety-related costs, which were derived in Step 4, with the annual turnover of EU companies that can be attributed to the production and/or sales of non-harmonised consumer products in the EU (Step 3). We applied the median cost estimate of 0.59% for all manufacturing sectors and the median cost estimate of 0.14% for all retail and wholesale services sectors. The results of this calculation, which still include business-as-usual costs, are presented in Table 19 below. Accordingly, EU companies' activities costs to comply with safety requirements for non-harmonised consumer products amount to EUR 2.7 billion, of which EUR 1.7 billion accrue to EU manufacturers, EUR 428 million to EU wholesalers and EUR 585 million to EU retailers. When considering the results by company size class, the extrapolation indicates that small size companies (with less than 50 employees) bear slightly more than a quarter of these costs (28%). This may be an underestimation, due to the above-mentioned scale effects.

[187] CSES (2014), for example, finds similar numbers for administrative and substantive costs for harmonised consumer products. See CSES (2014), Evaluation of the Internal Market Legislation for Industrial Products, Final report, 13 January 2014, p. 81. In most cases, total annual estimated compliance costs do not exceed 1% of annual turnover.

Table 19: Estimated annual product safety-related costs of companies producing and/or selling non-harmonised consumer products in the EU, by company size class, in million EUR

	Costs by company size			Total costs
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	***All size categories***
Total of manufacturing	393	504	816	**1 713**
Total of wholesale	157	109	162	**428**
Total of retail	309	58	218	**585**
Total	***859***	***671***	***1 196***	***2 726***

Source: Own calculation, based on company costs survey and Eurostat data, see previous tables.

Step 6: Deduction of business-as-usual costs and extrapolation of EU companies' annual compliance cost related to the GPSD

In our company survey and interviews, we asked businesses to indicate the share of the total product safety-related costs that they would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence), hereafter referred to as business-as-usual costs, BAU. The sample statistics of the responses are provided in Table 20.

Table 20: Sample statistics for the share of product safety-related costs that companies would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence)

	Distributors (import, wholesale, retail)[a)]	Manufacturer/ producer [b)]
Number of responses	10	21
Min	0%	10%
Max	100%	100%
Average	42%	76%
Q1	7%	70%
Q2 (median)	**25%**	**80%**
Q3	84%	100%
Q1 to Q3 (middle 50% of values)	7.25% - 83.75%	70% - 100%

Source: Civic Consulting, based on company survey. Notes: a) Distribution including online retail, excluding online marketplaces. b) Manufacturers/producers may also be involved in wholesale and retail.

As indicated in Table 20 above, for manufacturers, the empirical median estimate for business-as-usual costs is 80%. For distributors (importer, wholesaler and retailers), the empirical median estimate for business-as-usual costs is 25%. These estimates reflect the self-assessment of the companies that are part of the sample, and are therefore subjective in nature. However, as concerns differences between manufacturers, on the one hand, and wholesalers and retailers, on the other, we consider the estimates to be in line with expectations. Manufacturers have to consider product safety as a key precondition for their work, while wholesalers and retailers have to comply with consumer safety legislation that may go beyond the due diligence activities that they would conduct in absence of product safety legislation.

In a final step, we applied the empirical median values of these shares to the product safety-related cost estimates derived in Step 5. Excluding business-as-usual costs, we obtain compliance costs of EU companies that can be attributed to non-harmonised consumer products, i.e. the costs for businesses to comply with the GPSD. The results are shown in Table 21.

Table 21: Estimated annual cost for businesses to comply with the GPSD, by company size class, in million EUR (excluding business-as-usual costs)

	Cost by company size			Total costs
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	**All size categories**
Total of manufacturing	79	101	163	**343**
Total of wholesale	118	81	122	**321**
Total of retail	232	44	163	**439**
Total	***428***	***226***	***448***	***1 102***

Source: Own calculation, based on company costs survey and Eurostat data, see previous tables.

As indicated in the table, the estimated costs for businesses to comply with the GPSD amount to EUR 1.1 billion per year, of which EUR 343 million accrue to EU manufacturers, EUR 321 million to EU wholesalers and EUR 439 million to EU retailers.

7.1.1.3. SMEs

For the purpose of this analysis, we differentiate between small companies (1–49 employees) and medium-sized companies (50–249 employees). For small distributors and manufacturers with less than 50 employees, the median value for consumer product safety-related costs in total annual turnover from consumer products is found to be 1.96% (5 respondents provided estimates). For medium-sized distributors and manufacturers with 50 to 249 employees, the median value for consumer product safety-related costs is found to be 0.68% (6 respondents). In contrast, for large companies (25 respondents) this value is only 0.13%, as shown in Table 22. The pattern of decreasing relative compliance costs with increasing company size is generally robust when staff is replaced by annual turnover.

Table 22: Sample statistics for product safety-related compliance cost of companies, as percent of turnover related to consumer, by enterprise size

	1 – 49 employees	50 – 249 employees	250 or more employees
Number of responses to cost survey	5	6	25
Min	0.24%	0.14%	0.00%
Max	132%	7.92%	14.14%
Average	28%	2.01%	1.56%
Q1	1.68%	0.45%	0.02%
Q2 (median)	**1.96%**	**0.68%**	**0.13%**
Q3	3.33%	7.92%	0.61%
Q1 to Q3 (middle 50% of values)	1.68% - 3.33%	0.45% - 7.92%	0.02% - 0.61%

The negative correlation between companies' relative compliance costs and companies' size is plausible due to scale effects, as indicated before. The relative impact of regulatory obligations is generally higher for SMEs than for large companies. Due to their size (e.g. size in terms of annual turnover, annual profits and total staff), SMEs generally bear a larger relative cost burden resulting from due diligence costs that are not related to legal obligations, regulatory requirements and regulatory differences in national markets. This general pattern is confirmed by SMEs replies to the business stakeholder survey, and by previous research[188].

Due to the small sample size, we cannot distinguish between distributors and manufacturers for the assessment of SMEs' consumer product safety-related compliance cost. Yet, based on the overall pattern in the full sample data, we expect consumer product-safety costs to be generally higher for SME manufacturers of consumer products than for SME distributors of consumer products. Unlike distributors, manufacturers need to account for multiple product safety related issues (technical and legal) in the design, production and distribution of products as well as in the communication with suppliers of intermediate products, which is causing costs that typically do not arise on the side of wholesale and retail companies[189].

As concerns SMEs' estimated annual cost to comply with the GPSD, companies with less than 50 employees[190] are estimated to have GPSD-related costs (after business-as-usual costs such as costs related to general due diligence activities have been subtracted) of approx. 428 million EUR per year, and companies with 50 to 249 employees are estimated have GPSD-related costs of approx. 226 million EUR per year (see Table 21 above). Accordingly, SMEs account for 59% of the total of GPSD-related compliance costs in the EU, in line with their overall share in the market. It should be noted that due to the relatively high number of EU SMEs that engage in wholesale and (particularly in) retail sectors compared to manufacturing sectors (and compared to large EU companies which are more engaged in manufacturing activities), GPSD-related measures that impact on the distribution chains of non-harmonised consumer products can be expected to have a higher aggregate impact on EU SMEs, than measures that impact on manufacturers.

7.1.2. Member States

Assessing the costs of compliance of MSAs with the GPSD is complicated by institutional differences across EU Member States:

- EU Member States' market surveillance systems for consumer products differ in the extent to which market surveillance is conducted by MSAs with broader or with narrower sectoral responsibility. For example, in some countries there is only one (main) market surveillance authority for all non-food products, complemented by a small number of other MSAs in specific sectors (e.g. telecommunications,

[188] See, for example CSES (2014), Evaluation of the Internal Market Legislation for Industrial Products, Final report, 13 January 2014, p. 82, which concluded: "There were differences between firms in the level of compliance costs (administrative, substantive) by firm size, although this was difficult to substantiate based on the limited numbers of SMEs that agree to take part in the study. SMEs were found to experience significantly higher costs / unit for regulatory compliance compared with large firms that are better able to spread the costs across a high number of units. SMEs also appear to have a higher percentage of staff involved in compliance-related activities (familiarisation, testing) than large firms, although few are able to have individual staff members working full-time on compliance".

[189] In practice, distributors (i.e. wholesalers and retailers who are to a large extent SMEs) are aware of the relevance of compliance, but they rely mostly on documentation made available from the product manufacturer or the importer. See SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

[190] Our data do not allow to draw separate conclusions for micro businesses (less than 10 employees, less than 2 million EUR in annual turnover). Only two companies with less than 10 employees repsonded to the business stakeholder survey. These companies only provided rudimentary data with regard to impacts, costs and benefits.

chemicals). In other countries there are several MSAs with sectoral responsibilities for consumer products, with no clear lead agency for consumer products.

- Also, EU Member States' market surveillance systems for consumer products differ in the extent of centralisation. In some countries, responsibility for market surveillance is centralised, with no sub-national administrations being involved. This is true for small markets such as Malta, but also Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, Ireland, Netherlands, Latvia, Luxembourg, Sweden, Slovenia, and Slovakia follow this model. In contrast, other (often larger) countries also rely on sub-national administrations or regional networks for enforcement, in line with their overall administrative structure. This is the case in France, Croatia, Greece, Lithuania, Poland, Austria, Czech Republic, Germany, Hungary, Italy, Portugal, Romania, and Spain. For more details, see Table 7 in the problem analysis, above.

These organisational features affect how market surveillance of non-harmonised consumer products is organised, and in some cases the share of staff working on market surveillance of non-harmonised products (to which the GPSD fully applies) is not known. MSA respondents to our survey therefore found it frequently difficult to allocate costs to GPSD-related activities. For example, MSAs stated that they did not keep statistics of staff time, or that there was "no reliable estimate possible due to complex structure of market surveillance".

As responsibilities of national and sub-national MSAs differ significantly in terms of product categories, both for harmonised and non-harmonised product categories, MSA respondents also provided a very broad range of estimates for the share of their activities/resources that is devoted to non-harmonised products. MSAs' answers range from 0% to 100% (with a median of 34%), depending on the type of organisation and the competences in terms of actual product coverage and assigned market surveillance activities[191].

The differences in MSAs' product coverage, the degree of centralisation within their jurisdictions as well differences regarding the responsibilities for market surveillance activities resulted in a high variation of survey data on staff time requirements related to MSAs market surveillance activities (e.g. external testing). We therefore based our estimate of MSAs costs on comprehensive staff data for 20 EU Member States collected in the framework of the 2020 GPSD implementation study, which is based on country reports and interviews with MSAs in all countries.

7.1.2.1. Estimation of annual staff-related baseline costs

The estimation of MSAs' staff-related costs related to market surveillance activities for non-harmonised consumer products in the EU is based on the following three steps:

Step 1: Identification of MSAs annual FTEs for market surveillance activities related to non-harmonised consumer products

As described above, for our estimate we use the number of full time equivalent (FTE) staff for market surveillance of consumer products as provided in the country research. Twelve of the available country estimates relate to the market surveillance of non-harmonised consumer products, which was directly used in the calculation. For eight countries, the estimates relate to the total staff for market surveillance of both harmonised and non-harmonised consumer products (Estonia, Ireland, Latvia, Malta, the Netherlands, Poland, Portugal, Romania). For these countries, we allocated staff according to the 54%/46% ratio for harmonised/non-harmonised products circulating

[191] Overall, we received 42 replies from MSAs in 25 Member States. 24 MSAs provided person-day estimates for costs under the current legislation. 10 MSAs provided estimates for other costs related to market surveillance activities under the current regulation.

within the European Single Market to derive an estimate for related market surveillance activities[192]. It should be noted that a share of 46% in staff time for market surveillance of non-harmonised consumer products is 12 percentage points higher than the empirical median share indicated by MSAs for activities devoted to non-harmonised products in the stakeholder survey (34%), potentially causing an estimate at the higher end of MSAs' actual costs that can be attributed to market surveillance activities for non-harmonised consumer products. For seven countries, no information on staff numbers was available at all. The staff data in FTEs is outlined in Table 23.

Table 23: Estimated number of staff for market surveillance of non-harmonised consumer products, in FTEs by Member State

Country	Number of FTEs, market surveillance of non-harmonised consumer products	Number of FTEs per million population
Austria	19.0	2.1
Belgium	9.3	0.8
Bulgaria	69.0	9.9
Croatia**	:	:
Cyprus	4.0	4.5
Czech Republic	227.0	21.2
Denmark	32.5	5.6
Estonia*	22.5	17.0
Finland	2.0	0.4
France	57.5	0.9
Germany**	:	:
Greece	60.0	5.6
Hungary**	:	:
Italy**	:	:
Ireland*	4.6	0.9
Latvia*	12.4	6.5
Lithuania	10.0	3.6
Luxembourg	1.0	1.6
Malta*	3.7	7.2
Netherlands*	43.7	2.5
Poland*	216.2	21.0
Portugal*	33.6	3.3
Romania*	234.6	12.1
Slovenia**	:	:
Slovakia**	:	:
Spain**	:	:
Sweden	5.0	0.5

Source: GPSD implementation study and own calculations. Data provided for last available year, either 2019 or 2018. *Number of FTEs for market surveillance activities related to non-harmonised products calculated on basis of total staff (FTEs) for market surveillance activities multiplied by the share of non-harmonised consumer products circulating in the

[192] As mentioned before, the 2017 EU impact assessment for the new Market Surveillance Regulation estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products. See SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

EU Single Market (46%). **Number of staff for market surveillance activities not available (neither harmonised nor non-harmonised products). '.' = no data available.

Step 2: Approximation of annual FTEs for market surveillance activities related to non-harmonised consumer products for countries for which data was not available

For the seven countries, for which no staff data was available (Croatia, Germany, Hungary, Italy Slovenia, Slovakia, and Spain) we estimated the number of FTEs on the basis of the data for the remaining 20 Member States. To account for institutional differences with regard to the level of centralisation, we considered two clusters of countries, in line with the characteristics of the respective market surveillance systems as described above:

- Cluster 1: responsibility for market surveillance is centralised (no sub-national administrations involved);
- Cluster 2: responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country.

To derive estimates for the number of FTEs per million population for Slovenia and Slovakia (more centralised market surveillance), we applied the sample median of 3.5 FTEs per million population. To derive FTE estimates for the number of FTEs per million population for Croatia, Germany, Hungary, Italy and Spain (more decentralised market surveillance), we applied the sample median of 4.6 FTEs per million population (see Table 24). The differences in estimates are in line with expectations, as a more centralised structure could be expected to be somewhat leaner in terms of staff resources, as the need for coordination activities across levels of government is reduced.

Table 24: Sample statistics for number of staff for market surveillance of non-harmonised consumer products, in FTEs by country cluster

Country cluster	Sample statistics	Number of FTEs for market surveillance of non-harmonised consumer products	Number of FTEs per million population
Cluster 1: Responsibility for market surveillance is centralised (no sub-national administrations involved)	Number of countries	12	12
	Min	1.0	0.4
	Max	69.0	17.0
	Average	17.5	4.8
	Q1	3.92	0.9
	Q2 (median)	**7.15**	**3.5**
	Q3	25.03	6.7
	Q1 to Q3 (middle 50% of values)	3.92 - 25.03	0.9 - 6.7
Cluster 2: Responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the	Number of countries	8	8
	Min	10.0	0.9
	Max	234.6	21.2
	Average	107.2	8.7
	Q1	29.94	3.0
	Q2 (median)	**58.75**	**4.6**
	Q3	218.9	14.4

country	Q1 to Q3 (middle 50% of values)	29.94 - 218.9	3.0 - 14.4

Step 3: Calculation of annual staff costs for market surveillance activities related to non-harmonised consumer products

In the final step, we calculated the EUR equivalent of the estimated number of staff required for market surveillance of non-harmonised consumer products by multiplying the number of FTEs per million population by:

- The size of population for each country (in million);
- The number of person-hours per year (1 720) [193]; and
- The average wage of 28.00 EUR, which corresponds to the EU27 average wage of "administrative and support service activities" (18.70 EUR) and "professional, scientific and technical activities" (37.30 EUR) for 2017 (latest figure available in Eurostat database).

The results of this calculation are provided in Table 25 below. Total EU27 staff-related costs for market surveillance of non-harmonised consumer product amount to approximately EUR 122 million per year. Of this amount, EUR 14 million accrue in countries where responsibility for market surveillance is centralised and EUR 108 million in countries where responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations.

[193] Following EU Horizon 2020 guidelines, one person year corresponds to 1 720 person-hours per year. See, e.g. the H2020 Programme: User's Guide for the Personnel Costs Wizard.

Table 25: Annual staff-related costs for market surveillance of non-harmonised consumer products in EU Member States, in million EUR

Country cluster	Countries	Number of FTEs per million population	Total staff costs
Cluster 1: Responsibility for market surveillance is centralised (no sub-national administrations involved)	Malta	7.2	**14.2**
	Belgium	0.8	
	Cyprus	4.5	
	Denmark	5.6	
	Estonia	17.0	
	Ireland	0.9	
	Netherlands	2.5	
	Finland	0.4	
	Latvia	6.5	
	Luxembourg	1.6	
	Sweden	0.5	
	Bulgaria	9.9	
	Slovenia	3.5	
	Slovakia	3.5	
Cluster 2: Responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country	France	0.9	**108.2**
	Croatia	4.6	
	Greece	5.6	
	Lithuania	3.6	
	Poland	21.0	
	Austria	2.1	
	Czech Republic	21.2	
	Germany	4.6	
	Hungary	4.6	
	Italy	4.6	
	Portugal	3.3	
	Romania	12.1	
	Spain	4.6	
Total			***122.4***

7.1.2.2. Other costs for market surveillance of non-harmonised consumer products

Approximately four in ten MSAs report incurring costs other than staff costs for market surveillance activities related to consumer products, with the rest either not incurring other costs, or providing no information in this respect[194]. While the figures provided by MSA respondents show a relatively high variation, their absolute size compared to staff-related costs (see Table 25 above) are nevertheless overall small. Sample statistics are provided in Table 26 below.

[194] When asked about the actual occurrence of other costs, 18 MSA reported "Yes"194, with nine of them providing numerical estimates in EUR. 14 MSA reported "No" (i.e. EUR 0), and 10 MSAs did not know or did not answer this question.

Table 26: Sample statistics of MSAs' other costs to comply with product safety legislation, in EUR per year

Sample statistics	Other costs for harmonised and non-harmonised consumer products	Other costs for non-harmonised consumer products
Number of respondents	23	23
Min	0	0
Max	211 200	168 000
Average	29 835	12 880
Q1	0	0
Q2 (median)	**0**	**0**
Q3	27 000	4 200
Q1 to Q3 (middle 50% of values)	0 – 27 000	0 - 4 200

Note: The estimate for other costs related to surveillance of non-harmonised products is calculated on basis of the respondents' share of overall market surveillance activities related to non-harmonised consumer products.

According to the European Commission "[t]here are over 500 distinct market surveillance authorities (from 1 to over 200 per Member State) policing one Single Market for specific products." This number includes MSAs that share responsibility for harmonised and non-harmonised as well as consumer and non-consumer products[195]. Therefore, the number of authorities responsible for non-harmonised consumer products is considerably smaller. Based on the official list of national market surveillance authorities published by the European Commission, about 100 relevant authorities are in charge of "other consumer products under the GPSD"[196]. Based on the median value, non-staff related costs of market surveillance activities for non-harmonised consumer products in the EU can be considered negligible (EUR 0). But even when taking the 3rd Quartile value (Q3 in Table 26 above) of EUR 4 200 per organisation as basis for the extrapolation (to account for the fact that not all organisations that indicated costs provided a numerical estimate), the EU total would only amount to EUR 0.42 million. EU27 total annual non-staff related costs of market surveillance activities for non-harmonised consumer products would therefore at most account for the equivalent of 0.34% of total staff costs. This estimate is consistent with the results of the country research, in which authorities and stakeholders considered a lack of resources for market surveillance (including for testing) to be a major problem for enforcement.

7.1.3. Costs due to GPSD implementation differences in Member States and fragmentation of legislation

7.1.3.1. Costs for businesses due to differences in the national implementation of the GPSD

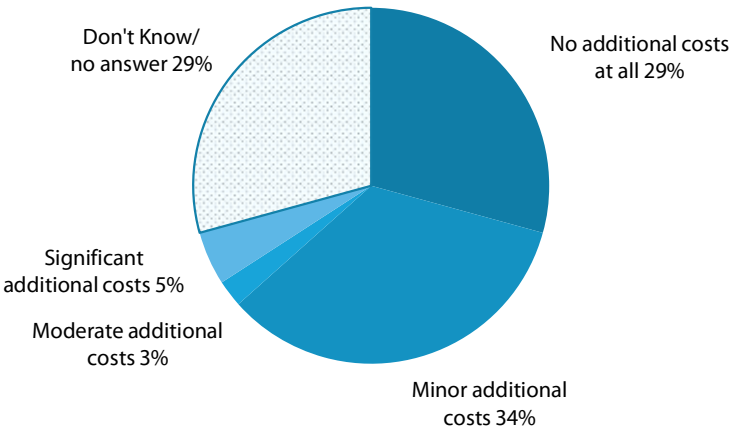
As indicated in Figure 10 below, minor to significant additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD currently affect 42% of companies that responded

[195] COM(2017) 787 final. European Commission Communication „The Goods Package: Reinforcing trust in the single market.

[196] European Commission, List of national market surveillance authorities by sector, see sector „30. Other consumer products under GPSD".

to our cost survey. 29% reported to not incur any additional costs due to this situation, and another 29% provided no answer or did not know.

Figure 10: To what extent do you [currently] incur additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements)? – reported by companies



It is notable that SMEs responding to the survey only reported 'minor' additional costs. None of the SME respondents indicated 'moderate' or 'significant' additional costs due to differences in the national implementation of the GPSD, a possible reason being that larger companies are more likely to operate in all EU Member States than SMEs, and therefore experience relevant legislative differences more often.

Companies also provided quantitative estimates regarding the share of their costs to comply with safety requirements for consumer products that are caused by differences in the national implementation of the GPSD. Sample statistics are provided Table 27 below.

Table 27: Sample statistics of businesses' estimated additional costs due to differences in the national implementation of the GPSD, as percent of total costs to comply with safety requirements for harmonised and non-harmonised consumer products

Sample statistics	Additional costs
Number of responses	26
Min	0%
Max	30%
Average	5%
Q1	0%
Q2 (median)	**2%**
Q3	5%
Q1 to Q3 (middle 50% of values)	0.00% - 5.00%

Applying the median cost share estimate of 2% to businesses' estimated product safety-related costs from harmonised and non-harmonised consumer products results in total additional costs for EU companies of 119 million EUR annually, of which 37 million EUR are borne by companies with up to 49 employees, 29 million EUR are borne by companies with 50-249 employees, and 52 million EUR are borne by large companies with more than 250 employees (Table 28).

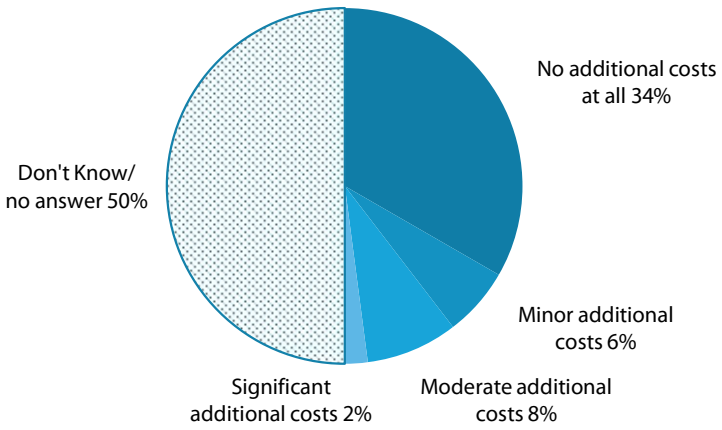
Table 28: Estimated additional costs of businesses due to differences in the national implementation of the GPSD, EU27, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	17	22	35	**74**
Total wholesale sectors	7	5	7	**19**
Total retail sectors	13	3	9	**25**
Total additional compliance costs related to consumer products	***37***	***29***	***52***	***119***

7.1.3.1. Costs for MSAs due to different provisions for market surveillance depending on whether the product is harmonised or non-harmonised

Under the current legislative framework, responsibilities and powers of market surveillance authorities are different for harmonised and non-harmonised consumer products. For some authorities, this leads to administrative burdens. In our survey of authorities, 16% of respondents reported to currently experience additional costs due to these differences (see Figure 11).

Figure 11: The EU legal framework for product safety contains different provisions for market surveillance depending on whether the product is harmonised or non-harmonised. To what extent do you [currently] incur additional costs due to this situation? –reported by authorities



In the survey, MSAs also estimated the share of their costs incurred due to different provisions for market surveillance. Sample statistics are provided in Table 29 below.

Table 29: MSAs estimated additional costs due to different provisions for market surveillance, in percent of total costs for market surveillance of harmonised and non-harmonised consumer products

Sample statistics	Additional costs due to different provisions for market surveillance
Number of responses	25
Min	0%
Max	30%
Average	4%
Q1	0%
Q2 (median)	**0%**
Q3	1%
Q1 to Q3 (middle 50% of values)	0.00% - 1.00%

More than half of those MSAs that provided cost estimates do not incur additional cost due to differences in EU market surveillance for harmonised and non-harmonised consumer products, which is reflected by a median cost share estimate of 0.00%. At the same time, a significant minority of MSAs (roughly one quarter of those respondents that provided quantitative assessments) reported low additional costs, which is reflected by the third quartile value (Q3) of 1%. Accordingly, assuming that for one quarter of MSAs in the EU the additional costs due to differences in market surveillance regulations amount to 1% of MSAs total market surveillance costs for harmonised and non-

harmonised consumer products, the additional cost burden amounts to EUR 0.7 million annually across the EU27 (total of all MSAs that reported additional costs)[197].

7.2. Benefits of the GPSD

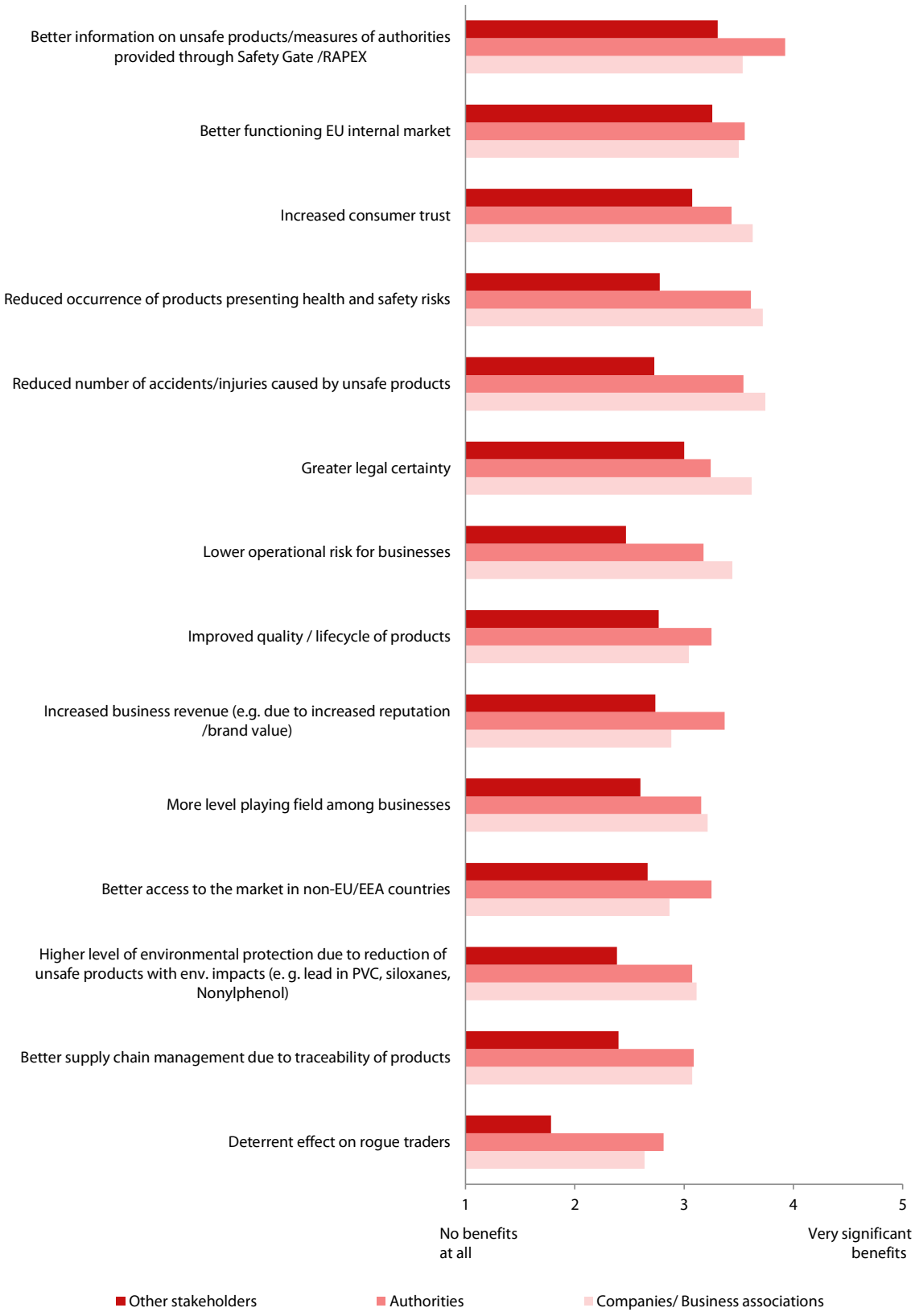
Based on our interviews and the research conducted, we identified the following potential benefits of the GPSD:

- Increased consumer trust;
- Increased business revenue (e.g. due to increased reputation /brand value);
- Improved quality / lifecycle of products;
- Better information on unsafe products/ measures taken by authorities provided through Safety Gate/RAPEX;
- Better supply chain management due to traceability of products;
- Greater legal certainty;
- Lower operational risk for businesses;
- Deterrent effect on rogue traders;
- More level playing field among businesses;
- Better functioning EU internal market;
- Reduced occurrence of products presenting health and safety risks, including products originating outside the EU;
- Reduced number of accidents/injuries caused by unsafe products;
- Higher level of protection of the environment due to reduction of unsafe products that also have environmental impacts (e.g. lead in PVC, siloxanes, Nonylphenol);
- Better access to the market in non-EU/EEA countries, due to the high level of safety achieved in the EU.

In our interviews and surveys, we asked stakeholders to assess in their perspective the significance of potential benefits from the product safety requirements of the GPSD. The results are presented in Figure 12:

[197] This figure is estimated on basis of total annual staff-related costs, which according to the baseline estimate in section 7.1.2 account for more than 99% of consumer product-related market surveillance costs of MSAs.

Figure 12: In your opinion, where do you see the most significant benefits that result from the product safety requirements of the GPSD?



Source: Civic Consulting surveys of authorities, companies, business organisations and other stakeholders. The average assessments are calculated based on the assessment of respondents that had an opinion (not included are respondents who indicated Don't know or provided no answer).

Figure 12 above indicates that authorities and companies/business associations tended to see moderate to significant benefits that result from the product safety requirements of the GPSD across the board, with better information on unsafe products/measures taken by authorities provided through Safety Gate/RAPEX, a better functioning internal market and increased consumer trust highest ranked on average. These and other listed benefits have been discussed in depths under the relevant evaluation questions concerning effectiveness in the GPSD evaluation (see Part 1 of this report). We have also analysed problems regarding market surveillance and enforcement, which are mirrored in the least positively assessed benefit: the deterrent effect of the GPSD on rogue traders, which is seen as minor (or minor to moderate) by all stakeholder groups. It is also notable that other stakeholders were in general less positive than authorities and businesses, and saw mostly moderate or less than moderate benefits of the Directive.

In the surveys conducted for the evaluation of the GPSD, stakeholder groups were asked to what extent they considered the costs due to product safety requirements of the GPSD to be proportionate to the resulting benefits. About nine in ten respondents that had an opinion considered the costs due to product safety requirements of the GPSD to be at least "moderately proportionate" to the resulting benefits. Close to six in ten respondents that had an opinion even found these costs to be "largely proportionate" or "very proportionate", including respondents from companies and business associations (see Part 1 of this report).

This largely positive assessment is consistent with the analysis of compliance costs presented in the previous section. A large part of costs related EU product safety legislation for consumer products are business-as-usual costs (BAU), i.e. costs that companies would incur anyway (i.e. even in absence of product safety legislation, for example because these costs relate to their due diligence procedures). Compliance costs due to the safety requirements of the GPSD that exclude business-as-usual costs are therefore limited, compared to the benefits the Directive brings, including in terms of contributing to the functioning of the internal market.

7.3. Current product-related detriment to consumers in the EU

In Part 1 of this study it is concluded that the available evidence points to a relatively stable situation in terms of the safety of consumer products, with some evidence pointing toward improvements over the last decade, at least as perceived by consumers and a plurality of stakeholders. The data also confirms that large numbers of unsafe products that could affect the safety of EU consumers are rejected at the borders, withdrawn from the market or recalled. This implies that a reduction of unsafe products on the market is achieved in practice, in line with the objective of the GPSD. However, there remains a continuing influx of new unsafe products on the market, indicating that the GPSD does not create a sufficient deterrent effect to avoid that unsafe products are placed on the market. This limits the effectiveness of the GPSD, as not all products on the market can be inspected by authorities to safeguard that the general safety requirement is adhered to (see problem analysis, section 4).

In spite of the elaborated legislative framework for product safety at EU level, as well as the considerable efforts by businesses and authorities to comply with and enforce the GPSD, as discussed in the previous sub-sections, EU consumers continue to experience substantial detriment related to products, including due to non-harmonised consumer products. Such detriment may accrue in several ways:

- Unsafe products may cause physical harm to consumers, or damage other goods. For example, cords attached to children's clothing in a way that they can become trapped during play activities, can lead to strangulation; unsafe lanterns or lighting chains may cause fires;

- Unsafe products lose their value. They are typically purchased by consumers that would not have bought them had they known the products were unsafe.

In the following, we present estimates regarding the size of product-related consumer detriment, which were specifically elaborated for this study. We first consider the number of product-related injuries and deaths in the EU, and estimate the related detriment in monetary terms. We subsequently present an estimate of the value of unsafe products[198], and discuss the extent to which this estimate can be used as a proxy for consumer detriment.

7.3.1. Detriment due to product-related injuries

To assess the detriment due to product-related injuries, we use data from the European Injury Database (IDB), which was hosted by the European Commission until 2019[199]. The IDB aims to provide information on the circumstances and consequences of non-fatal injuries to facilitate their prevention and improve safety. The IDB does not contain data on product related injuries only, but also keeps record of injuries occurring in the workplace, at home, at school, during leisure and sports as well as injuries occurring as a result of road traffic accidents, interpersonal violence and deliberate self-harm. The data is collected from the emergency departments of a number of selected hospitals, which, based on their size (small, medium, large) and type (e.g. general hospitals, children hospitals, university hospitals) are assumed to constitute a representative sample for the respective Member State[200]. The data is voluntarily contributed by the Member States participating in the IDB, which were 15 out of 28 Member States in 2016[201]. It should be noted however that while injuries that related to a product can be ascertained, the IDB cannot provide information with regards to whether the injury was actually caused by the product design or the lack of product safety.

For the analysis conducted for this impact assessment, we focused on accidental, non-intentional injuries and excluded transport injury events and work-related injuries. From the remaining injury incidents, we selected the ones that are related to any object/product, except for food, drinks, pharmaceutical substances, and weapons (other non-product agents as animals and other persons were also excluded)[202]. The resulting data on average product-related injuries per year (between 2013 and 2017) is presented in Table 30.

198 Data concerning the extent to which unsafe products cause damage to other products was not available, so that this component of detriment is not considered here.

199 DG SANTE has announced to terminate IDB-hosting due to resource constraints by end of 2020. At present, the database is hosted by Swansea University Medical School but shall be transferred in the course of 2020 to the Italian Ministry of Health. For more details on the IDB, see Annex I.

200 EUROSAFE (2017), 'Injuries in the European Union 2013-2015, supplementary report to the 6th edition of 'Injuries in the EU', p. 9.

201 Ibid., p. 26.

202 As IDB data has also been used as an indicator for the European Commission's Consumer Market Scoreboard, we selected the same product groups used by the Consumer Market Scoreboard to define relevant products as represented in the IDB. See European Commission (2014), 'Consumer Markets Scoreboard. Making markets work for consumers', 10th edition, p. 60-61.

Table 30: Product-related non-fatal injuries (EU27, annual average 2013-2017, harmonised and non-harmonised products)

Product group/ mechanism (as provided in IDB)	**Main products involved** (The listed products account for two thirds of cases or more in each category, listed in order of frequency)	**Total**
05 FURNITURE/ FURNISHING	Bed/bunk bed, chair/stool/sofa, cupboard/side board, table	**1 297 317**
06 INFANT OR CHILD PRODUCT	Swing, other playground climbing apparatus/equipment, slide, tricycle or other ride-on toy, other toy	**529 202**
07 APPLIANCE MAINLY USED IN HOUSEHOLD	Electric or gas radiator/heater, scissors, stove/oven, vacuum cleaner, food processor/blender/juicer, cord of household appliance/extension cord, other specified household appliance, tools for needlework, refrigerator/ freezer, television, electric lamp, other electric cooking/ food processing appliance, other heating or cooling appliance, washing machine	**207 355**
08 UTENSIL OR CONTAINER	Knife, drinking glass/cup, glass bottle/jar	**476 737**
09 ITEM MAINLY FOR PERSONAL USE	Shoe/sandal, walker/walking stick, wheelchair, clothes, bag, coins, razor (blade)	**392 257**
10 EQUIPMENT MAINLY USED FOR SPORTS/ RECREATIONAL ACTIVITY	Ball, trampoline, snow ski, roller skates/in-line skates, skateboard	**1 620 339**
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	Ladder/movable step, power saw, nail/screw, cutting tool, chainsaw, grinder/buffer/polisher, chopping tool, hammer	**673 181**
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	Stairs/steps, floor, door/door sill	**4 716 406**
15 GROUND SURFACE OR SURFACE CONFORMATION	Ground surface	**962 163**
17 FIRE, FLAME, OR SMOKE	Unspecified fire or flame, other specified fire or flame, unspecified smoke	**38 679**
18 HOT OBJECT/ SUBSTANCE NEC*	Boiling water (other than tap water), other specified hot liquid, unspecified hot liquid	**96 197**
A. TOTAL PRODUCT-RELATED INJURIES		***11 009 833***

Source: Civic Consulting, based on IDB-FDS and IDB-MDS data provided by EuroSafe in July 2020. Table provides the number of accidental, non-intentional product-related injuries, in which consumers visited hospital emergency department. Excluded are transport injury events and work-related injuries (paid work). Data obtained from IDB-FDS has been extrapolated to the EU27 based on data obtained through IDB-MDS. *NEC = not elsewhere classified.

As the table shows, an estimated 11 million non-fatal product-related injuries, in which consumers visited a hospital emergency department due to the injury, occur in the EU each year. In addition, approximately 8 632 fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurred on average in the EU27 outside of work-related locations - and not including transportation accidents - during the period 2013 to 2016 per year[203].

The IDB data on injuries illustrates that accidents can happen with a large variety of products. The data also shows that most of the product-related injuries occur at home as opposed to sports and athletics areas and school and educational areas; and vulnerable consumer groups such as children and elderly are more affected than the working age population. While children and elderly account for 54% of all product-related injuries, these two groups together only account for 35% of the EU population[204]. It is notable that the product groups that are related to the highest number of injuries do not show much correlation with the notifications in RAPEX. Very different reasons can be a cause for this disconnect: transport injury events are excluded from the table

[203] As reported to the WHO. Note that fatalities are not included in Table 30. See Annex I for more details.

[204] Eurostat, Population: Structure indicators [demo_pjanind], EU27 in 2017, data extracted 16.06.20.

above; the table also includes injuries, where a product was involved, but not classified as unsafe in terms of the GPSD; notification of products to RAPEX might be affected by multiple factors (e.g., as mentioned before, inspection priorities, differences in efficiency of market surveillance and market developments), and only reflect injury events if these are communicated to the market surveillance authorities, which is not systematically the case and not based on the actual frequency of injuries. This does not in any way limit the value of RAPEX, but shows that RAPEX data cannot be simply used as proxy for product safety trends or for analysing the preventive potential of enhanced product design or safety features.

For this impact assessment, the size of the detriment for consumers and society due to product-related injuries in the EU has been estimated for the first time, using the above presented injury data from the IDB and mortality data reported to the WHO. The analysis is presented as Annex I of this report. Table 31 summarises the key results, and provides the main components of the estimated detriment suffered by EU consumers and society. For non-fatal injuries, these are health care utilization costs, productivity losses and loss of quality of life for hospitalised cases. For fatal injuries, this is the cost of premature death.

Table 31: Estimated detriment suffered by EU consumers and society per year (EU27, in million Euro, harmonised and non-harmonised products)

	Type of costs/loss	Cost/loss (in million €)
Injuries	Health care utilization	6 673.7
	Productivity losses	1 802.7
	Loss of quality of life (hospitalized cases)	28 396. 7
Fatalities	Premature death	39 792. 8
Total		***76 665. 9***

Source: Civic Consulting, see Annex I. All amounts in EUR 2017. Indicated is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations. This figure excludes losses caused by work and transportation accidents.

As shown in Table 31 above, the detriment suffered by EU consumers and society is estimated to be EUR 76.6 billion per year.

As indicated before, while the available data allows estimating the number of non-fatal injuries that are related to a product, it cannot provide information with regard to whether the injury was actually caused by the product design or the lack of product safety. The situation is even more difficult with respect to fatalities, due to the limitations of the ICD-10 coding system used, so that we have based the estimate on the best possible approximation of product-related fatalities.

Previous research has explored how many of the injuries and fatalities that are related to products were caused by the product, or could have been prevented through better design, instruction or a safety device (see Annex I for more details). On basis of this research and interviews with product safety experts it was concluded that 15% is a reasonable and conservative estimate for the proportion of the total consumer detriment that was caused by products, or could have been prevented through better design, instruction or a safety device. On this basis, the preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at EUR 11.5

billion per year[205]. This includes detriment related to both harmonised and non-harmonised product categories. Due to the categorisation used in the IDB, it is not possible to separately consider the detriment related to non-harmonised products only.

7.3.2. Detriment due to the loss of value of unsafe products

Baseline detriment

Products that are unsafe typically lose their value. Consumers therefore suffer detriment by having purchased (unknowingly) an unsafe product, even if it does not lead (or has not yet led) to concrete harm. The reason is that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. In the following analysis, we therefore consider that the detriment due to the loss of value of unsafe products (not considering potential harm to persons or other goods) to be equal to its purchase price[206].

No consistent data is available on the incidence of unsafe products on the EU market. In the surveys for this study, we therefore asked market surveillance authorities, companies/business associations and other stakeholders to provide their best estimate of the share of unsafe products on the market in their respective area of activity, both for consumer products sold in brick-and-mortar shops and for consumer product sold online by traders targeting consumers in their country. The average assessment for each stakeholder group is provided in Table 32 below (for reasons of convenience repeated from the problem analysis).

Table 32: In your view, what is the best estimate of the share of unsafe products on the market in your area of activity (i.e. the estimated number of unsafe products per 100 products sold on the market)? – average assessment by stakeholders

Sales channel	Companies/ Business associations	Authorities	Other stakeholders	Average
Brick-and-mortar shops	3%	4%	5%	**4%**
Online	10%	7%	10%	**9%**

Source: Civic Consulting surveys of authorities, businesses, business organisations and other stakeholders. Average assessments by stakeholder group, not considering responses of 'Don't know/no answer'. For detailed results by stakeholder group, see Annex. N=153. Note: The average figures are calculated based on 100 (brick-and-mortar)/105 (online) stakeholders that had an opinion (53/48 indicated Don't know or provided no answer).

The results presented in the table above clearly show that respondents tended to see on average a higher incidence of unsafe products in the online sales channel. However, authorities, businesses and other stakeholders often provided very differentiated

[205] In a sensitivity analysis for the assessment of detriment suffered by EU consumers and society, several assumptions were varied (see Annex I). It concluded that under all scenarios the loss of quality of life and the costs of premature death remain the most important components of the total detriment suffered by EU consumers and society even under the scenario using the most conservative estimates for lost life expectancy and for quality adjusted life year. The sensitivity analysis also showed that under a variety of different scenarios, the preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at between EUR 9.1 billion to EUR 14.3 billion.

[206] This detriment can be reduced where consumers get reimbursement of the product in case of product recall, see later in this section and Annex V.

answers in the surveys conducted for this study and in complementary interviews during our case studies, which show a complex picture (see section 4.2 above, and Part 1 of this report, EQ3). Also, not all business stakeholders agreed that there was a difference between sales channels in terms of the incidence of unsafe products at all[207]. In general, however, a majority of respondents considered the differences between sales channels to be very significant[208].

In the analysis presented in Annex IV, we have used this stakeholder assessment as best available estimate to first analyse the potential detriment accruing currently to consumers due to unsafe products on the EU market, and then to consider the impact that increasing e-commerce and the implementation of different policy options could be expected to have on this baseline situation.

In our baseline analysis of business costs (section 7.1, Table 16), we have estimated the total EU27 household consumption of non-harmonised consumer products (excluding food and medical products) at EUR 428 664 million per year. Combining this data with the previously presented estimate of the incidence of unsafe consumer products, we derive at the estimate presented in Table 33 below.

Table 33: Estimated value of unsafe non-harmonised products (baseline estimate for 2019, EU27, EUR million)

Sales channel	Share in retail (2019)[a)]	Retail value of non-harmonised products[b)] (EUR million)	Share of unsafe products estimated by stakeholders[c)]	Estimated value of unsafe non-harmonised products[d)] (EUR million)
Brick-and-mortar shops[e)]	89.8%	384 940	4%	15 398
Online	10.2%	43 724	9%	3 935
Total	***100%***	***428 664***	***n.a.***	***19 333***

Source: Civic Consulting. Notes: a) Western Europe, www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected b) Based on the estimated total EU27 household consumption of non-harmonised consumer products (excluding food and medical products). c) Based on surveys of authorities, businesses, business organisations and other stakeholders. d) Calculated by multiplying the incidence of unsafe products with retail value. Due to data limitations, we assume that incidence of unsafe products is similar across all categories of non-harmonised consumer products. e) Includes all other retail sales channels that are not e-commerce.

As the table indicates, the value of unsafe non-harmonised products per year (which is in our approach equivalent to the related consumer detriment) is estimated at EUR 3.9 billion for online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion. This figure is by its nature an approximate estimate, as the data on which it is based has considerable limitations, and the result is affected by the underlying assumptions.

The first assumption is to apply the stakeholder estimate of incidence of unsafe products to the market as a whole. This appears to be justified, as market surveillance authorities and companies/business associations from a wide range of consumer product sectors have provided an assessment. Also, while there were some dissenting opinions among respondents, overall, there was a great degree of consistency between most respondents in each stakeholder category, and between stakeholder categories.

[207] For example, a large online retailer suggested that "overall, products on the market tend to be safe and one must diligently try to find ones that are not safe". This respondent assessed for both online and offline sales channels an incidence of 0.01% or less of products.

[208] See footnote 41.

The second assumption is that detriment is equally distributed across (non-harmonised) product categories and price ranges. This implies that non-harmonised products of all product categories and price ranges have the same likelihood to be unsafe. This assumption is likely a major simplification, as unsafe products may be more frequent in lower price ranges (e.g., low priced lighting chains). Also, specific product categories targeted at children or the elderly may be more likely to be considered unsafe than products targeted at other consumers, due to the vulnerability of the respective target groups. However, there are also some indications that unsafe products can be found in all price categories, and for all target groups. Unfortunately, no empirical data is available regarding these issues, which could be applied to adjust the methodology of the estimation accordingly. This is an important limitation of this analysis, which needs to be considered when interpreting the results.

The third and final assumption underlying this estimate is that consumers do not obtain reimbursement of the unsafe product's value, even in cases where the product is recalled. In reality, consumers may be compensated in case a product is recalled and this information reaches them, and thereby overall detriment is reduced to some extent. The effect of product recalls on consumer detriment is further elaborated in the following sub-section.

Effect of product recalls on baseline detriment

A fundamental obligation that derives from the GPSD is the obligation of producers and distributors to notify the authorities and take the necessary actions for consumer protection, once one of the products that they have placed on the market is identified as dangerous[209]. Corrective measures to be taken by producers may include withdrawing products from the supply chain, adequately and effectively warning consumers and, as a measure of last resort, recalling products that have already been supplied to consumers[210]. As elaborated in section 4.5 of this report, evidence collected through surveys of MSAs and general stakeholders as well as from other studies indicates that the effectiveness of product recalls from consumers is relatively low[211].

For estimating the effect of recalls on consumer detriment, we follow the approach explained above, namely to use the value of an unsafe product as a proxy for the detriment it causes to consumers that have bought it. This approach leads to a conservative estimate, as additional detriment that may be caused by recalled products in terms of injuries or damage to other goods, or the environment is not considered. When using the value of a recalled product to analyse consumer detriment, two situations can be differentiated:

1. *An unsafe product is recalled and returned to a producer.* Assuming that it is repaired or replaced by a good of the same quality, consumer detriment is compensated in terms of the value of the good. The resulting consumer detriment can be approximated as being zero[212];
2. *An unsafe product is recalled and <u>not</u> returned to a producer.* In this case the consumer detriment is the value of the product, as discussed.

Both situations have been considered in the detailed analysis presented in Annex V. The analysis focuses on non-harmonised products, for which the GPSD fully applies.

[209] GPSD Art 5 (3).

[210] See GPSD Art 5 (1), (b) of the third subparagraph, and last paragraph.

[211] See Part 1 of this report, EQ6.

[212] In reality, even in this situation consumers incur a detriment due to the time spent for the transaction, e.g., for returning the product by mail or in person to a shop. However, this additional detriment is not considered here, to provide a conservative, simplified estimate.

Currently, no comprehensive register of recalls exists in the EU. We therefore estimated both the total number of recalls regarding non-harmonised products, and the number of affected items. The first data set we used for this purpose are notifications in Safety Gate/RAPEX, which include the information whether a notified product was recalled or not. In the period 2013 to 2019, a total of close to 6 000 recalls were notified in Safety Gate/RAPEX, of which 1 320 related to ten product categories that are clearly not harmonised. Four of these product categories account for close to 90% of recalls of non-harmonised products: Clothing, textiles and fashion items; childcare articles and children's equipment; lighting chains; and hobby/sports equipment (see Table 34).

Table 34: Number of recalls in non-harmonised product categories notified in Safety Gate/RAPEX (2013-2019)

Product category	Total number of recalls 2013-2019	Average per year	In percent of total
Clothing, textiles and fashion items	698	100	53%
Childcare articles and children's equipment	203	29	15%
Lighting chains	131	19	10%
Hobby/sports equipment	130	19	10%
Jewellery	45	6	3%
Decorative articles	41	6	3%
Laser pointers	30	4	2%
Furniture	25	4	2%
Lighters	16	2	1%
Gadgets	1	0	0%
Total	***1320***	***189***	***100%***

Source: Civic Consulting, based on data from Safety Gate/RAPEX. All alerts, risk level: products with serious risks and products with other risk levels

However, the figures presented in the table above may not provide the full picture, as not all recalls in a country are necessarily notified at EU level. Member States are required to notify corrective measures in cases where the effects of the product risk can go beyond the territory of the Member State, implying that not all recalls in a country are necessarily notified at EU level. We therefore collected data on recalls directly from the relevant Member States' market surveillance authorities [213]. The number of recalls related to non-harmonised products was available for 17 Member States (see Annex V). Based on a detailed analysis of the available data, we estimated that in the EU27 approximately 189 recalls with EU relevance (and therefore notified through Safety Gate/RAPEX) are recorded per year, and in addition 869 national recalls of non-harmonised products.

To establish the number of affected items per recall, we drew on a dataset presented in detail in Part 1 of this study (section 6.1). Notifications may include information concerning the number of items that are being affected by the measures taken. This information is part of the RAPEX notification that is only accessible for market surveillance authorities. Based on this data, we arrived at an estimate of 20.6 million items subject to recalls with EU relevance, and 13.9 million items subject to national

[213] See GPSD implementation study.

recalls of non-harmonised products. Note that this is a rough approximation for the purpose of this estimation[214].

Assuming that the number of affected items is similar across product categories, and that the recalls notified in Safety Gate/RAPEX are similarly distributed across product categories as national recalls, we calculated the number of recalled items in each product category per year. Based on our research, several additional assumptions were made regarding the average value of products in each product category, and related return rates for baseline scenario and scenarios of improved recall effectiveness, based on a conservative approach. Table 35 below provides the estimate for the baseline scenario. In the table, we list the following information items for each category of non-harmonised products subject to recalls:

- Total number of items recalled (in million)
- Average value per item assumed for the scenario analysis (in EUR)
- Total value of recalled products (in EUR million)
- Return rates under the baseline scenario (in %)
- Value of products that remain with consumers (in EUR million)
- Value of products collected from consumers (equivalent to reduction in consumer detriment, EUR million)

[214] These estimates have been elaborated for the purpose of assessing consumer benefit of recalls. Actual numbers may differ, as 10 Member States did not report figures, and an extrapolation method was applied to approximate the missing values.

Table 35: Reduction of consumer detriment due to recalls (baseline scenario with low recall effectiveness), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products that remain with consumers (EUR million)	Value of recalled products collected from consumers (equivalent to reduction in consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1 096	25%	822	274
Childcare articles and children's equipment	5.3	30	159	25%	120	40
Lighting chains	3.4	15	51	5%	49	3
Hobby/sports equipment	3.4	80	272	25%	204	68
Jewellery	1.2	10	12	5%	11	0.6
Decorative articles	1.1	5	5	0%	5	0
Laser pointers	0.8	5	4	0%	4	0
Furniture	0.7	150	98	25%	74	25
Lighters	0.4	0.3	0.1	0%	0.1	0
Gadgets	0.03	20	0.5	5%	0.5	0
Total	*34.6*		*1 699*		*1 290*	***410***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124. b) See Table 125. Number of recalls and number of recalled items estimated on basis of data from Safety Gate/RAPEX and data on national recalls provided in the GPSD implementation study. For more details on the methodology, see Annex V.

As indicated in Table 35, the value of recalled non-harmonised products that are collected from consumers is estimated under the baseline scenario with low recall effectiveness to be EUR 410 million. In other words, the estimated baseline consumer detriment in the EU related to unsafe non-harmonised products is currently reduced due to recalls by approximately EUR 0.4 billion per year.

7.3.3. Conclusions regarding product-related consumer detriment in the baseline situation

The data listed in Table 30 above shows that about 11 million injuries occur in the EU every year that are related to – but not necessarily caused by – products, leading to a large detriment for EU consumers and society. In the analysis presented in Annex I, we have estimated this detriment to be EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations. The analysis therefore excludes losses caused by work and transportation accidents.

We concluded based on previous research and interviews with product safety experts that 15% is a reasonable and conservative estimate for the proportion of the total detriment that was caused by products, or could have been prevented through better design, instruction or a safety device. On this basis, the preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at EUR 11.5 billion per year. This estimate concerns the total of preventable detriment due to

harmonised and non-harmonised products. As mentioned above, due to the categorisation used in the IDB, it is not possible to separately consider the detriment related to non-harmonised products only.

We have also estimated the detriment that consumers suffer by having purchased (unknowingly) an unsafe product, even if it does not lead (or has not yet led) to concrete harm. For reasons provided above (and further elaborated in Annex IV), we consider the detriment due to the purchase of unsafe products (not considering potential harm to persons or other goods) to be equal to its purchase price. We have used survey-based estimates of market surveillance authorities, companies/business associations and other stakeholders (including consumer organisations) to establish the incidence of unsafe products sold in brick-and-mortar shops and online. Our analysis concludes that the consumer detriment in the EU due to unsafe non-harmonised products estimated on basis of product value is EUR 3.9 billion for the online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion per year[215]. This detriment is reduced under a scenario of low recall effectiveness (as is currently the case) by approximately EUR 0.4 billion per year, assuming that consumers are compensated fully for all non-harmonised products they returned to producers in response to a product recall.

Due to methodological limitations, both the detriment due to product-related injuries and the detriment due to the purchase of unsafe products are estimates that have a considerable range of uncertainty. However, they provide an indication of the dimension of detriment suffered by consumer in the EU due to unsafe products. In principle, both dimensions of consumer detriment are complementary, i.e. detriment due to product related injuries accrues in addition due to the loss of value of unsafe products. However, as mentioned above, due to the categorisation of injury data, the estimates cannot be simply added, as it is not clear which share of product-related accidents is due to non-harmonised products. We therefore use in the following sections detriment estimated on basis of product value as a proxy for the consumer detriment related to unsafe non-harmonised products[216]. As this does not include the detriment due to harm caused by unsafe products to persons or other goods, this is by definition a conservative approach. This conclusion is confirmed when comparing it with similar estimates from other jurisdictions (see Annex IV). However, wherever policy measures are expected to potentially reduce product-related injuries in the EU, this is indicated as an additional benefit.

7.4. Potential impacts of the COVID-19 crisis on the baseline situation

In this section, the potential impacts of the COVID-19 crisis on the baseline situation is discussed in light of evidence concerning the recent macroeconomic developments, and changes experienced at firm level.

Macroeconomic impacts

A modelling analysis performed in July 2020 predicted an overall GDP decrease of 13% across the EU27 as a result of the COVID-19 pandemic. This forecast is based on an analytical framework which accounts for firm liquidity constraints. As a result of these constraints, the decline in gross operating surplus that follows the pandemic and associated lockdowns also induces a strong reduction in corporate investment (-20.2% in 2020), contributing to a sharp decrease of GDP. According to the forecast, certain policy measures, such as short-term work (STW) allowances and liquidity support measures, can moderate the adverse economic impacts from COVID-19. Some

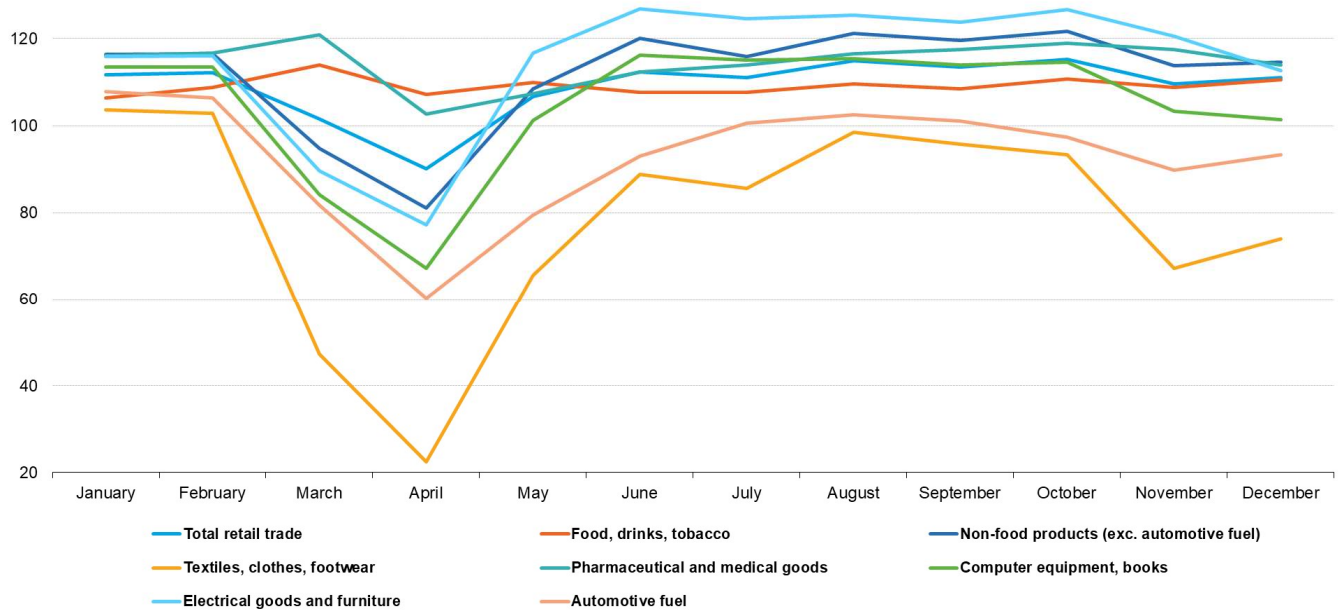
[215] Calculated for the baseline year 2019, see Annex IV.

[216] Including in the assessment of different policy scenarios in terms of reduced incidence of unsafe products (elaborated in Annex IV) and in terms of increased recall effectiveness (elaborated in Annex V).

measures could also moderate the decline in consumption (an estimated -10.8% with policy measures instead of -14.1% without relevant policy measures in place). However, the analysis also outlines that policy measures alone are unable to prevent a decline in production and consumption during the time of the lockdown. For 2021, the analysis predicts a decline in GDP of -4.8% without policy measures, and a decline of only -2.5% if both STW and liquidity support measures are in place. The corresponding figures for investment are -13.6% and -6.3%. Also, consumption is estimated to decrease by -3% in 2021 without policy measures, and by -2.3% with policy measures in place[217].

Since this analysis, more data has become available regarding recent market developments, including in the area of retail. The following figure shows the development of retail trade regarding key product groups. Total retail sales returned quickly to pre-crisis levels after lockdown-related strong decreases in April 2020. In September 2020, total retail had 100.7% of the volume reached in February. However, new measures to contain COVID-19 taken since autumn 2020 continue to affect retail trade volumes, as is illustrated by the figure below.

Figure 13: Development of retail trade volume according to product groups, EU27, January to December 2020



Source: Eurostat (sts_trtu_m). Monthly data, seasonally and calendar adjusted (2015=100)

As elaborated in section 4.2 above, the decline in overall retail sales in the first half of the year was accompanied by a rise of e-commerce sales that are expected to increase by 16.9% in 2020 in Western Europe, according to a recent forecast[218]. The boost in new spending is expected to leave e-commerce permanently ahead of its previous pace, with higher sales figures than it otherwise would have through 2023. According to the estimate, retail e-commerce will account for 13.8% of total retail in 2023[219]. Also, results

[217] Pfeiffer, P. et al. (2020), "The COVID-19 pandemic in the EU: Macroeconomic transmission & economic policy response", Discussion Paper 127, July 2020. Available at: https://cepr.org/content/covid-economics-vetted-and-real-time-papers-0

[218] See: https://www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected

[219] Ibid.

of a recent international survey performed by UNCTAD suggest that COVID-19 has changed trends of online shopping significantly. According to the survey, an accelerated shift towards a more digital world can be observed with lasting changes in online shopping behaviours[220]. The survey confirms that online purchases have risen, while the biggest gainers being ICT/electronics, gardening/do-it-yourself, pharmaceuticals, education, furniture/ household products, cosmetics/personal care categories. At the same time, consumer spending declined, which is reflected by lower average monthly online spending per shopper. Overall, the growth of e-commerce is expected to change the sales and consumption patterns in national and international retail markets. The importance of key digital services is expected to grow further (e-commerce, online payments, online communication services), and many changes are expected to outlast the COVID-19 pandemic (e.g. preferences for local travel, online shopping, remote working).

Firm level impacts

To explore the impact of COVID-19 at the firm level, specifically with respect to product safety measures and related topics, we conducted a series of interviews with companies producing/selling (also) non-harmonised consumer products. Next to discussing the impacts of specific policy options (see section 8.5 below), we discussed several questions on COVID-19 in detail. Key messages from the interviews regarding the baseline situation include:

- In line with the economic data presented above, almost all respondents mentioned that their companies were affected by the COVID-19 crisis. In many companies, sales decreased significantly due to store closures, which was particularly detrimental to companies that rely on the classic model of retail stores in the form of "brick-and-mortar" shops. Companies tried to compensate this loss by cost saving measures such as short-time work and unpaid holidays. However, there were also companies that reported to be largely unaffected. An interviewee from a company in the childcare product sector, who only experienced minor effects, indicated as an explanation that "baby articles are needed even in a pandemic situation";

- However, most companies mentioned that they were to some extent able to benefit from increased e-commerce, which compensated some of the losses. One company even mentioned that overall, they benefitted during the COVID-19 crisis as sales of particular products used for do-it-yourself home improvements (such as paints) increased dramatically. Other companies also benefitted from government contracts for the supply of specific goods (such as PPE). Companies mentioned that they were able to shift their suppliers to overcome shortages, or that they launched new assortments during the crisis to compensate shortages.

When asked regarding their expectation concerning the expected time span of the effects and potential permanent changes in business practices, interviewees mostly stated that the effects of the pandemic will remain relevant until at least 2022. Individual companies mentioned that it will take more time to estimate the full impact of COVID-19. Respondents also suggested that some business practices may change permanently, e.g. that the number of business trips will be reduced and online platforms will likely remain much more relevant for team and project communication.

Interviewed companies were split regarding whether the crisis in any way affected how product safety in their company was safeguarded, including through effects on their supply chain. Several interviewees clearly stated that this was not the case, as products

[220] UNCTAD, 2020, "COVID-19 has changed online shopping forever, survey shows". Available at: https://unctad.org/news/covid-19-has-changed-online-shopping-forever-survey-shows

were produced in the same way as before, and they had also not experienced any supply chain issues.

On the other hand, about half of the interviewees confirmed that the COVID-19 crisis indeed has had such an effect. For example, an interviewee pointed out that personal contact with suppliers is essential when discussing product safety features. The same interviewee explained: "Having discussions on product safety without physically having these products available and in front of you will remain. In the new normal, you will just get test results by email and you have to believe what you see in the email. It will require a lot of trust with suppliers".

Some companies were affected by shortages in assortments due to supply chain problems. Generally, companies mentioned that there were a lot of supply chain issues as there were only a few suppliers available which caused delays in delivery and, occasionally, production stops. Another interviewee reported that supply chain effects were also noted once initial lockdowns were over. After the crisis some of these suppliers reopened while others did not. The company had therefore to contract several new suppliers, that previously had been indirectly contracted through first level suppliers. After the lockdown, more direct contracting with second level suppliers occurred, which led to increased efforts in terms of contracting, possibly also affecting product safety efforts.

In conclusions, macroeconomic data and firm level experiences confirm that the baseline situation is significantly affected by the COVID-19 crises, with main effects being temporary decreases in demand for some products and increasing demand for others, with a clear shift to online sales channels. However, in general terms, product safety processes at companies including with respect to related supply chain management appear to remain largely unchanged, except with the increasing reliance on electronic communication instead of physical meetings.

For more details, including with respect to specific comments of SMEs (which were largely in line with the views reported above), see Annex IX.

8. Assessment of options

8.1. Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD

As described in section 6 above in more detail, Option 1 would focus on an improved implementation and enforcement of the existing legal framework, without revision of the GPSD. This option would include the following policy actions, which are presented in Table 36:

Table 36: Main policy actions related to Option 1: Improved implementation and enforcement of the existing legal framework, without revision of the GPSD

Specific policy objectives	Description of policy actions
Ensure general safety rules, including for product risks linked to new technologies	Guidance for businesses that cybersecurity threats and other risks of new technologies affecting physical or mental health are covered. Exploring use of European Standards for new risks
Address safety challenges in the online sales channels	Update of the Product Safety Pledge, its promotion in order to expand it to further signatory marketplaces
Make product recalls more effective	Guidance on product recalls for market surveillance authorities and economic operators
Enhance market surveillance and ensure better alignment of rules	Increased funding of joint market surveillance activities among Member States, including joint testing of consumer products
Address safety issues related to food-imitating products	Revision of the Food-imitating Products Directive, clarifying the way to assess level of risk of these products without integrating into GPSD

In the following analysis of the impacts of Option 1, we first consider the extent to which the suggested policy actions under Option 1 are likely to achieve the specific policy objectives. We then discuss the extent to which the option contributes to administrative simplification. Subsequently, we elaborate on the economic impacts, as well as impacts on Member States. Finally, we analyse the expected social impacts, impacts on fundamental rights and environmental impacts of this option.

8.1.1. Effectiveness in achieving the policy objectives

8.1.1.1. Assessment by specific policy objective

The extent to which the option is expected to address the specific policy objectives is assessed in Table 37 below, which is followed by a description of related stakeholder views.

Table 37: Assessment of Option 1: Improved implementation and enforcement of the existing legal framework, without revision of the GPSD

Specific policy objectives	Areas	Achievement of specific objectives	Assessment
Ensure general safety rules, including for product risks linked to new technologies	*Certainty regarding coverage of new risks*	The general safety requirement of the GPSD already encompasses protection against all kinds of risks arising from the product to the safety and health of persons. The envisaged guidance would clarify that this is the case, including with respect to cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect physical or mental health, with complementary measures in the standardisation field to address safety requirements for consumer products concerning certain new risks. The provision of guidance at EU level would likely lead to a reduced uncertainty of business operators and MSAs regarding the applicable procedures.	Option will to some extent contribute to certainty regarding coverage of new risks, without being legally binding. Implementation differences in MS may remain
	Certainty regarding coverage of software	While harmonisation legislation already partly covers stand-alone software (e.g. Radio Equipment Directive 2014/53/EU and Medical Devices Regulation (EU) 2017/745), gaps regarding the coverage of software updates and stand-alone software interacting with products will remain in all consumer product domains where the GPSD fully applies, or where harmonisation legislation does not cover related risks.	Option will not close existing gaps regarding stand-alone software
Address safety challenges in the online sales channels	*Safety of products sold on online platforms*	Under Option 1, the Product Safety Pledge will be updated and promoted through awareness campaigns, and other online marketplaces will be encouraged to sign the Pledge, which potentially leads to improved coverage of online platforms. However, online platforms that do not sign the Product Safety Pledge or do not adhere to its voluntary commitments will continue to create difficulties for notice-and-take-down procedures. Unsafe products will continue to enter the market from third countries via online platforms, potentially causing detriment to consumers.	It is unlikely that safety risks for EU consumers due to products sold on online platforms will be significantly reduced
	Information of consumers on essential safety aspects	No measures planned regarding the information of consumers on essential product safety aspects in the online environment. While reputable online traders often already provide such information, this will continue to depend on the initiative of each trader.	No change to the current situation
Make product recalls more effective	*Reaching out to consumers affected by recalls*	New EU guidance on recall would address current deficiencies concerning the effectiveness and efficiency of recall procedures and concern e.g. the provision of more transparent information to consumers regarding the safety risk that led to the recall, the use of customer data for direct notifications and cooperation between different actors in the recall process. This would replace the wide variety of guidance documents in use in Member States and likely lead to more uniform approaches across the EU. It would also reduce to some extent related uncertainty for business operators and authorities. It is, however, unlikely to increase the effectiveness of recalls, which depends, among others, on availability of adequate customer data and clear communication of the risks related to the recalled products.	Option will to some extent contribute to certainty regarding recall procedures, without, however, addressing the underlying reasons for limited recall effectiveness
	Information provided in recall notices	Likely to be covered by guidance, with no other measures foreseen.	
	Monitoring of recall effectiveness	Likely to be covered by guidance, with no other measures foreseen.	
	Remedies for consumers affected by recalls	No measures foreseen. Consumers affected by a recall would continue to have to rely on existing, limited remedies.	No change to the current situation

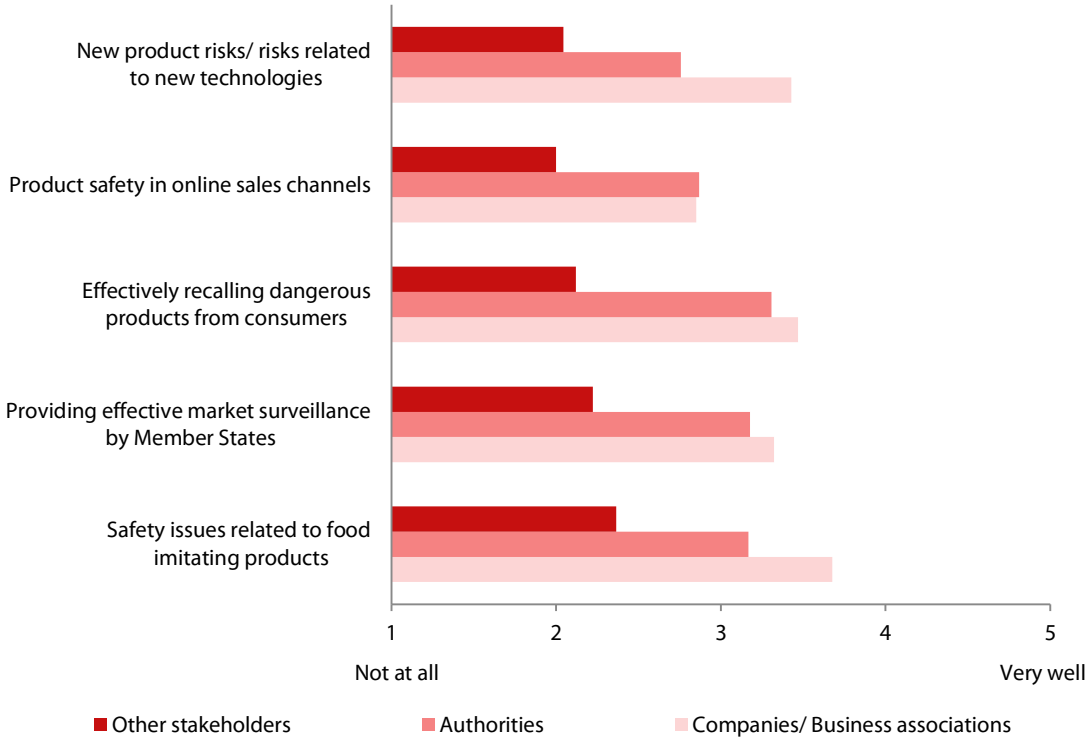
Enhance market surveillance and ensure better alignment of rules	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	The market surveillance framework for harmonised and non-harmonised consumer products would not be aligned. However, increased funding of joint market surveillance activities among Member States, including joint testing of consumer products can potentially contribute to better and more harmonised enforcement.	Improved EU funding may enhance enforcement, but no change to the current fragmentation of legal framework for market surveillance
	Deterrence effect	No measures foreseen.	No change to the current situation
	Diverging risk assessments by Member States' MSAs	No measures foreseen.	
	Simplification of standardisation procedures	Standardisation procedures at the Commission level under the GPSD would not be simplified.	
Address safety issues related to food-imitating products	*Addressing risks of food-imitating products*	A revision of the Food-imitating Products Directive (87/357/EEC) will clarify its scope and safeguard that the Directive is applied consistently across EU Member States. The revised Directive will clarify that an evaluation of the risks posed by the specific food-imitating product is required, as it is done for other consumer products.	Option will align the regime of the Food-imitating Products Directive with the GPSD regime, as risk assessment will be required

8.1.1.2. Stakeholder views on Option 1

Companies/business associations, MSAs and other stakeholders were asked in the stakeholder survey to what extent they consider Option 1 to effectively address five challenges mirroring the five specific policy objectives. As shown in Figure 14 below, out of all stakeholder groups, companies/business associations were most positive (average of 3.4 on a scale of 1 to 5, covering all five challenges). MSAs were slightly less positive on the effectiveness of Option 1. MSAs found on average that Option 1 moderately well addresses the stated challenges (average of 3.1). Stakeholders other than businesses and MSAs were far less positive and consider that Option 1 would rather not effectively address these challenges (average of 2.2). Both MSAs and other stakeholders saw Option 1 as less effective in addressing the first two objectives (related to new product risks and online sales channels) than other objectives.

The overall average assessment on the effectiveness of Option 1 across all respondents and stakeholder groups was 2.9.

Figure 14: In your view, to what extent would Option 1 effectively address the following challenges for product safety? Please assess.



8.1.2. Potential for administrative simplification

Guidance provided under Option 1 could to some extent reduce regulatory complexity and uncertainty regarding the coverage of risks by the GPSD, as well as regarding applicable procedures for recalls. Also, complementary measures in the standardisation field to address safety requirements for consumer products concerning certain new risks could have a similar effect. However, as these guidelines and standards would not be legally binding and implementation and interpretation differences between Member States will continue, this reduction can be expected to be minor. In addition, as gaps regarding the coverage of stand-alone software will remain, uncertainty in this respect

will likely not be reduced. Overall, current regulatory complexity is not reduced, which implies the continuation of related administrative burdens for businesses.

Option 1 does not include any additional administrative requirements for specific types of operators. Only very low burdens are expected for businesses from getting familiar with new guidance documents (to the extent that businesses are following developments at EU level).

8.1.3. Economic impacts

The following section outlines the economic impacts for businesses that are likely to result from the implementation of Option 1, focusing first on expected benefits and expected costs.

8.1.3.1. Benefits for businesses

As outlined in the baseline, businesses currently incur additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). These are estimated to amount to 119 million EUR annually (see section 7.1.3 above, Table 28). As no legislative measures are planned under Option 1, no significant reduction in this amount is expected.

In the survey, we asked all stakeholder groups to assess a set of potential benefits, identified on basis of previous research. The question specifically provided the following potential benefits of Option 1 for businesses (some of them are also relevant for MSAs):

- Greater legal certainty
- Reduced legal complexity
- Easier compliance with product safety requirements for SMEs
- Better information on unsafe products/ measures taken by authorities provided through Safety Gate/RAPEX
- Increased business revenue (e.g. due to increased reputation/brand value)
- Lower operational risk for businesses
- Better supply chain management due to improved traceability of products

The results of the stakeholder survey are presented in Figure 15 below:

Figure 15: Where do you see the greatest additional benefits that would result from the implementation of Option 1? – Direct benefits for businesses

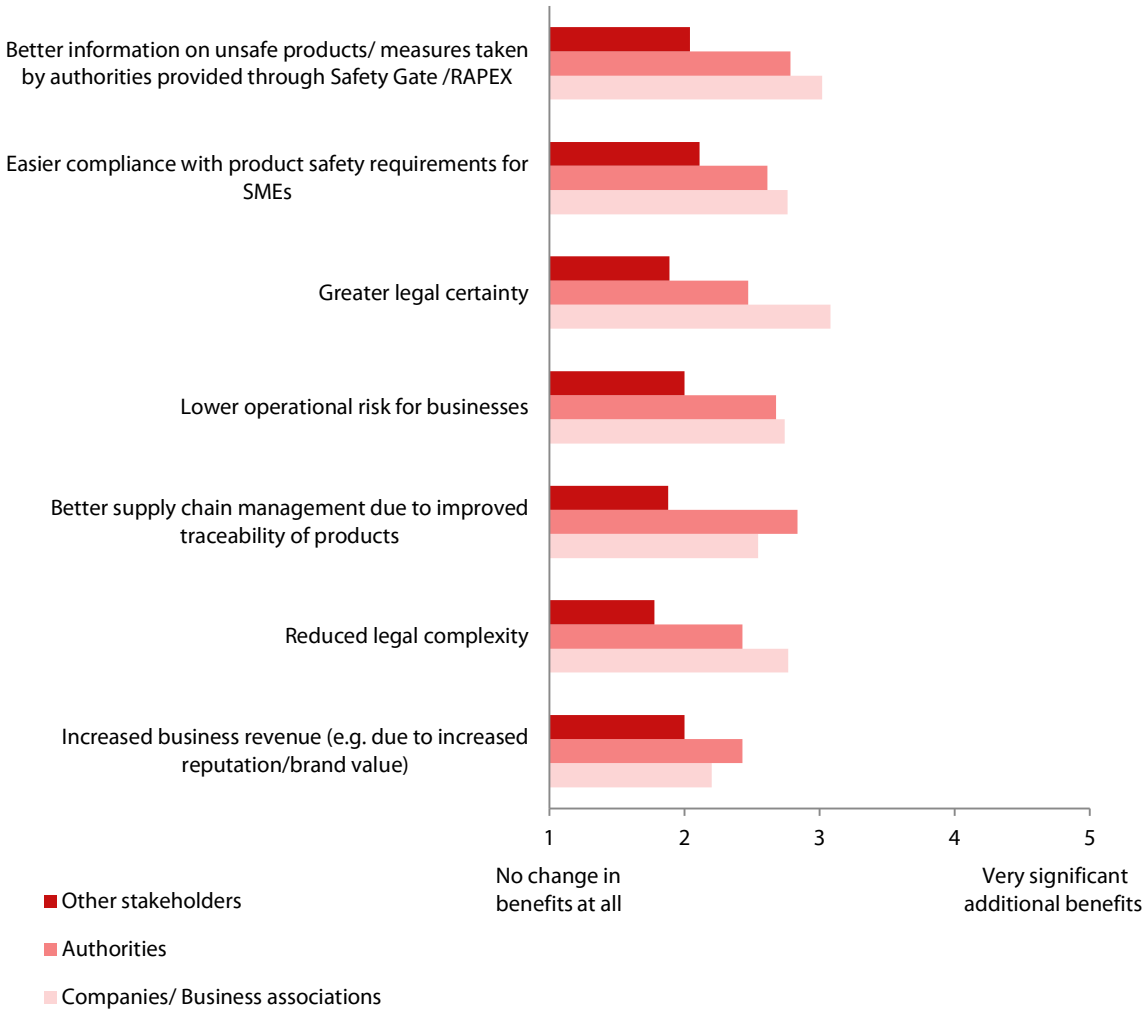


Figure 15 above shows that companies/business associations and MSAs expect considerably more benefits from Option 1 than other stakeholders, but overall, on a comparatively low level. On average, companies and business associations assessed benefits from Option 1 to be 'moderate' (indicated by the value 3). Businesses only assessed the benefits to be 'minor' when it comes to increased business revenue. MSAs average assessment is 2.6 for all benefits. By contrast, other stakeholders on average only saw 'minor' benefits (i.e. an average value of 2). The assessment of other stakeholders is particularly low with respect to the reduction of legal complexity and improved supply chain management due to improved traceability of products (values of 1.8 and 1.9 respectively).

8.1.3.2. Costs of businesses

In this section, we consider the potential impact of Option 1 in term of recurrent costs (e.g. staff costs) and one-off costs (e.g. familiarisation costs, costs for external advice)[221].

[221] Due to the nature of policy options and the questions asked in the survey with respect to the related recurrent and one-off costs, the estimate elaborated in this section focuses on the overall impact of the implementation of Option 1 on businesses' recurrent costs and one-off costs.

Recurrent costs

Businesses' replies overwhelmingly indicate that implementing Option 1 would not increase companies' recurrent regulatory compliance costs. This is true for both manufacturers and distributors[222]. Several business respondents indicated that nothing substantial would change with the implementation of Option 1 compared to the status quo. At the same time, it was outlined that better guidance documents could generally improve clarity and legal certainty, cooperation with MSAs and, as a result, create cost savings.

To estimate the impact of the implementation of Option 1 on EU businesses' recurrent costs, we applied the percentage change in recurrent (annual) costs as assessed by respondents to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (see section 7 for the baseline estimates). Due to a relatively low number of responses from distributors and inconsistencies of the stated changes in costs, we decided to base the estimation of recurrent costs for the EU as a whole on the sample statistics for the full sample of businesses' stated changes in recurrent costs (the sample statistics are provided in Table 38).

Table 38: Sample statistics of businesses' estimated change in recurrent costs in product safety-related costs under Option 1 (as percentage of recurrent costs to comply with safety requirements for consumer products)

Sample statistics	Full sample of business respondents, change of recurrent costs
Number of responses	27
Min	-20.00%
Max	30.00%
Average	0.19%
Q1	0.00%
Q2 (median)	**0.00%**
Q3	0.00%
Q1 to Q3 (middle 50% of values)	0.00% - 0.00%

Applying the sample median of 0.00% (see previous table) as best estimate for the extent to which recurrent costs would change under Option 1, we find no additional recurrent costs for manufacturers and distributors of consumer products at the EU aggregate level.

One-off costs

Businesses may need additional staff time for the implementation of new policy measures, e.g. to adapt internal procedures. Responses from companies and business associations indicate that Option 1 would only create minor additional one-off costs for businesses related to getting familiar with new guidance provided at EU level. Sample statistics are provided in Table 39. The quantitative estimates provided by company

[222] 16 out of 25 manufacturers expect that recurrent costs would remain the same after the implementation of Option 1, whereas three manufacturers indicated that costs would fall. Two manufacturers indicated that their recurrent cost would increase only slightly. With regard to distributors' recurrent costs, six out of 11 distributors indicated that costs would remain the same, whereas three distributors expect costs to rise slightly.

respondents confirm that no additional one-off cost are expected at the EU aggregate level, when extrapolating on basis of the sample median.

Table 39: Sample statistics of businesses' estimated one-off costs under Option 1 as percentage share of annual EU turnover from consumer products (total of additional staff and additional non-staff costs)

Sample statistics	Full sample of business respondents, one-off costs
Respondents	20
Min	0.00%
Max	0.69%
Average	0.04%
Q1	0.00%
Q2 (median)	**0.00%**
Q3	0.00%
Q1 to Q3 (middle 50% of values)	0.00% - 0.00%

Total costs

Our analysis indicates that the implementation of Option 1 would not be expected to change one-off and recurrent costs of EU businesses.

8.1.3.3. Firm level impacts for specific types of operators

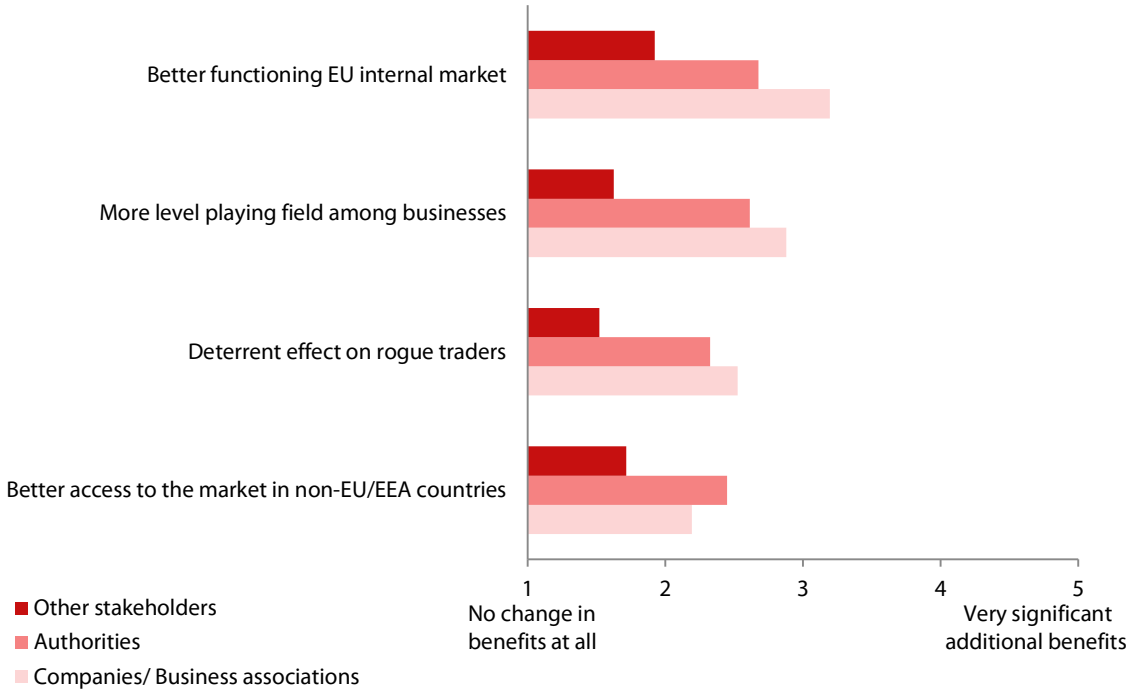
We have separately considered the economic impacts for several types of operators which are of specific interest (such as SMEs) or may be specifically affected by the proposed measures under some of the options (online marketplaces, online traders in general, and producers and distributors of food-imitating products). In line with the overall results presented above, no significant firm level impacts are to be expected due to the implementation of Option 1 for specific types of operators. An exception are businesses that are manufacturing or distributing food-imitating products. Currently, the Food-imitating Products Directive is applied differently across EU countries, as MSAs can take action on products such as food-shaped shampoos or bath gels, even though no specific risk evaluation has been made (interpretation of the Directive as a per se prohibition of food-imitating products). We expect that a targeted revision to better detail the specific requirements of the Food-imitating Products Directive and criteria for the evaluation of the risks posed by specific food-imitating products could help manufacturers and distributors to better assess the potential risks of the products offered by them. As both manufacturers and sellers already have to comply with the current Directive, we do not expect additional costs from a revision that merely aims at providing greater clarity and legal certainty respectively. A greater level-playing field regarding the implementation and enforcement of the Food-imitating Products Directive in the EU, as envisaged under Option 1, could lead to minor cost savings on the side of manufacturers and distributors of food-imitating products.

8.1.3.4. Macroeconomic impacts

The results of the consultation conducted for this study show that businesses and business associations assess the potential benefits from better functioning of the EU internal market and more level playing field among businesses as 'moderate'. The deterrent effect on rogue traders is considered 'minor' to 'moderate', while the benefit of a better access to non-EU/EEA markets is assessed to be 'minor'. On average, MSAs expect lower benefits than businesses. When it comes to other stakeholders, their

assessment of Option 1 is much lower at an average of only 1.7 (i.e. below 'minor', see Figure 16).

Figure 16: Where do you see the greatest additional benefits that would result from the implementation of Option 1? – Benefits for internal market and trade



The following sub-sections will discuss these and other potential impacts of the implementation of Option 1 that are relevant in terms of trade and competition.

Impact on internal market and trade

The evaluation of the GPSD found that legal uncertainty concerning key GPSD concepts currently has negative effects in that it may prevent MSAs from taking action for perceived lack of competence or perceived lack of the fulfilment of relevant requirements for taking action, in particular the lack of safety of a product; which may lead to a lack of enforcement of the GPSD, and to an uneven application of the GPSD by MSAs of different Member States which does not only impact on the level of consumer protection but also on the free movement of goods within the internal market. Additional guidance, as foreseen under Option 1, can to some extent address these uncertainties without however, being legally binding. Implementation differences in Member States will therefore remain. Significant impacts of the implementation of Option 1 on internal market or trade appear to be highly unlikely.

Impact on competition and innovation

Significant impacts on competition and innovation are not to be expected under Option 1, as the benefits of guidance in this respect are limited and all measures are cost-neutral for businesses (except in the area of food-imitating products, where a slight benefit is possible due to increased legal clarity).

Additional macroeconomic effects

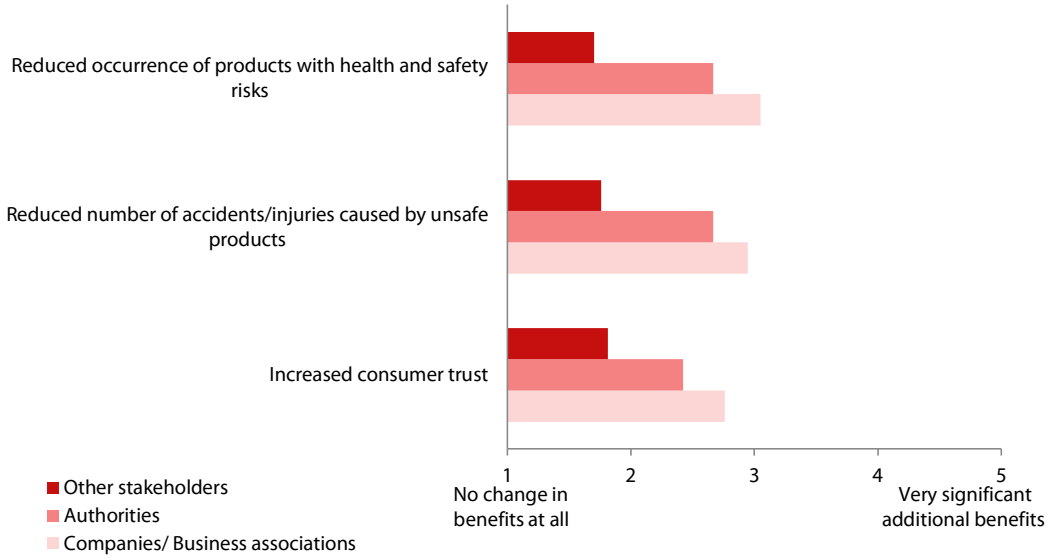
We do not expect significant additional macroeconomic effects, due to the fact that measures under Option 1 are voluntary in nature and are largely cost neutral (except

with respect to increased funding of joint market surveillance activities among Member States).

8.1.4. Impact on consumers and households

Companies and business associations on average assess the benefits that would result from the implementation of Option 1 for consumers to be 'moderate' (see Figure 17). MSAs assess the benefits to be lower, between 'minor' and 'moderate'. In contrast, other stakeholders assess the benefits of Option 1 to be negligible (lower than 'minor').

Figure 17: Where do you see the greatest additional benefits that would result from the implementation of Option 1? – Benefits for consumers



The following sections discuss several aspects of the impact on consumers in more detail. These include the impact on consumer prices, consumer choice, and the overall impact on consumer safety and impacts on vulnerable consumers.

8.1.4.1. Impact on consumer prices

The implementation of Option 1 would, overall, not result in increasing consumer product safety-related costs (one-off costs and recurrent costs) for companies operating in manufacturing as well as wholesale and retail sectors. Option 1 is therefore not expected to impact on the prices for consumer products in the EU.

8.1.4.2. Impact on consumer choice

Due to their voluntary character, we do not expect an impact on consumer choice from any of the measures considered under Option 1.

8.1.4.3. Overall impact on consumer safety and impacts on vulnerable consumers

The guidance provided under Option 1 and additional funding of joint market surveillance activities among Member States could slightly improve enforcement of the GPSD, with related benefits for consumers. However, consumers that purchase unsafe products sold on online platforms from traders in non-EU/EEA countries would continue to incur detriment, until platforms take down the product based on a notification by a third party (e.g. MSA, consumer organisation). This situation is not expected to change,

even if the Product Safety Pledge is further promoted. With an increasing role of online platforms in the EU retail sector in the future, costs for society due to unsafe products entering the market through online channels from third countries could increase, although this will also depend whether other measures are taken at EU level, including in the framework of the new Digital Services Act. Option 1 would therefore not be expected to increase the level of protection of EU consumers, including vulnerable consumer groups such as children, the elderly or disabled persons. In consequence, it would also not be expected to reduce consumer detriment compared to the baseline option.

8.1.5. Impacts on Member States

8.1.5.1. Benefits for MSAs

Option 1 is not expected to provide significant benefits for MSAs, except the above-mentioned reduction in uncertainty due to the provision of guidance and the additional funding for joint market surveillance activities of Member States. No efficiency gains and related costs savings are expected, as the current fragmentation of the legislative framework for market surveillance of harmonised and non-harmonised products will continue to lead to additional costs for some MSAs (see baseline).

8.1.5.2. Costs for MSAs

In the following, we first analyse recurrent and subsequently one-off costs of MSAs that would be expected to accrue under Option 1.

Recurrent costs

When asked in our survey of MSAs about the extent to which they consider that the implementation of Option 1 would change recurrent costs, 20 MSAs reported that their recurrent costs would remain the same, two MSAs reported that their costs would increase slightly and one MSA reported that its costs would increase significantly. MSAs did generally not comment on the nature of changes in recurrent costs. In total, 23 MSAs provided estimates regarding the percentage changes in recurrent costs if Option 1 was implemented, compared to current cost related to market surveillance of consumer products (see Table 40 for sample statistics).

Table 40: MSAs' estimated changes in recurrent costs, Option 1

Sample statistics	Increase in recurrent costs
Number of responses	23
Min	-40.00%
Max	20.00%
Average	-0.40%
Q1	0.00%
Q2 (median)	**0.00%**
Q3	0.00%
Q1 to Q3 (middle 50% of values)	0.00% - 0.00%

As indicated in the table, more than three quarters of all MSAs that provided quantitative cost assessments do not expect increases in their recurrent market surveillance costs, which is reflected by a median cost estimate for recurrent costs of 0.00%. Based on these estimations, we expect that, overall, MSAs' recurrent costs will remain the same under Option 1, compared to the baseline situation.

One-off costs

Asked about the extent to which MSAs expect that the implementation of Option 1 would lead to changes in one-off costs, 14 MSAs report no additional costs at all, whereas three MSAs expect minor additional one-off costs and six MSAs expect moderate additional one-off costs. It was stated that one-off costs may result from the development of new guidance documents, and, potentially, the set-up of technical capacities for carrying out market surveillance activities related to new risks.

It can be concluded that overall, additional one-off costs under Option 1 can be expected to be very low.

8.1.5.3. Other effects on Member States

The proposed measures would not be expected to have other effects on Member States. Specific gaps such as legal difficulties to conduct mystery shopping for authorities in some Member States would not be addressed, and there would be no increased deterrence effect on rogue traders. The efficiency of market surveillance processes with cross-border implications in the EU would not be increased. The European Commission would continue to lack powers to intervene in case of divergences in the product safety risk assessment between national authorities, and there would be a continued reliance on informal mechanisms in case risk assessments diverge.

8.1.6. Social impacts, impacts on fundamental rights and environmental impacts

Due to their limited scope and voluntary character, we do not expect that the measures implemented under Option 1 would have significant social or environmental impacts, or impacts on fundamental rights.

8.1.7. Summary assessment

The summary assessment of the option is presented in Table 41 below.

Table 41: Summary assessment of Option 1 compared to baseline situation

Area	Assessment
Effectiveness in achieving the policy objectives	
Ensure general safety rules, including for product risks linked to new technologies	neutral / +
Address safety challenges in the online sales channels	neutral
Make product recalls more effective	neutral
Enhance market surveillance and ensure better alignment of rules	neutral
Address safety issues related to food-imitating products	+
Administrative simplification	
Reduction of regulatory complexity and uncertainty	neutral / +
Economic impact	
Benefits for businesses	neutral / +
Cost of businesses	neutral
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral
Impact on consumers and households	
Consumer prices	neutral
Consumer choice	neutral
Consumer safety and vulnerable consumers	neutral
Impact on Member States	
Benefits for MSAs	neutral / +
Costs for MSAs	neutral
Other effects on Member States	neutral
Social impacts, impacts on fundamental rights and environmental impacts	
Social impacts	neutral
Impacts on fundamental rights	neutral
Environmental impacts	neutral

Note: Magnitude of impact as compared with the baseline scenario: neutral = no significant difference to baseline situation; + = positive impact compared to baseline; ++ = significant positive impact compared to baseline. An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

8.2. Option 2. Targeted revision of the GPSD (Directive or Regulation)

As described in section 6 above in more detail, Option 2 would consist of a targeted revision of the GPSD, either as a Directive or recast as a Regulation. In case the new instrument is also a Directive, changes to the GPSD would need to be transposed by Member States into national legislation. The related policy actions are presented in Table 42, which is structured according to the specific policy objectives:

Table 42: Main policy actions related to Option 2: Targeted revision of the GPSD (Directive or Regulation)

Specific policy objectives	Description of policy actions
Ensure general safety rules, including for product risks linked to new technologies	New risks (see Option 1) explicitly covered through revision of GPSD, without extending the definition of product to standalone software
Address safety challenges in the online sales channels	Legal revision making most provisions of the Product Safety Pledge legally binding
Make product recalls more effective	Clarify/create legal basis for economic operators to use available customer contact details to notify the owners of recalled products. Mandatory key elements defined that are to be included in recall notice and prohibition to use the terms decreasing the perception of risk
Enhance market surveillance and ensure better alignment of rules	Align GPSD with market surveillance rules in Regulation (EU) 2019/1020, to have more uniform framework for harmonised and non-harmonised consumer products while keeping different legal instruments. Simplifying standardisation procedures
Address safety issues related to food-imitating products	Incorporation of food-imitating products into the GPSD general framework

In the following analysis related to Option 2, we first assess the extent to which the suggested policy actions are likely to achieve the specific policy objectives. We then discuss the extent to which the option contributes to administrative simplification. Subsequently, we elaborate on the economic impacts, as well as impacts on Member States. Finally, we analyse the expected social impacts, impacts on fundamental rights and environmental impacts of this option.

8.2.1. Effectiveness in achieving the policy objectives

8.2.1.1. Assessment by specific policy objective

The extent to which the option is expected to address the specific policy objectives is assessed in Table 43 below, which is followed by a description of related stakeholder views.

Table 43: Assessment of Option 2: Targeted revision of the GPSD (Directive or Regulation)

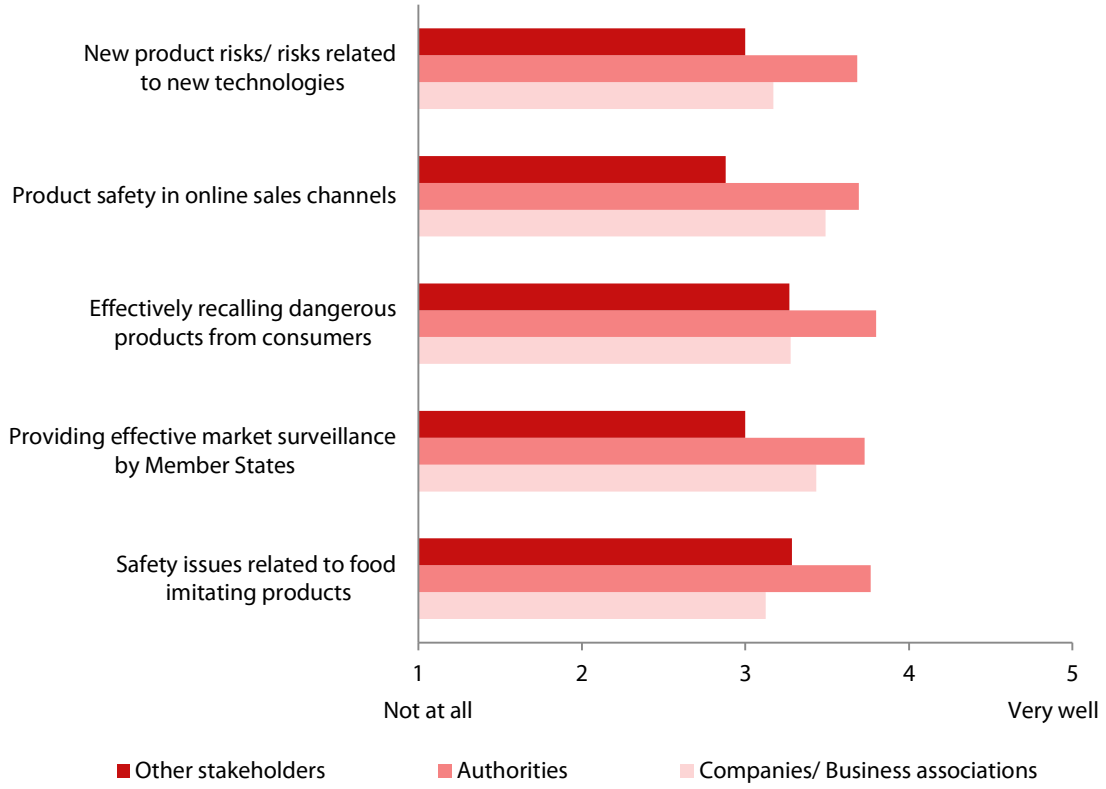
Specific policy objectives	Areas	Achievement of specific objectives	Assessment
Ensure general safety rules, including for product risks linked to new technologies	*Certainty regarding coverage of new risks*	Under Option 2, the definition of safety in the GPSD will be revised to clarify that the covered risks arising from the product to the safety and physical/mental health of persons include not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect health (similar to the guidance that will be provided under Option 1). For harmonised products there is relevant work ongoing in relation to the Radio Equipment Directive, the Machinery Directive, and the Low Voltage Directive. A similar provision in the GPSD will avoid any gaps in product coverage that may remain in this respect. This will create legal certainty for business operators and MSAs.	Legally binding clarifications will avoid uncertainty. Depending on the choice of instrument, implementation differences in MS may remain
	Certainty regarding coverage of software	The definition of product in the GPSD will not be changed, so that safety risks stemming from software are only covered if the software is integrated in a product at the time of its placing on the market (as is currently the case). There will not be specific provisions on or references to software updates, and also standalone software would not fall under the safety requirements of the GPSD. Therefore, gaps regarding safety risks stemming from software updates and stand-alone software interacting with products will remain in all consumer product domains where the GPSD fully applies, or where harmonisation legislation does not cover related risks.	No change to the current situation
Address safety challenges in the online sales channels	*Safety of products sold on online platforms*	Making most provisions of the Product Safety Pledge legally binding for all online marketplaces targeting EU consumers will improve accessibility of platforms for notice-and-take-down procedure, and increase consumer safety regarding products sold on platforms that are currently not covered by the Pledge. While safety risks for EU consumers due to products sold on online platforms could be partly reduced, their mitigation will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and the further development of the EU legal framework, most notably the new DSA.	Safety risks for EU consumers due to products sold on online platforms could be partly reduced, with the effectiveness also depending on other factors
	Information of consumers on essential safety aspects	No measures planned regarding the information of consumers on essential product safety aspects in the online environment. While reputable online traders often already provide such information, this will continue to depend on the initiative of each trader.	No change to the current situation
Make product recalls more effective	*Reaching out to consumers affected by recalls*	Encouraging the use of customer registration systems for the purpose of product safety and the clarification/creation of a legal basis for economic operators to use any available customer contact details at their disposal to directly notify the owners of recalled products – without the need of consumer consent – will contribute to effectively reaching out. The requirements for businesses to disseminate recall announcements on their website/social media and other appropriate channels to ensure the widest possible reach, will also contribute to this aim, although this is (especially regarding websites) frequently already done.	The change can be expected to facilitate the use of available customer data, and avoid that outreach measures are prevented by data protection concerns
	Information provided in recall notices	The definition of mandatory key elements to be included in every recall notice and the prohibition to use terms which decrease the perception of risk in recall notices can be expected to lead to better and clearer information on recalled products, if enforced adequately	Improvement in the information provided in recall notices is expected to be achieved
	Monitoring of recall effectiveness	No measures foreseen.	No change to the current situation

	Remedies for consumers affected by recalls	No measures foreseen. Consumers affected by a recall would continue to have to rely on existing, limited remedies.	No change to the current situation
Enhance market surveillance and ensure better alignment of rules	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	Aligning the market surveillance framework for harmonised and non-harmonised consumer products will simplify the EU legal framework and can be expected to improve traceability through clarification of related requirements and the requirement of an EU representative. It can be expected that the objective to create largely uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products will be achieved. Whether the traceability of consumer products will improve in practice will also depend on enforcement of these requirements, and the extent to which measures will be taken to avoid that the obligation for an EU representative is not circumvented by rogue traders, including those that access EU consumers through online platforms.	Largely uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products expected to be achieved
	Deterrence effect	No measures that go beyond the enforcement powers in Chapter V of Regulation (EU) 2019/1020 on market surveillance and compliance of products (such as penalties and sanctions) would be incorporated under this option.	Largely unchanged situation in terms of deterrence of placing unsafe products on the market
	Diverging risk assessments by Member States' MSAs	No measures foreseen.	No change to the current situation
	Simplification of standardisation procedures	Simplification of standardisation procedures at the Commission level under the GPSD can be expected to increase the efficiency of the process, and possibly reduce the time for the overall standardisation process.	Simplification of standardisation procedures is expected to be achieved
Address safety issues related to food-imitating products	*Addressing risks of food-imitating products*	Food-imitating products will be included in the scope of the GPSD and the Food-imitating Products Directive repealed. The revised GPSD will clarify that an evaluation of the risks posed by the specific food-imitating product is required, as it is done for other consumer products.	Option will integrate the regime for food-imitating products into the GPSD

8.2.1.2. Stakeholder views on Option 2

In the stakeholder survey, we asked companies/business associations, MSAs and other stakeholders to what extent they consider Option 2 to effectively address five different challenges (see Figure 18 below), which mirror the five specific policy objectives. All stakeholder groups considered that Option 2 addressed all challenges at least moderately well. Overall, the average assessment across all respondents and stakeholder groups was 3.4. MSAs were most positive, assessing on average that Option 2 would considerably well address all of the stated challenges for product safety (average of 3.7 on a scale of 1 to 5, covering all five challenges). Businesses and business associations were less positive, with an average assessment of 3.3 and 3.1, respectively, across all five challenges.

Figure 18: In your view, to what extent would Option 2 effectively address the following challenges for product safety? Please assess.



8.2.2. Potential for administrative simplification

Option 2 is expected to reduce regulatory complexity and uncertainty, and thereby to reduce administrative burdens for businesses, as key clarifications regarding the coverage of new risks will be provided in the new legal instrument. As these will be legally binding, this reduction can be expected to be more significant than under Option 1. Also, general requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products, which is likely to contribute to reduced regulatory complexity and thereby to reduced administrative burdens for businesses. This effect is quantified below (see benefits for businesses and benefits for MSAs).

However, depending on the choice of instrument, implementation and interpretation differences between Member States may remain (if a Directive was chosen). In addition,

as gaps regarding the coverage of stand-alone software will remain, uncertainty in this respect will likely not be reduced. At the same time, Option 2 would cause limited additional requirements for specific operators, such as requirements for online platforms resulting from making mandatory most provisions of the Product Safety Pledge, and requirements regarding mandatory key elements that are to be included in recall notices.

Ensuring alignment with harmonised market surveillance rules has the potential to reduce administrative burdens on MSAs. Similarly, simplified standardisation procedures at the Commission level under the GPSD could lead to savings on the side of Member State MSAs. Finally, the integration of the Food-imitating Products Directive in the GPSD would reduce regulatory complexity.

8.2.3. Economic impacts

The following section outlines the economic impacts for businesses that are likely to result from the implementation of Option 2, focusing first on benefits and costs to be expected.

8.2.3.1. Benefits for businesses

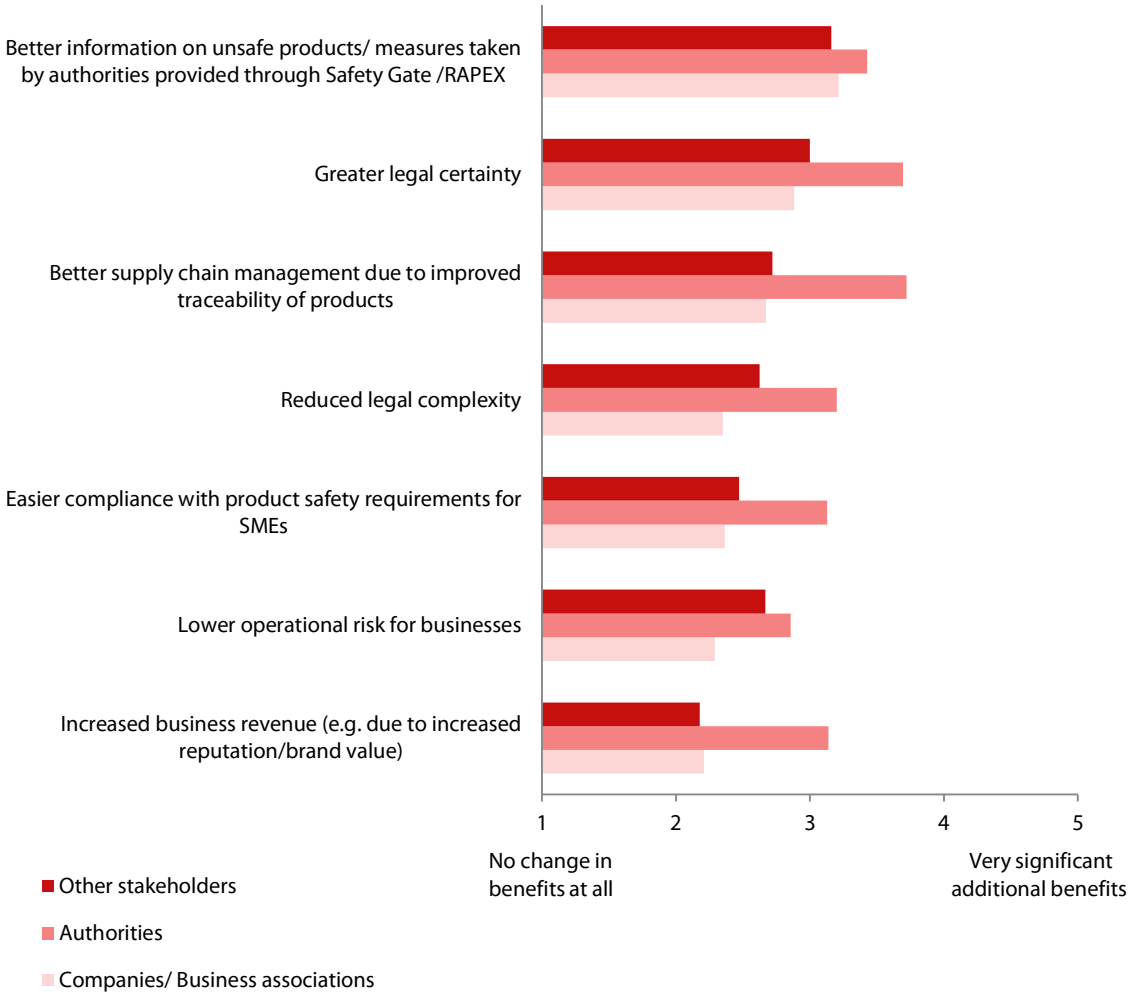
As outlined in the baseline, businesses currently incur additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). These are estimated to amount to 119 million EUR annually (see section 7.1.3 above, Table 28). If a revised GPSD under Option 2 would be recast as a Regulation, implementation differences would be avoided at the legislative level (due to the direct applicability of the new regulation in Member States). As explained in the context of Option 3, it can, however, be expected that some differences in the national interpretation of rules will remain. Accordingly, we do not expect a full reduction of businesses' additional costs that currently accrue due to implementation differences in Member States, but rather a 50% reduction of businesses' additional costs in this respect, similar to the situation under Option 3. Option 2 (if implemented as Regulation) would therefore be expected to result in benefits for businesses (cost savings compared to the baseline) of 59 million EUR annually, of which 34 million EUR would be saved by EU SMEs (see Table 56 in the discussion of Option 3, below). In case that a revised GPSD would remain a Directive, we would still consider it likely that implementation differences would be somewhat reduced (as certain aspects would be clarified), but less so than if it was implemented as Regulation.

To further explore expected benefits for businesses, we asked in our surveys all stakeholder groups to assess a set of potential benefits, identified on basis of previous research. The question specifically provided the following potential benefits of Option 2 for businesses (some of them are also relevant for MSAs):

- Greater legal certainty
- Reduced legal complexity
- Easier compliance with product safety requirements for SMEs
- Better information on unsafe products/measures taken by authorities provided through Safety Gate/RAPEX
- Increased business revenue (e.g. due to increased reputation/brand value)
- Lower operational risk for businesses
- Better supply chain management due to improved traceability of products

The results of the stakeholder survey are presented in Figure 19 below:

Figure 19: Where do you see the greatest additional benefits that would result from the implementation of Option 2? – Direct benefits for businesses



As Figure 19 illustrates, MSAs expect considerably more benefits from implementation of Option 2 than businesses/business associations and other stakeholders. Overall, MSAs provided an average assessment of 3.3, i.e. they expect more than 'moderate' benefits for businesses. MSAs expect especially 'significant' benefits from greater legal certainty and better supply chain management due to improved traceability of products (values of 3.7). By contrast, both businesses and business associations as well as other stakeholders expect considerably less benefits for businesses than MSAs on average (2.6 for companies/business associations and 2.7 for other stakeholders, i.e. below 'moderate' on average). Note, however, that all respondent groups assigned similar values to the benefits resulting from better information on unsafe products/measures taken by authorities provided through Safety Gate/RAPEX.

8.2.3.2. Costs of businesses

In this section, we consider the potential impact of Option 1 in term of recurrent costs (e.g. staff costs) and one-off costs (e.g. familiarisation costs, costs for external advice)[223].

[223] Due to the nature of policy options and the questions asked in the survey with respect to the related recurrent and one-off costs, the estimate elaborated in this section focuses on the overall impact of the implementation of Option 2 on businesses' recurrent costs and one-off costs.

Recurrent costs of businesses

Businesses expect that implementing Option 2 would increase companies' recurrent regulatory compliance costs[224] to some extent. Several companies reportedly found it difficult to assess the quantitative impacts of Option 2, and stated that the accuracy of the given estimates depended on the implementation details. Accordingly, the estimates provided below are not precise forecasts, but rather indicate the direction and relative magnitude of changes in recurrent costs under Option 2 compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates[225].

To estimate the impact of the implementation of Option 2 on EU businesses' recurrent costs, we applied the percentage change in recurrent (annual) costs as assessed by respondents to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (see section 7 for the baseline estimates). Due to a relatively low number of responses from distributors and inconsistencies of the stated changes in costs, we decided to base the estimation of recurrent costs for the EU as a whole on the sample statistics for the full sample of businesses' stated changes in recurrent costs (see Table 44)[226].

Table 44: Sample statistics of businesses' estimated change in recurrent costs in product safety-related costs under Option 2 (as percentage of recurrent costs to comply with safety requirements for consumer products)

Sample statistics	Full sample of business respondents, change of recurrent costs
Number of responses	22
Min	-10.00%
Max	30.00%
Average	4.32%
Q1	0.00%
Q2 (median)	**0.50%**
Q3	10.00%
Q1 to Q3 (middle 50% of values)	0.00% - 10.00%

Applying the sample median of 0.50% (see Table 44) as best estimate for the extent to which recurrent costs would increase under Option 2 to the estimated annual consumer product safety-related costs of EU businesses, results in additional annual cost of EUR

[224] 8 out of 25 manufacturers expect rising recurrent costs resulting from the implementation of Option 2, six manufacturers indicated that costs would remain the same and four manufacturers indicated that cost would be slightly reduced. With regard to distributors recurrent costs, five out of 11 distributors indicated that costs would rise. Three distributors expect that costs would remain the same for Option 2 compared to the baseline. As concerns the views of business associations regarding impacts on companies' recurrent costs, 11 out of 36 business associations stated that these costs would increase slightly after the implementation of the provisions of Option 2, three business associations expect cost reductions, whereas six business associations expect more significant cost increases.

[225] This also applies for the estimation of one-off costs.

[226] We therefore did not distinguish between distributors (retailers and wholesalers) and manufacturers. Similar to a previous study, for the overall estimation of businesses' costs we also assumed that the compliance costs as a percentage of turnover for product safety-related costs are the same for large enterprises and for SMEs. See CSES (2014), Evaluation of the Internal Market Legislation for Industrial Products, 13 January 2014.

18.6 million for EU manufacturers, EUR 4.7 million for EU wholesalers and EUR 6.4 million for EU retailers (see Table 45).

Table 45: Estimated changes in EU businesses' annual recurrent costs, EU total under Option 2, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	4.3	5.5	8.9	**18.6**
Total wholesale sectors	1.7	1.2	1.8	**4.7**
Total retail sectors	3.4	0.6	2.4	**6.4**
Total additional recurrent costs	***9.3***	***7.3***	***13.0***	***29.6***

One-off costs of businesses

Businesses generally need additional staff time for the implementation of new policy measures. Businesses are also confronted with additional non-staff costs, e.g. costs arising from external support for changes to IT systems, staff training etc. Our estimation of EU businesses' total one-off costs is based on individual respondents' estimates for the total additional staff needed and the total additional non-staff costs that arise from familiarisation and implementation efforts under Option 2. Based on the respondents' estimates, we calculated staff costs in Euro terms and added other costs. The calculation of Euro-denominated costs for staff is based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour[227]. To account for overhead costs, a 25% mark-up was added to staff-related costs.

The total one-off costs for each company were divided by the EU turnover for consumer products, i.e. we expressed companies' total additional one-off costs resulting from activities to comply with safety requirements for consumer products under Option 2 as a share of the related turnover. Again, we did not distinguish between distributors (retailers and wholesalers) and manufacturers due to data limitations, and based the estimation of one-off costs for the EU aggregate on the sample statistics for the full sample of businesses' cost estimates (a total of 20 respondents). Sample statistics are provided in Table 46.

Table 46: Sample statistics of businesses' estimated one-off costs under Option 2 as percentage share of annual EU turnover from consumer products (total of additional staff and additional non-staff costs)

Sample statistics	Full sample of business respondents, one-off costs
Number of responses	20
Min	0.00%
Max	1.38%
Average	0.15%
Q1	0.00%
Q2 (median)	**0.0003%**

[227] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

Q3	0.05%
Q1 to Q3 (middle 50% of values)	0.00% - 0.05%

Applying the sample median of 0.0003% to the estimated annual turnover for manufacture, wholesale and retail of consumer products in the EU results in additional one-off cost of EUR 2.1 million for EU manufacturers, EUR 2.2 million for EU wholesalers and EUR 3.0 million for EU retailers (see Table 47).

Table 47: Estimated changes in EU businesses' one-off costs, EU total under Option 2, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	0.5	0.6	1.0	**2.1**
Total wholesale sectors	0.8	0.6	0.8	**2.2**
Total retail sectors	1.6	0.3	1.1	**3.0**
Total additional one-off costs	***2.9***	***1.5***	***2.9***	***7.3***

As concerns the impacts on one-off costs that result from the specific measures taken into consideration under Option 2, companies did not comment further on the precise nature and magnitude of these costs, nor did they indicate the time horizon for these costs to occur and when they would phase out. Only few respondents provided more detailed information on their expected one-off costs, with an example being a manufacturer, who also imports to the EU, highlighting that "internal procedures would need to be updated to reflect the provisions of the revised legislation and the resulting guidelines would need to be communicated in the organisation".

Total costs of business under Option 2

Even though business respondents did not provide detailed information about the exact time dimension for one-off costs to arise, we assume that one-off costs unfold within one year after the implementation of the regulatory changes. Absolute changes in one-off and recurrent costs within the first year after the implementation of Option 2 as well as absolute changes in annual recurrent costs after the first year of the implementation of Option 2 are outlined in Table 48. Total costs of businesses in the EU27 in the first year of implementation are estimated at EUR 36.9 million, equivalent to 0.004% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in subsequent years to EUR 29.6 million.

Table 48: Changes in EU companies' costs within and after the first year of implementation of Option 2, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	4.8	6.1	9.9	**20.7**
Total wholesale sectors	2.5	1.7	2.6	**6.9**
Total retail sectors	5.0	0.9	3.5	**9.4**
Total additional costs	***12.2***	***8.8***	***15.9***	***36.9***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	4.3	5.5	8.9	**18.6**
Total wholesale sectors	1.7	1.2	1.8	**4.7**
Total retail sectors	3.4	0.6	2.4	**6.4**
Total additional costs	***9.3***	***7.3***	***13.0***	***29.6***

Note: Estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in recurrent and one-off costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

8.2.3.3. Firm level impacts for specific types of operators

In the following, we consider the economic impacts for several types of operators which are of specific interest (such as SMEs) or may be specifically affected by the proposed measures under Option 2 (online marketplaces, online traders in general, and producers and distributors of food-imitating products).

Impacts on SMEs

The implementation of Option 2 is expected to address some of the current gaps in the product safety regime for non-harmonised products and thereby support the continued free movement of goods in the Single Market[228]. This would likely contribute to positive spillover effects on consumer trust, demand, production and employment, compared to the baseline scenario. As concerns the benefits for SMEs, small companies generally estimate that a revision of the product safety requirements of the GPSD according to Option 2 would bring a variety of at least 'minor' to 'moderate' benefits. Small companies on average estimate that Option 2 would result in significant benefits due to improved quality/lifecycle of products and a deterrent effect on rogue traders. Other areas where SMEs expect relatively strong benefits are increased consumer trust, better supply chain management due to improved traceability of products and better access to the market in non-EU/EEA. These areas are seen as benefits that SMEs assess to be 'moderate' to 'significant'. This is also the case for lower operational risks for businesses and easier compliance with product safety requirements. By contrast, SMEs considered several benefits to be less than 'moderate', including a more level playing field among businesses and greater legal certainty.

Option 2 would impose additional adjustment (e.g. familiarisation cost) as well as compliance costs on SMEs. This is particularly the case for SMEs that (voluntarily) decide to install and operate customer registration systems. Similarly, mandatory elements for product recalls (product description with a photograph, description of risk, instructions on what to do, link to a recall website and free phone number or online service for

[228] For a similar assessment, see SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final.

queries) would increase the cost of SMEs that have put unsafe consumer products on the market.

Option 2 would not entail stricter regulation for a particular type of SMEs, but may entail a higher relative cost burden for manufacturers than distributors. The total additional cost burden for SMEs in manufacturing and distribution sectors is reported in Table 48 (above), which shows estimates that are based on the full sample of companies' assessments of changes in costs. As indicated in the table, total costs for SMEs manufacturing, wholesale and retail of non-harmonised consumer products in the EU27 in the first year of implementation of Option 2 are estimated at EUR 21.0 million[229]. They would fall in subsequent years to EUR 16.6 million. Compared to the full sample results for the impact of Option 2 on businesses one-off and recurrent costs, SMEs would likely face higher compliance costs than large companies from the implementation of the proposed policy measures[230].

Even though the relative costs increases are generally higher for SMEs, the net impact on SMEs overall costs depends on the benefits that can result from a revised GPSD aligned to the market surveillance rules in Regulation (EU) 2019/1020. We expect that SMEs could save some of the costs that currently arise from inconsistencies in the implementation and enforcement of the GPSD across the EU. Taking into consideration these benefits and the fact that the changes in SMEs' costs from Option 2 are very small, we expect that the overall net effect from Option 2 on SMEs' costs is rather low and therefore unlikely to affect SMEs' operations.

Impact on online marketplaces

Option 2 would include to make legally binding most provisions of the voluntary Product Safety Pledge for online marketplaces. In the stakeholder survey of business operators, five companies responded that operate as either retailers or manufacturers and at the same time operate online platforms. As concerns the benefits of policy measures considered under Option 2, platform respondents offered a mixed picture on the potential manifestation of benefits. They generally agreed that the measures would improve consumer trust, provide better information on unsafe products and ensure more effective measures taken by MSAs through Safety Gate/RAPEX, and provide greater legal certainty and less complexity. Online platforms respondents also tended to agree that the measures in Option 2 would have a deterrent effect on rogue traders and reduce the occurrence of products presenting health and safety risks in the Single Market. One platform respondent, for example, stated that '[t]he major benefit is in reducing dangerous product offered online'. Another platform stated that 'Option 2 will provide similar benefits as those presented in Option 1; however, with the targeted legal revision, it is possible that both legal complexity and operational risks for business could increase.'

Four of the five respondents that (also) operate an online marketplace provided information about their consumer product safety-related compliance cost and information regarding the potential impacts from the implementation of Option 2. As concerns the cost impacts of Option 2, three platform respondents expect increases in recurrent costs, while one platform (with a comparatively high share of non-harmonised consumer products in total turnover) stated that recurrent costs would remain the same (see Table 49). Similar replies were made for changes in online platforms one-off costs following the implementation of Option 2.

[229] Sum of the firm size categories 0 to 49 employees and 50 to 249 employees, see table above.

[230] Higher relative cost impacts for SMEs compared to large companies are also reported in European Commission (2020), Study on due diligence requirements through the supply chain, Final Report, 20 Febraury 2020.

Table 49: Changes in costs to comply with safety requirements for consumer products – assessment by companies that also operate online marketplaces

	Change in costs to comply with safety requirements	
	Recurrent costs	One-off costs
Respondent 1	Increase costs significantly	Significant additional costs
Respondent 2	Costs would remain the same	No additional costs at all
Respondent 3	Increase costs slightly	Moderate additional costs
Respondent 4	Increase costs slightly	Minor additional costs

Two platform companies provided quantitative estimates for the expected impact on recurrent costs, stating that their companies' overall consumer product safety-related costs would increase by 10%.

As regards the obligations from the Product Safety Pledge, the additional costs from Option 2 for online platforms by making most of them binding would be minor for those platforms that already signed the Products Safety Pledge. By contrast, non-signatory platforms would likely face additional compliance costs. In particular, some stakeholders were concerned that these compliance costs might specifically affect small platforms and create a deterrent effect on new market entrants, with negative effects on competition between platforms. This impact appears likely but would also depend on the size of the additional costs and the actual deterrent effect respectively. As most obligations under the Product Safety Pledge relate to 'notice and takedown' (i.e. imply a reactive approach), additional costs are likely to be limited.

Impact on other online sellers

For online sellers, no additional impacts are expected that would go beyond those found for other businesses, including those that only sell via brick-and-mortar stores.

Impact on producers of food-imitating products

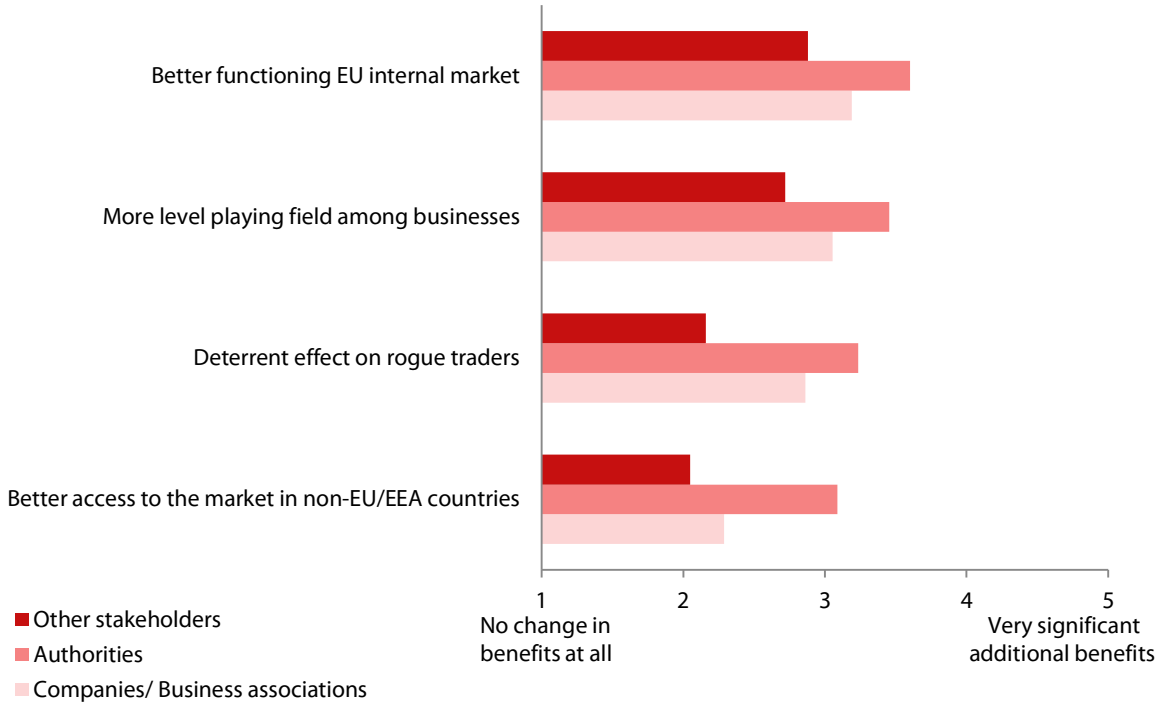
As for Option 1, we expect that a targeted revision to better detail the specific requirements of the Food-imitating Products Directive and criteria for the evaluation of the risks posed by specific food-imitating products could help manufacturers and distributors to better assess the potential risks of the products offered by them. As both manufacturers and sellers already have to comply with the current Directive, we do not expect additional costs from a revision that merely aims at providing greater clarity and legal certainty respectively. A greater level-playing field regarding the implementation and enforcement of the Food-imitating Products Directive in the EU, as envisaged under Option 2, could lead to minor cost savings on the side of manufacturers and distributors of food-imitating products.

8.2.3.4. Macroeconomic impacts

The results of the consultation conducted for this study show that MSAs expect at least 'moderate' benefits with regard to a better functioning of the EU internal market, a more level playing field among businesses, a deterrent effect on rogue traders and better access for EU businesses to the market in non-EU/EEA countries (see Figure 20 below). For companies/business associations, this is only the case for the functioning of the EU internal market and a more level playing field for businesses in the EU. While other stakeholders also see most benefits regarding these two aspects, they are overall more sceptical, and consider that Option 2 does only bring minor benefits regarding the deterrence of rogue traders and better market access for EU businesses in non-EU/EEA countries. Overall, MSAs are on average most positive about the benefits that would result from the implementation of Option 2 with an average of 3.8 (i.e. seeing close to

'significant' benefits). By contrast, the averages for both companies/business associations and other stakeholders are slightly lower (3.2 and 3.4 respectively, i.e. between 'moderate' and 'significant' benefits).

Figure 20: Where do you see the greatest additional benefits that would result from the implementation of Option 2? – Benefits for internal market and trade



These and other potential impacts from the implementation of Option 2 are also relevant for trade and competition, which are discussed in the following sub-sections.

Impact on internal market and trade

As indicated before, the evaluation of the GPSD found that legal uncertainty concerning key GPSD concepts currently has negative effects in that it may prevent MSAs from taking action for perceived lack of competence or perceived lack of the fulfilment of relevant requirements for taking action, in particular the lack of safety of a product; which may lead to a lack of enforcement of the GPSD, and to an uneven application of the GPSD by MSAs of different Member States. This does not only impact on the level of consumer protection but also on the free movement of goods within the internal market. Measures to clarify the coverage of new risks in a revised legal instrument, as foreseen under Option 2, can address a part of these uncertainties, whereby uncertainties would remain with respect to the actual effectiveness of such measures, but also with respect to the coverage of software.

As indicated in Part 1 of this study, the GPSD has been effective in achieving the free movement of products and level playing field in the internal market with respect to non-harmonised products. This could, however, be affected by the uncertainty about the applicability of product safety law to software, which has produced an uneven level of protection between Member States (see Part 1, EQ4). Option 2 would not address the safety of software, so that a gap would remain for products not covered by relevant harmonisation legislation. It is possible that Member States could resort to national

measures in this respect, which would create an obstacle to the free movement of goods or services and lead to an uneven level playing field for businesses in the future [231].

Still, benefits can be expected from clarification of safety risks from new technologies, recall procedures and more coordinated actions by MSAs. Reduced legal complexity and uncertainty could reduce companies' administrative burdens to some extent, which could have a moderate positive impact on functioning of the EU's internal market and international trade.

Impact on competition and innovation

The impact of Option 2 on competition and innovation is generally difficult to assess ex-ante. Similar to Option 1, the impacts from Option 2 on EU companies' competitiveness are expected to be relatively small as companies' current compliance costs from consumer product safety legislation are already relatively low, accounting for relatively small shares of total revenues (for both distributors and manufacturers, although somewhat higher for manufacturers). Moreover, most companies do not expect decreasing costs from the implementation of Option 2.

As outlined above, Option 2 would lead to a more aligned legislative framework for harmonised and non-harmonised consumer products, which could generally reduce companies' compliance costs in this respect, without new regulatory requirements that could counteract this effect. At the same time, most businesses surveyed do only expect small changes in one-off or recurrent costs from the implementation of Option 2. Accordingly, we do not expect significant impacts on competition for EU businesses, neither for competition within the Single Market nor with regard to non-EU competitors.

As concerns innovation, due to the limited impact on companies' compliance costs we do not expect significant impacts on EU companies' overall innovative capacities, i.e. higher budgets resulting from savings in compliance costs that translate to expanded research and business development activities. On the other hand, new regulatory requirements for online platforms might result in less competitive dynamism and innovation in online platform business models over time, depending on the extent to which new requirements lead to additional costs, which appear, however, to be limited under Option 2.

Additional macroeconomic effects

We do not expect significant additional macroeconomic effects. Generally, increased consumer trust would have a positive impact on consumption and economic activity respectively. At the same time, higher costs for businesses generally drive a wedge between supply and demand, which could have a depressing effect on the consumption of consumer products, with adverse feedback effects on production and imports respectively. However, since the additional costs from the implementation of Option 2 (one-off and recurrent costs) are very low for manufacturers, wholesalers, and retailers, the negative impacts on consumption in the EU is expected to be negligible.

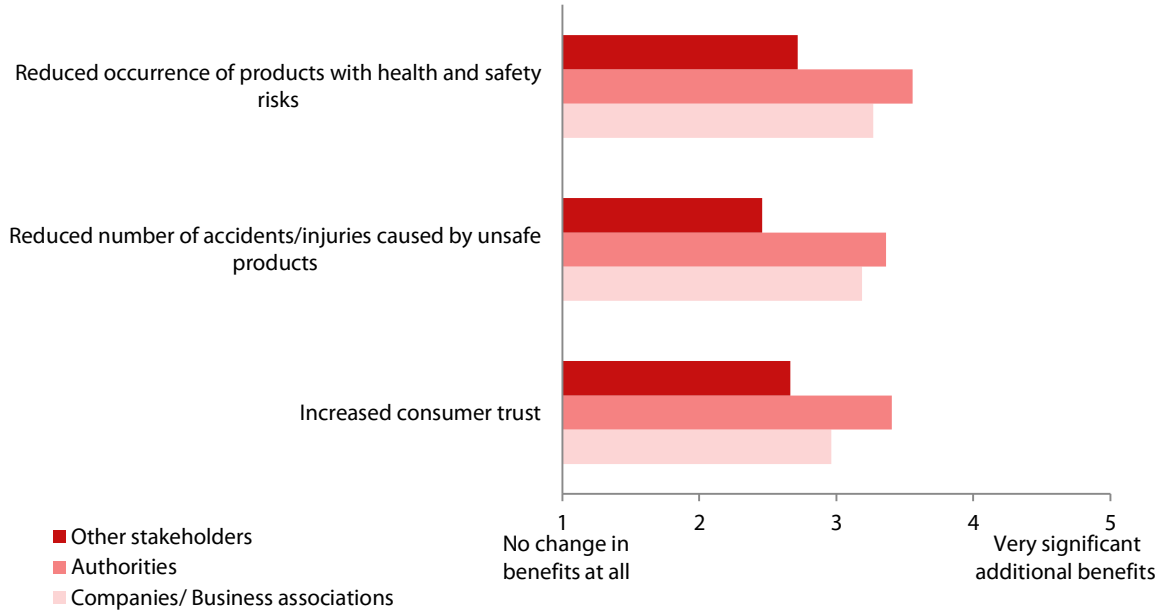
8.2.4. Impact on consumers and households

Companies/business associations and MSAs consider that Option 2 would generally create 'moderate' benefits for consumers. Benefits include a reduced occurrence of unsafe products and a reduced number on injuries caused by them, as well as a resulting increase in consumer trust (average values of 3.1 for companies/business associations and 3.4 for MSAs, see Figure 21). Other stakeholders are less positive and only assess benefits that are below 'moderate' (average of 2.6). The benefits are assessed to be

[231] The evaluation of the GPSD presented in Part 1 found no indication that this is currently already case.

especially low when it comes to a reduced number of accidents/injuries caused by unsafe products (value of 2.5, i.e. between 'minor' and 'moderate').

Figure 21: Where do you see the greatest additional benefits that would result from the implementation of Option 2? – Benefits for consumers



In the following sections, we discuss several aspects of the impact on consumers in more detail. This includes the impact on consumer prices, consumer choice, and the overall impact on consumer safety and impacts on vulnerable consumers.

8.2.4.1. Impact on consumer prices

As the implementation of Option 2 would only result in minor increases of consumer product safety-related costs for EU companies, the impacts from Option 2 on prices of consumer products in the EU are expected to be negligible.

8.2.4.2. Impact on consumer choice

None of the measures considered under Option 2 would be expected to have a significant impact on consumer choice in the EU.

8.2.4.3. Overall impact on consumer safety and impacts on vulnerable consumers

Measures taken under Option 2 are likely to be more effective than Option 1 to address the challenges for product safety posed by online sales channels. Relevant measures include the alignment with the provisions of Regulation (EU) 2019/1020 and clarifications provided in the new legal instrument, which could improve enforcement of the GPSD, with related benefits for consumers. Also, the detriment that consumers incur from purchasing unsafe products sold on online platforms from traders in non-EU/EEA countries could be expected to decrease to some extent, as the obligations of the Product Safety Pledge would become legally binding for all platforms. The scenario estimate for Option 2 (see Annex IV) therefore assumes that measures under this option contribute to aligning the level of product safety (in terms of the incidence of unsafe products) between the online sales channels and brick-and-mortar stores somewhat, and thereby to reduce the incidence of unsafe products on the market to a limited

extent. Table 50 below provides the scenario estimates for the baseline and for Option 2, as well as the expected reduction of consumer detriment under this option.

Table 50: Expected consumer detriment due to unsafe non-harmonised products under scenario estimates for baseline and Option 2 (EU27, in EUR million per year)

Scenario	2025	2026	2029	2034
Option 0. 'Status quo': Baseline scenario not involving any new actions	20 873	21 237	20 078	21 941
Option 2. Targeted revision of the GPSD (Directive or Regulation)	20 540	20 533	19 257	20 910
Expected reduction in consumer detriment under scenario for Option 3 compared to baseline (equivalent to consumer benefit)	**333**	**704**	**821**	**1 031**

Source: Civic Consulting. Notes: Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. The expected annual consumer benefit in the scenario estimate for Option 2 (i.e. the expected reduction in detriment compared to the baseline) increases over the years due to the expected growth in online retail and a reduction of the incidence of unsafe products in online sales channels to a limited extent due to enshrining provisions of the Product Safety Pledge in law. For details on the methodology for the analysis and the scenario assumptions regarding size of total retail, the share of online in total retail, and the respective incidence rates of unsafe products, see Annex IV.

Consumer detriment is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce. Table 50 shows that benefits of Option 2 in terms of reduced consumer detriment in the EU related to non-harmonised products are expected to amount to EUR 333 million in the first year of implementation, increasing to approximately EUR 1.0 billion per year over the next decade. These estimates are based on scenario assumptions, and should therefore be interpreted as an indication of the approximate size of benefits, rather than precise predictions. The extent to which these benefits materialise, will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of measures taken at EU level, including in the framework of the new Digital Services Act.

An additional benefit under Option 2 is the potentially reduced consumer detriment due to slightly more effective recalls, due to facilitating the use of available customer data, improvement in the information provided in recall notices etc. In our quantitative analysis of benefits of measures in the field of recalls (Annex V), we compare consumer detriment in baseline scenario with low recall effectiveness (current situation) to a scenario where recall effectiveness is slightly improved. Table 35 in section 7.3.2 above provided the estimate for the baseline scenario. Total consumer detriment under the baseline scenario with low recall effectiveness is about EUR 1.3 billion per year. Under the assumption that return rates of recalled products are somewhat increased due to legislative measures foreseen under Option 2, this detriment is expected to be reduced to approximately EUR 1.1 billion per year (see Table 51).

Table 51: Consumer detriment due to recalls (improved effectiveness scenario), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products collected from consumers (EUR million)	Value of recalled products that remain with consumers (equivalent to consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1096	38%	411	685
Childcare articles and children's equipment	5.3	30	159	38%	60	100
Lighting chains	3.4	15	51	8%	4	48
Hobby/sports equipment	3.4	80	272	38%	102	170
Jewellery	1.2	10	12	8%	0.9	11
Decorative articles	1.1	5	5	0%	0	5
Laser pointers	0.8	5	4	0%	0	4
Furniture	0.7	150	98	38%	37	61
Lighters	0.4	0.3	0.1	0%	0	0.1
Gadgets	0.03	20	0.5	8%	0	0.5
Total	*34.6*		*1 699*		*615*	*1 085*
Consumer benefit *(= reduction of detriment compared to baseline)*						***205***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124. b) See Table 125. Number of recalls and number of recalled items estimated on basis of data from Safety Gate/RAPEX and data on national recalls provided in the GPSD implementation study. For more details on the methodology, see Annex V.

It can be concluded that under a scenario of somewhat improved recall effectiveness (as expected under Option 2), consumer detriment in the EU is reduced by approximately EUR 205 million per year compared to the baseline. This estimate is based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to somewhat improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price[232]. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product causes damage to persons, other goods or the environment.

It can be concluded that Option 2 would be expected to increase the level of protection of EU consumers to some extent. This impact could be also relevant for vulnerable consumer groups such as children, the elderly or disabled persons, although no specific measures are taken in this respect other than a possible clarification of risk assessments criteria for food-imitating products.

[232] A key element of the justification for this assumption is that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased by a consumer, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. For a detailed justification, see Annexes IV and V.

8.2.5. Impacts on Member States

8.2.5.1. Benefits for MSAs

MSAs that responded to the survey only provided few comments on the potential benefits expected from the implementation of Option 2. They stated that Option 2 is expected to be more suitable than Option 1 to improve the current legal framework managing the risk of unsafe products being placed in the EU market. However, respondents from market surveillance authorities also pointed out that the exact benefits would depend on the actual implementation of Option 2.

Generally, a better alignment of rules – resulting from aligning the GPSD with market surveillance rules in Regulation (EU) 2019/1020 and from aligning the traceability requirements for non-harmonised products to those for harmonised products – would result in a more uniform framework for harmonised and non-harmonised consumer products. As indicated in Figure 11 above, 16% of MSAs reported to currently incur additional costs due to the fact that the EU legal framework for product safety contains different provisions for market surveillance depending on whether the product is harmonised or non-harmonised. In contrast, 34% reported to have no additional costs due to this situation, and 50% did not know or did not answer. Therefore, the efficiency gains by MSAs due to aligning market surveillance provisions between harmonised and non-harmonised products under Option 3 are not expected to accrue to all authorities.

As outlined in the baseline (section 7.1.3 above), taking these results into account, current additional costs for MSAs due to legislative fragmentation are estimated to amount to 0.7 million EUR annually (total for the EU27). The proposed measures under Option 2 would align provisions for the market surveillance of harmonised and non-harmonised consumer products so that this cost burden will be reduced accordingly. Option 2 would therefore result in estimated annual benefits (cost savings) for MSAs of 0.7 million EUR. Additional benefits include a simplification of standardisation procedures and a clarification of rules regarding product recalls which could, over time, contribute to an additional, limited reduction of administrative burdens for MSAs.

8.2.5.2. Costs for MSAs

As concerns the policy measures considered under Option 2, Member State MSAs could be impacted by a broadening of market surveillance responsibilities. New responsibilities for market surveillance might evolve from modified definitions with regard to risks posed by new technologies. New responsibilities are generally reflected by greater need for internal and external resources respectively. At the same time, savings for MSAs could result from more aligned market surveillance rules for harmonised and non-harmonised products across the EU (although only a minority of MSAs report related costs, see Option 1) and also from simplified standardisation procedures. In the following sub-sections, we analyse potential changes in MSAs' recurrent and one-off costs under Option 2.

Recurrent costs

Asked about the extent to which MSAs consider that the implementation of Option 2 would change their recurrent costs, nine MSAs reported that their recurrent costs would increase, and eight MSAs reported that costs would remain the same. Five MSAs reported that costs would likely decrease, the rest of respondents did not know or did not provide an answer. Most MSAs did not comment on the nature of changes in recurrent costs. One MSA stated that "[t]he costs in case of implementation of Option 2 would slightly be increased due to strengthening of a coordination role of our MSA in surveillance on the product market."

In total, 17 of the MSAs provided estimates regarding the percentage changes in recurrent costs if Option 2 was implemented, compared to MSAs' current cost related to the market surveillance of consumer products (see Table 52 for sample statistics).

More than half of the MSAs that provided cost estimates do not expect any increases in recurrent cost, which is reflected by a median cost estimate of 0.00%. At the same time, a significant minority of MSAs expect cost increases (roughly one quarter of the respondents that provided quantitative assessments), which is reflected by the third quartile value (Q3) value of a 10% increase in recurrent costs. Assuming that for one quarter of MSAs in the EU Option 2 would bring an increase in recurrent costs of 10% of total annual staff-related costs (which, according, to the baseline estimate, account for more than 99% of consumer product-related market surveillance costs of MSAs), this would imply total additional costs of MSAs in the EU27 of approx. EUR 6.7 million annually. For the remaining MSAs we would assume that costs remain the same, in line with the distribution of the quantitative estimates. It should be noted that the actual percentage changes would differ for individual MSAs due to different national institutional market surveillance systems and organisational characteristics, e.g. the degree of centralisation, MSAs' product coverage and the actual assignment of new competences and enforcement requirements.

Table 52: MSAs' estimated changes in recurrent costs, Option 2

	Increase in recurrent costs
Number of responses	17
Min	-60.0%
Max	20.0%
Average	2.0%
Q1	0.0%
Q2 (median)	0.0%
Q3	10.0%
Q1 to Q3 (middle 50% of values)	0.00% - 10.00%

One-off costs

A majority of MSAs expect that the implementation of Option 2 would lead to changes in one-off costs. While eight MSAs report 'no additional costs', 14 MSAs expect additional costs (however, none of the MSAs expected these costs to be 'significant'). Most MSAs did not comment further on the nature of the expected changes in one-off costs.

It should be noted that data on changes in one-off costs are rare. Due to the low number of responses from MSAs that provided estimates, the data cannot be extrapolated to the EU level. However, the few cost estimates that were provided by MSA respondents indicate that the one-off adaption and implementation costs are considered to be moderate.

8.2.5.3. Other effects on Member States

The proposed measures would align the enforcement powers of MSAs regarding non-harmonised products with their powers for certain categories of harmonised products under Regulation (EU) 2019/1020. Thereby, specific gaps such as legal difficulties to conduct mystery shopping for authorities in some Member States would be addressed. However, the deterrence effect on rogue traders would not be increased, as enforcement powers would not be further strengthened through penalties and sanctions. The efficiency of market surveillance processes with cross-border implications in the EU would be not increased. No arbitration mechanism would be created for cases of divergences in the product safety risk assessment between authorities, and there would be a continued reliance on informal approaches in case risk assessments of MSAs diverge.

8.2.6. Social impacts, impacts on fundamental rights and environmental impacts

Potential social or environmental impacts, as well as impacts on fundamental rights of Option 2 are discussed in the following sub-sections.

8.2.6.1. Social impacts

The implementation of Option 2 is expected to potentially have some positive social impacts with regards to public health and safety and health systems. The clarification of covered risks, mandatory obligations for online platforms (in line with the Product Safety Pledge) and the alignment with the provisions of Regulation (EU) 2019/1020 regarding traceability and enforcement powers of authorities may to some extent improve market surveillance and enforcement. To the extent that the number of unsafe products on the market is somewhat reduced by these measures in the mid- to long term, this potentially could lead to a reduction in consumer detriment due to product-related injuries and related health care costs for society. However, this impact is far from being sure, as discussed in more detail under Option 3. Also, due to the limited amount of measures taken under Option 2 that could reduce related consumer detriment in the EU, any impact on health systems would be expected to be considerably more uncertain and smaller in size than under Option 3.

8.2.6.2. Impacts on fundamental rights

As elaborated above, Option 2 is expected to improve consumer safety to some extent. Also, measures under Option 2 would be expected to reduce product-related environmental risks (see below). The implementation of a revised GPSD according to Option 2 shall hence have a positive impact and ensure a somewhat higher level of consumer protection and a higher level of environmental protection in line with the Charter of Fundamental Rights of the European Union[233].

At the same time Option 2 imposes additional requirements for businesses. The additional requirements imposed to economic operators do not affect the fundamental freedom to conduct a business[234] as they are necessary to pursue the general European Union interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be very low compared to the businesses' turnover.

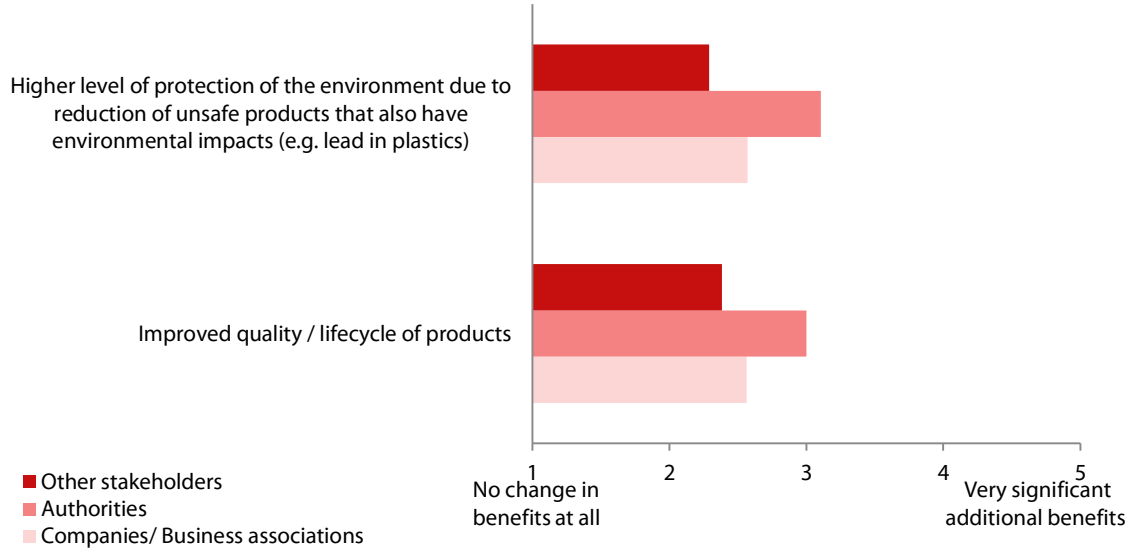
8.2.6.3. Environmental impacts

Figure 22 below presents stakeholder views on benefits related to environment of Option 2. While authorities see 'moderate' benefits regarding improved lifecycle/quality of products and a higher level of the protection of the environment due to the reduction of unsafe products that also have environmental impacts, companies/business associations and other stakeholders only see between 'minor' and 'moderate' benefits.

[233] Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 37 on environmental protection and article 38 on consumer protection.

[234] Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 16.

Figure 22: Where do you see the greatest additional benefits that would result from the implementation of Option 2? – Benefits for environment



The implementation of Option 2 likely has positive environmental impacts, to the extent that it clarifies the application of the general safety requirement to products containing environmentally harmful substances that also pose a risk to human health and safety. Hazardous chemicals that are often being found in consumer products such as clothes/textiles, furniture, electrical appliances, furnishings and surfaces, childcare articles, sports and playground equipment, have the potential to adversely affect human health but are also harmful for the environment[235]. Numerous studies have shown that chemical emissions from consumer products affect the quality of indoor environment[236] and are to a large extent responsible for the exposure to air toxics given that consumers spend up to 90% of their time indoors[237]. Chemicals in consumer goods are also an environmental concern when products are discarded as they may pollute waste and end up in the environment or even worse, continue their life cycle through recycling.

As the effects of the presence of hazardous chemicals in consumer goods to the health and safety of consumers cannot be easily disentangled from their impact to the environment, a revision of GPSD that would contribute to the effective mitigation of chemical risks of consumer products to the health and safety of consumers can be assumed to have proportionately the same extent of positive impact for the environment. As an indication, under the current provisions of the GPSD, for the period 2013-2019 approximately 25% of the products notified in Safety Gate/RAPEX,

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235 EU Commission (2017), Study for the for the strategy for a non-toxic environment of the 7th Environment Action Programme final report, p. 11-16; ANEC and BEUC (2020), Views for a modern regulatory framework on Product Safety: Achieving a higher level of consumer safety through a revision of the General Product Safety Directive, p. 1-19, at: https://www.anec.eu/publications/position-papers/856-beuc-and-anec-views-for-a-modern-regulatory-framework-on-product-safety-achieving-a-higher-level-of-consumer-safety-through-a-revision-of-the-general-product-safety-directive.

236 McDonald B.C. et al. (2018), "Volatile chemical products emerging as largest petrochemical source of urban organic emissions", *Science* 359, p. 760-764; Nematollahi, N., Kolev, S. D. & Steinemann, A. (2019). "Volatile chemical emissions from 134 common consumer products", *Air Quality, Atmosphere & Health* 12(11), pp. 1259-1265; Abbatt J. P.D. & Wang C. (2020), "The atmospheric chemistry of indoor environments", *Environmental Science: Processes and Impacts* 22, pp. 25-48.

237 Joint European Environmental Agency and Joint Research Centre Report (2013), 'Environment and Human Health', p. 40; European Environmental Agency (2020), 'Safeguarding people from environmental risks to health' in *State of the Environment Report 2020*.

presented a chemical substance risk with adverse health effects to consumers[238]. The relevant chemicals were often also harmful to the environment (e.g. lead and mercury).

However, as the measures under Option 2 in the area of product recalls are only expected to lead to a somewhat improved recall effectiveness, and deterrent effect and enforcement possibilities of the GPSD under Option 2 are not significantly improved, the expected positive effect on the environment is lower than under Option 3. Unsafe consumer products that include chemical substances with adverse environmental effects and are recalled for this reason will only to a limited extent be more effectively recalled than currently.

8.2.7. Summary assessment

The summary assessment of the option is presented in Table 53 below.

[238] See above section 4.3 regarding extend of adaptation of GPSD to environmental issues with health impact.

Table 53: Summary assessment of Option 2 compared to baseline situation

Area	Assessment
Effectiveness in achieving the policy objectives	
Ensure general safety rules, including for product risks linked to new technologies	+
Address safety challenges in the online sales channels	neutral / +
Make product recalls more effective	neutral / +
Enhance market surveillance and ensure better alignment of rules	++
Address safety issues related to food-imitating products	+
Administrative simplification	
Reduction of regulatory complexity and uncertainty	neutral / +
Economic impact	
Benefits for businesses	neutral / + Benefits of max. EUR 59 million/year (less if Directive)
Cost of businesses (EU27)	increase by < EUR 37 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral / +
Impact on consumers and households	
Consumer prices	neutral
Consumer choice	neutral
Consumer safety and vulnerable consumers	+ Benefits of EUR 330 million within the first year of implementation, increasing over the years with the expected growth in online retail and a reduction of the incidence of unsafe products in online sales channels to a limited extent. Additional benefits of EUR 205 million/year due to somewhat improved recall effectiveness
Impact on Member States	
Benefits for MSAs	++ Benefits of > EUR 0.7 million/year
Costs for MSAs (EU27)	Costs increase by < EUR 7 million/year
Other effects on Member States	neutral / +
Social impacts, impacts on fundamental rights and environmental impacts	
Social impacts	neutral / +
Impacts on fundamental rights	neutral / +
Environmental impacts	neutral / +

Note: Magnitude of impact as compared with the baseline scenario: neutral = no significant difference to baseline situation; + = positive impact compared to baseline; ++ = significant positive impact compared to baseline. An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

8.3. Option 3. Full revision of the GPSD and recasting as Regulation

As described in section 6 above in more detail, Option 3 would repeal the GPSD and ensure even application of its implementation through the choice of a Regulation. This option would build on all elements of Option 2 and, in addition, it would provide a number of policy actions that are briefly described in Table 54:

Table 54: Main policy actions related to Option 3: Full revision of the GPSD and recasting as Regulation

Specific policy objectives	Description of policy actions
Ensure general safety rules, including for product risks linked to new technologies	The new Regulation would explicitly cover new risks (as in Option 2), and extend the definition of product to standalone software
Address safety challenges in the online sales channels	As in Option 2. Additional obligations for online marketplaces beyond the provisions of the Product Safety Pledge, as well as to businesses selling online to consumers to provide all safety information online that are also required 'offline' and marketplaces required to make sure that third party sellers provide this information
Make product recalls more effective	As in Option 2. Additional requirements include possibility to set out further requirements for product registration; use of a template for recall notices; consumers' right to an effective, cost-free and timely remedy; and requirements for businesses to register voluntary recalls in an EU database
Enhance market surveillance and ensure better alignment of rules	Aligned market surveillance framework for harmonised and non-harmonised consumer products while keeping different legal instruments. Simplifying standardisation procedures (as Option 2). Enforcement rules are further strengthened on penalties and sanctions. Arbitration mechanism (Member States and/or Commission) in case Member States have diverging product safety risk assessments
Address safety issues related to food-imitating products	Incorporating provisions on food-imitating products into the new Regulation, and consider banning their marketing and sale in the EU market

In the following analysis related to Option 3, we first assess the extent to which the suggested policy actions under Option 3 are likely to achieve the specific policy objectives listed above. We then present stakeholder views in this respect. Subsequently, we elaborate on the economic impacts, including on companies, consumers and households, as well as impacts on Member States. Finally, we analyse the expected social impacts, impacts on fundamental rights and environmental impacts of this option.

8.3.1. Effectiveness in achieving the policy objectives

8.3.1.1. Assessment by specific policy objective

The extent to which the option is expected to address the specific policy objectives is assessed in Table 55 below, which is followed by a description of related stakeholder views.

Table 55: Assessment of Option 3: Full revision of the GPSD and recasting as Regulation

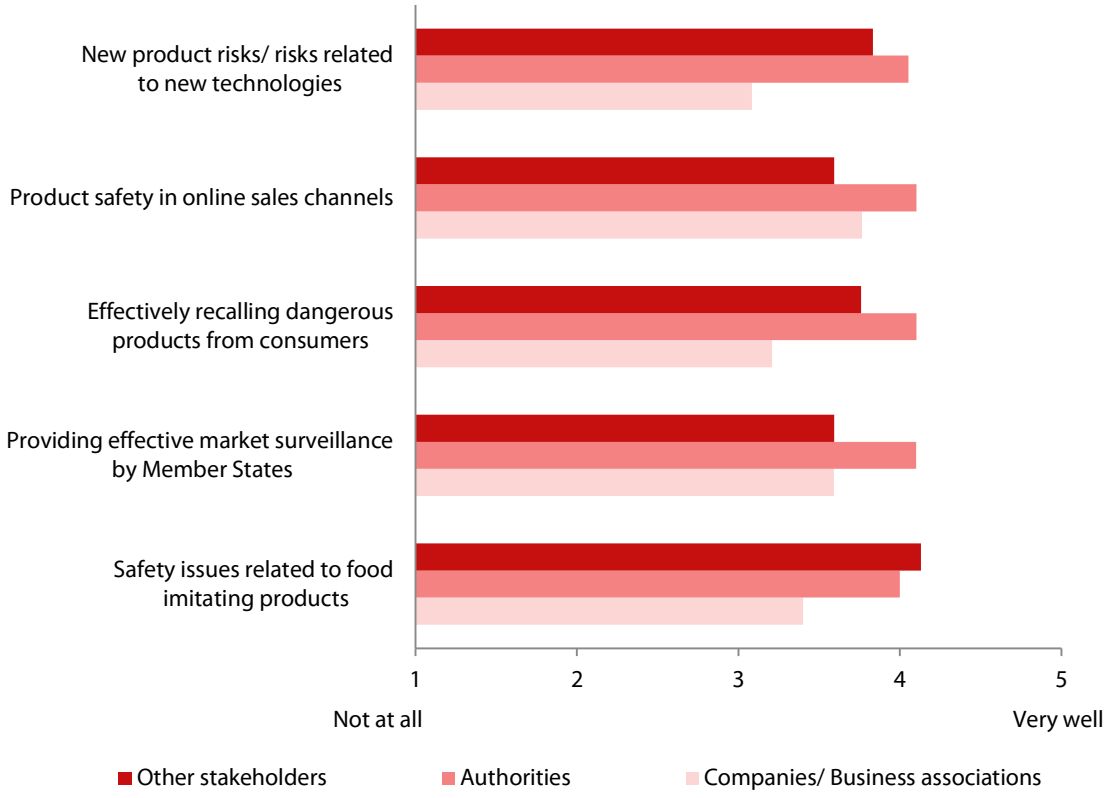
Specific policy objectives	Areas	Achievement of specific objectives	Assessment
Ensure general safety rules, including for product risks linked to new technologies	*Certainty regarding coverage of new risks*	The revision of the definition of safety in the GPSD is expected to clarify that the covered risks arising from the product to the safety and physical/mental health of persons include not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect health. For harmonised products, there is relevant work ongoing in relation to the Radio Equipment Directive, the Machinery Directive, and the Low Voltage Directive. A similar provision in the GPSD will avoid any gaps in product coverage that may remain in this respect. This will create legal certainty for business operators and MSAs.	Legally binding clarifications will avoid uncertainty. The choice of a Regulation will avoid implementation differences in MS
	Certainty regarding coverage of software	A change in the definition of product in the GPSD will clarify that safety risks stemming from software updates and stand-alone software interacting with products are in the scope of the Regulation. This means that gaps regarding the coverage of software updates and stand-alone software interacting with products by the GPSD will be closed, and related uncertainty and diverging approaches in Member States avoided.	Gaps related to coverage of software by GPSD closed
Address safety challenges in the online sales channels	*Safety of products sold on online platforms*	The coverage of all online platforms by legal obligations similar to those in the Product Safety Pledge will improve accessibility of platforms for notice-and-take-down procedure, and increase consumer safety regarding products sold on platforms that are currently not covered by the Pledge. While safety risks for EU consumers due to products sold on online platforms could be partly reduced (and likely more so than under Option 2, as online platforms would have a duty of care), their mitigation will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of the platforms' duty of care and the further development of the EU legal framework, most notably the new DSA.	Safety risks for EU consumers due to products sold on online platforms could be partly reduced (and more so than under Option 2), with the effectiveness also depending on other factors
	Information of consumers on essential safety aspects	As businesses selling online to consumers will have to provide all safety information online that are also required 'offline', and marketplaces will be required to make sure that third party sellers provide this information, consumer information regarding essential safety aspects can be expected to be improved.	Achievement of objectives can be expected
Make product recalls more effective	*Reaching out to consumers affected by recalls*	As in Option 2, the clarification/creation of a legal basis for economic operators to use any available customer contact details at their disposal to directly notify the owners of recalled products – without the need of consumer consent – will contribute to effectively reaching out. The requirements for businesses to disseminate recall announcements on their website/social media and other appropriate channels to ensure the widest possible reach, would also contribute to this aim, although this is (especially regarding websites) frequently already done. The option that economic operators with product registration systems (e.g. for warranty or technical support) should offer consumers the possibility to register their contact details specifically to receive possible safety notifications and the possibility to set out (through implementing acts) further requirements for product registration and to determine categories of products subject to mandatory supply-side registration can further improve the outreach to consumers affected by recalls. The challenge for mandatory supply-side registration of products – which is expected to be limited to high-risk products as a measure of last resort – is to balance the related administrative burdens with the expected benefits in terms of consumer safety. It will therefore require a careful analysis of data on risks and injuries on a case-by-case basis, to safeguard the proportionality of the measure.	The option can be expected to facilitate the use of available customer data and the increased collection of customer data for high-risk product categories, while avoiding that outreach measures are prevented by data protection concerns

	Information provided in recall notices	Binding requirement for economic operators to use a template for recall notices (annex of the Regulation) can be expected to lead to better and clearer information on recalled products, if enforced adequately.	Improvement in the information provided in recall notices is expected to be achieved
	Monitoring of recall effectiveness	Several requirements for businesses are foreseen in this area under Option 3, such as registering voluntary recalls in an EU public database and monitoring recall effectiveness; the possibility of MSAs to pre-approve proposed remedies and communication strategy before the recall for a dangerous product goes public; the possibility of MSAs to request monitoring data on the effectiveness of a product recall from economic operators. These measures are expected to increase the effectiveness of recalls, if appropriately implemented by MSAs.	Improvement in the effectiveness of recalls is expected to be achieved, also depending on implementation
	Remedies for consumers affected by recalls	Under this option, consumers' right to an effective, cost-free and timely remedy would be set out, so that existing, limited remedies for consumers affected by recalls will be improved and related detriment compensated.	Reduction of consumer detriment due to recalls expected
Enhance market surveillance and ensure better alignment of rules	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	Aligning the market surveillance framework for harmonised and non-harmonised consumer products will simplify the EU legal framework and can be expected to improve traceability through clarification of related requirements and the requirement of an EU representative. It can be expected that the objective to create largely uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products will be largely achieved. Whether the traceability of consumer products will improve in practice will also depend on enforcement of these requirements, and the extent to which measures will be taken to avoid that the obligation for an EU representative is not circumvented by rogue traders, including those that access EU consumers through online platforms.	Largely uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products expected to be achieved
	Deterrence effect	Under this option, stronger enforcement powers (in addition to the ones in Chapter V of Regulation (EU) 2019/1020 on market surveillance and compliance of products) will be incorporated in the GPSD, such as penalties and sanctions.	Deterrence effect likely to be achieved, depending on the maximum levels of penalties and sanctions foreseen
	Diverging risk assessments by Member States' MSAs	According to Option 3, in case Member States have diverging assessments of the risk posed by a notified product (a major point of criticism by stakeholders), a mechanism could be triggered where either a group of Member States or the Commission are called to arbitrate. This could apply for the close to 30 cases each year in which Safety Gate/RAPEX notifications are subject to dispute by notifying Member States, and formalise procedures that currently require informal agreement	Risk assessments are likely to become more harmonised, achieving the desired effect
	Simplification of standardisation procedures	Simplification of standardisation procedures at the Commission level under the GPSD can be expected to increase the efficiency of the process, and possibly reduce the time for the overall standardisation process.	Simplification of standardisation procedures is expected to be achieved
Address safety issues related to food-imitating products	*Addressing risks of food-imitating products*	The provisions of the Food-imitating Products Directive will be integrated in the new Regulation. Sub-option a): Specific types of products that could be confused with real food by vulnerable consumer groups such as children, will be banned throughout the Union. A ban will simplify enforcement of safety regarding food-imitating products, as there will be no need to conduct risk assessment for each specific product. However, consumer harm due to food-imitating products would need to be evidenced to safeguard the proportionality of the measure. Sub-option b) The new Regulation will clarify that an evaluation of the risks posed by the specific food-imitating product (or child-appealing product, if broader scope) is required, as it is done for other consumer products. In this case enforcement would be similar to other consumer products, and no evidence regarding proportionality of measure would be required.	While a ban would be an effective measure to achieve objective, the degree to which it is justified by evidence of consumer harm is unclear. Also, a ban may not be proportionate

8.3.1.2. Stakeholder views on Option 3

In our stakeholder survey, we asked companies/business associations, market surveillance authorities and other stakeholders to what extent they consider Option 3 to effectively address five challenges, which mirror the five specific policy objectives (see Table 54 above). All stakeholder groups considered that Option 3 addressed all challenges at least moderately well (see Figure 23). Authorities and other stakeholders were most positive, and found on average that this option considerably well addressed all challenges (averages of 4.1 and 3.8 respectively, on a scale of 1 to 5, covering all five challenges). Companies and business association were slightly less positive, with an average assessment of 3.4 across all five challenges. The overall average assessment across all respondents and stakeholder groups was 3.8, i.e. considerably higher on average than for Option 2 (where the average across all respondents was 3.4)[239].

Figure 23: In your view, to what extent would Option 3 effectively address the following challenges for product safety? Please assess.



[239] Companies/business associations assessed Option 3 only slightly better than Option 2, with 3.4 vs 3.3. on average.

8.3.2. Potential for administrative simplification

New regulatory measures have the potential to reduce regulatory complexity and uncertainty, as well as cutting red tape and thereby reducing administrative burdens "created by bureaucracy and paperwork"[240]. In the following we therefore assess the extent to which Option 3 could be expected to have effects in this respect.

As described above, Option 3 would provide legally binding clarifications regarding the coverage of new risk and software by the GPSD, reducing regulatory uncertainty in this respect. General requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products, and implementation differences in Member States would be reduced, which is likely to contribute to reduced regulatory complexity and thereby to reduced administrative burdens for businesses. This effect is quantified below (see benefits for businesses and benefits for MSAs).

On the other hand, Option 3 would include some additional administrative requirements for specific types of operators: This includes the requirement to provide essential safety information online (relevant for online traders), the requirement for mandatory supply-side registration for specific categories of products (for sellers of these products). The most comprehensive requirements would apply in the context of recalls, such as the requirement for businesses to register voluntary recalls in an EU public database, to use a template for recall notices, to submit proposed remedies and communication strategy to the responsible MSA for approval before the recall goes public (if requested), and to provide on request monitoring data on the effectiveness of a product recall. While these requirements likely lead to related administrative burdens, they would be limited to those companies that have brought unsafe products on the market and as a measure of last resort have to recall products from consumers. As currently the effectiveness of recalls is considered to be limited, these additional measures and the related administrative burdens appear to be proportionate.

The simplification of the standardisation process has the potential to reduce administrative burdens on Member States by streamlining the related EU process for elaborating safety requirements and the standardisation request, e.g. through the involvement of only one instead of two EU Committees. Finally, the integration of the Food-imitating Products Directive in the GPSD would reduce regulatory complexity.

8.3.3. Economic impacts

The following section outlines the economic impacts for businesses that are likely to result from the implementation of Option 3, focusing first on benefits and costs to be expected.

8.3.3.1. Benefits for businesses

As outlined in the baseline, businesses currently incur additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). These are estimated to amount to 119 million EUR annually (see section 7.1.3 above, Table 28). As Option 3 foresees to recast the GPSD as regulation, implementation differences would be avoided at the legislative level (due to the direct applicability of the new regulation in Member States). At the same time, it can be expected that some differences in the national interpretation of rules will remain. Accordingly, we do not expect a full reduction of businesses' additional costs that currently accrue due to

[240] See OECD 2009, Overcoming Barriers to Administrative Simplification Strategies: Guidance for Policy Makers, www.oecd.org/regreform/42112628.pdf.

implementation differences in Member States, but assume a 50% reduction of businesses' additional costs in this respect under Option 3 (see Table 56 below).

Table 56: Estimated savings of costs that are currently caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements) under Option 3, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	9	11	18	37
Total wholesale sectors	3	2	4	9
Total retail sectors	7	1	5	13
Total reduction in compliance costs related to consumer products	***19***	***15***	***26***	***59***

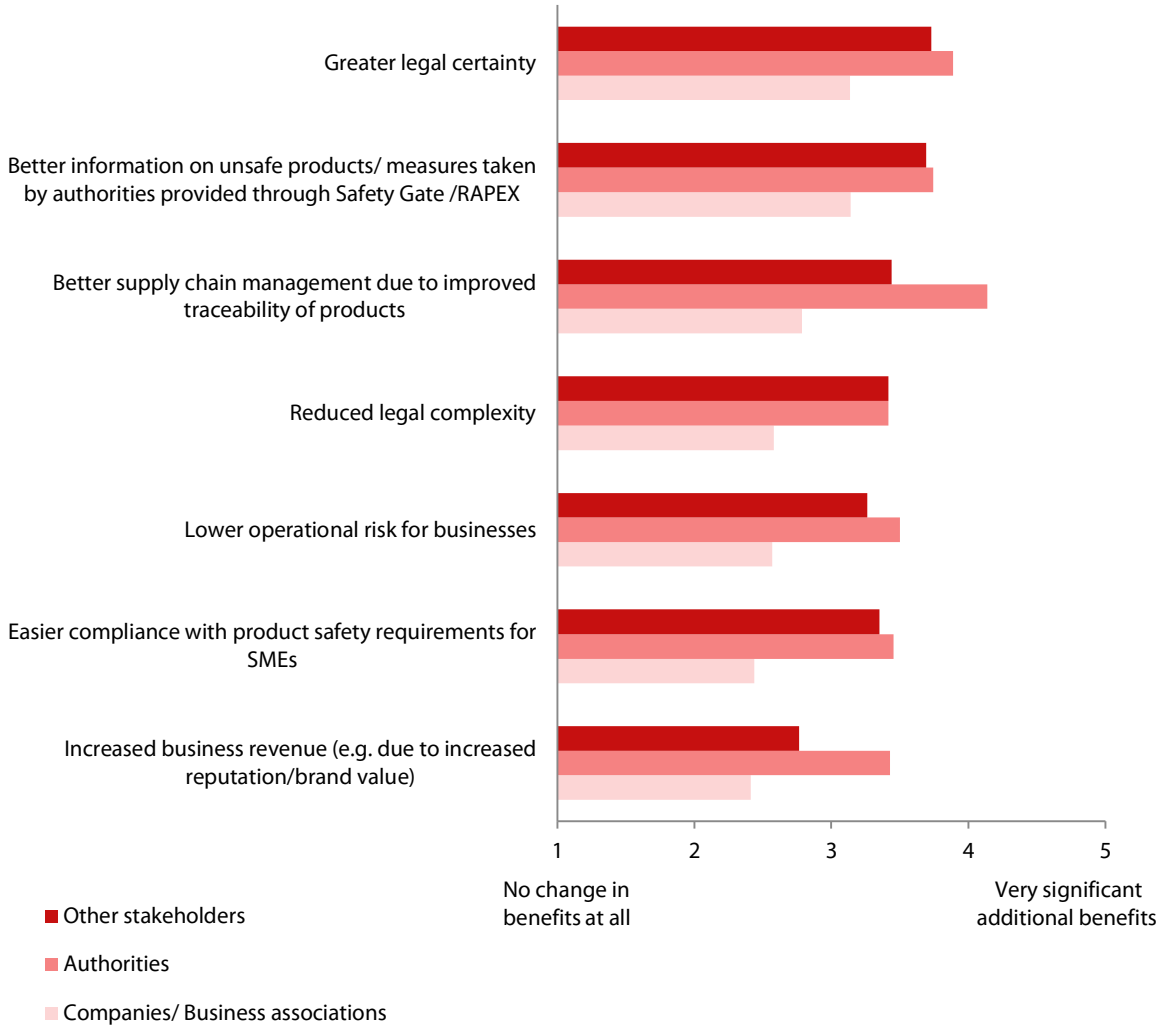
As indicated in the table, Option 3 would result in benefits for businesses (cost savings compared to the baseline) of 59 million EUR annually, of which 34 million EUR would be saved by EU SMEs.

To further explore expected benefits for businesses, we asked in our surveys all stakeholder groups to assess a set of potential benefits, identified on basis of previous research. The question specifically provided the following potential benefits of Option 3 for businesses (some of them are also relevant for MSAs):

- Greater legal certainty
- Reduced legal complexity
- Easier compliance with product safety requirements for SMEs
- Better information on unsafe products/ measures taken by authorities provided through Safety Gate/RAPEX
- Increased business revenue (e.g. due to increased reputation/brand value)
- Lower operational risk for businesses
- Better supply chain management due to improved traceability of products

The results of the stakeholder assessment are presented in Figure 24 below:

Figure 24: Where do you see the greatest additional benefits that would result from the implementation of Option 3? – Direct benefits for businesses



As Figure 24 above illustrates, companies and business associations saw less benefits than MSAs and other stakeholders, who assessed benefits to be mostly considerably more than 'moderate' (indicated by 3 on the scale in the figure above) and close to 'significant' (4). In contrast, companies and business associations on average saw mostly between 'minor' and 'moderate' benefits. Regarding greater legal certainty and better information through Safety Gate/RAPEX, their assessment was slightly above 'moderate'.

8.3.3.2. Costs of businesses

The results of the following analysis indicate that companies expect the implementation of Option 3 to cause changes in their recurrent costs, e.g. costs related to additional staff and additional resources for due diligence measures such as IT systems and external services, in addition to one-off costs, such as familiarisation costs and costs from adapting to regulatory changes (e.g. for external advice)[241]. Both types of costs are analysed in the following sub-sections.

[241] Due to the nature of policy options and the questions asked in the survey with respect to the related recurrent and one-off costs, the estimate elaborated in this section focuses on the overall impact of the implementation of Option 3 on businesses' recurrent costs and one-off costs. Businesses' additional staff

Recurrent costs of businesses

Businesses expect that implementing Option 3 would increase companies' recurrent regulatory compliance costs. Companies that are manufacturers generally expect more significant changes than wholesalers and retailers[242]. It is plausible that manufacturers would be more affected by regulatory changes than distributors, as they might have to adjust different stages of the value-adding process to new regulatory requirements, e.g. consider relevant steps in the manufacturing process, but also sales and aftersales procedures. For the entire group of respondents, only one distributor vaguely indicated a potential driver of additional costs from Option 3, referring to increased bureaucracy.

Several companies reportedly found it difficult to assess the quantitative impacts of Option 3, and stated that the accuracy of the given estimates depended on the implementation details. Accordingly, the estimates provided below are not precise forecasts, but rather indicate the direction and relative magnitude of changes in recurrent costs under Option 3 compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates[243].

To estimate the impact of the implementation of Option 3 on EU businesses' recurrent costs, we applied the percentage change in recurrent (annual) costs as assessed by respondents to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (see section 7 for the baseline estimates). Due to a relatively low number of responses from distributors and inconsistencies of the stated changes in costs, we decided to base the estimation of recurrent costs for the EU as a whole on the sample statistics for the full sample of businesses' stated changes in recurrent costs (the sample statistics are provided in Table 57)[244].

requirements and other costs resulting from the implementation of compliance related measures and processes are well documented in the impact assessments for consumer safety-related policies, e.g. European Commission (2013), Product Safety and Market Surveillance Package, Commission Staff Working Document Impact Assessment, 13 February 2013; CSES (2014), Evaluation of the Internal Market Legislation for Industrial Products, report under the Framework Service Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations, 13 January 2014, VVA europe (2015), Implementation of the New Regulation on Market Surveillance: Indication of Origin, Final Report, 6 May 2016; European Commission (2017), SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final. In these and other studies, cost estimates are usually provided for one-time costs resulting from preparatory measures needed to comply with the regulations as well as recurrent costs. Costs are usually expressed in annual numbers on a per company or per sector basis. Some studies aggregate these numbers to arrive at a total cost for all companies affected by the respective regulation or of individual industries repectively.

[242] 12 out of 25 manufacturers expect rising recurrent costs resulting from the implementation of Option 3, four manufacturers indicated that costs would remain the same and only one manufacturer indicated that cost would be reduced significantly. With regard to distributors recurrent costs, one out of 11 distributors indicated that costs would be reduced significantly, without further clarifying the potential drivers of cost reduction. At the same time, four distributors expect that costs would remain the same for Option 3 compared to the baseline, while four other distributors expect their recurrent costs to rise from the implementation of Option 3. Detailed survey results are provided in the Annex of Part 1.

[243] This also applies for the estimation of one-off costs.

[244] We therefore did not distinguish between distributors (retailers and wholesalers) and manufacturers. Similar to a previous study, for the overall estimation of businesses' costs we also assumed that the compliance costs as a percentage of turnover for product safety-related costs are the same for large enterprises and for SMEs. See CSES (2014), Evaluation of the Internal Market Legislation for Industrial Products, 13 January 2014.

Table 57: Sample statistics of businesses' estimated change in recurrent costs in product safety-related costs under Option 3 (as percentage of recurrent costs to comply with safety requirements for consumer products)

Sample statistics	Full sample of business respondents, change of recurrent costs
Count	22
Min	-5.00%
Max	70.00%
Average	12.82%
Q1	0.00%
Q2 (median)	**3.00%**
Q3	17.50%
Q1 to Q3 (middle 50% of values)	0.00% - 17.5%

Applying the sample median of 3.00% (see Table 57) as best estimate for the extent to which recurrent costs would increase under Option 3 to the estimated annual consumer product safety-related costs of EU businesses, results in additional annual cost of EUR 111.7 million for EU manufacturers, EUR 27.9 million for EU wholesalers and EUR 38.2 million for EU retailers (see Table 58).

Table 58: Estimated changes in EU businesses' annual recurrent costs, EU total under Option 3, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	25.7	32.9	53.2	**111.7**
Total wholesale sectors	10.2	7.1	10.6	**27.9**
Total retail sectors	20.2	3.8	14.2	**38.2**
Total additional recurrent costs	***56.1***	***43.8***	***78.0***	***177.8***

One-off costs of businesses

Businesses generally need additional staff time for the implementation of new policy measures. Businesses are also confronted with additional non-staff costs, e.g. costs arising from external support for changes to IT systems, staff training etc.

Our estimation of EU businesses' total one-off costs is based on individual respondents' estimates for the total additional staff needed and the total additional non-staff costs that arise from familiarisation and implementation efforts under Option 3. Based on the respondents estimates, we calculated staff costs in Euro terms and added other (non-staff) one-off costs. The calculation of Euro-denominated costs for staff is based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour[245]. To account for overhead costs, a 25% mark-up was added to staff-related costs.

[245] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

The total one-off costs for each company were divided by the EU turnover for consumer products, i.e. we expressed companies' total additional one-off costs resulting from activities to comply with safety requirements for consumer products under Option3 as a share of the related turnover. Again, we did not distinguish between distributors (retailers and wholesalers) and manufacturers due to data limitations, and based the estimation of one-off costs for the EU on the sample statistics for the full sample of businesses' cost estimates (a total of 22 respondents). Sample statistics are provided in Table 59 below.

Table 59: Sample statistics of businesses' estimated one-off costs under Option 3 as percentage share of annual EU turnover from consumer products (total of additional staff and additional non-staff costs)

Sample statistics	One-off costs as share of turnover from consumer products
Count	22
Min	0.00%
Max	2.75%
Average	0.25%
Q1	0.00%
Q2 (median)	**0.0008%**
Q3	0.07%
Q1 to Q3 (middle 50% of values)	0.00% - 0.07%

Applying the sample median of 0.0008% to the estimated annual turnover for manufacture, wholesale and retail of consumer products in the EU results in additional one-off cost of 5.3 million EUR for EU manufacturers, 5.7 million EUR for EU wholesalers and 7.8 million EUR for EU retailers (see Table 60).

Table 60: Estimated changes in EU businesses' one-off costs, EU total under Option 3, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	1.2	1.6	2.5	**5.3**
Total wholesale sectors	2.1	1.5	2.8	**5.7**
Total retail sectors	4.1	0.8	2.9	**7.8**
Total additional one-off costs	***7.5***	***3.8***	***7.6***	***18.8***

As concerns the impacts on one-off cost that result from the specific measures taken into consideration under Option 3, companies did not comment further on the nature and magnitude of these costs, nor did they indicate the time horizon for these costs to occur and when they would phase out. Only few respondents provided some information on their expected one-off costs, with an example being a manufacturer, who also imports to the EU, highlighting that "[m]ost of our products are already regulated by harmonised directives and regulations. Improvement of the GPSD on those points won't change anything to our one-off cost because we already do the maximum".

Total costs of businesses under Option 3

Even though business respondents did not provide detailed information about the exact time dimension for one-off costs to arise, we assume that one-off costs unfold within one year after the implementation of the regulatory changes. Absolute changes in one-off and recurrent costs within the first year of the implementation of Option 3 as well as absolute changes in annual recurrent costs after the first year of the implementation of Option 3 are outlined in Table 61[246] below. Total costs of businesses in the EU27 in the first year of implementation are estimated at EUR 196.6 million, equivalent to 0.019% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in subsequent years to EUR 177.8 million (or 0.017% of turnover).

Table 61: Changes in EU companies' costs within and after the first year of implementation of Option 3, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	26.9	34.4	55.7	**17.0**
Total wholesale sectors	12.3	8.5	12.7	**33.6**
Total retail sectors	24.3	4.6	17.1	**46.0**
Total additional costs	***63.5***	***47.6***	***85.6***	***196.6***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	25.7	32.9	53.2	**111.7**
Total wholesale sectors	10.2	7.1	10.6	**27.9**
Total retail sectors	20.2	3.8	14.2	**38.2**
Total additional costs	***56.1***	***43.8***	***78.0***	***177.8***

Note: Estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in recurrent and one-off costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

As mentioned above, the increase in the expected costs (compared to Option 2) is due to the fact that businesses expect that implementing Option 3 would increase their recurrent regulatory compliance costs, with manufacturers generally expecting more significant changes than wholesalers and retailers. In their comments, respondents pointed out, for example, that risk of financial penalty would require more accuracy, with the effect being that "bureaucratic costs will increase", or, as another respondent put it, the "need for mechanisms to ensure compliance" would increase costs. Others referred to the potential costs of mandatory registration schemes, also depending on the implementation details. As pointed out before, respondents frequently highlighted the considerable uncertainty in their estimates, as implementation details were not yet known. Expected costs savings of companies due to further harmonisation and the use of a Regulation as legislative instrument were also highlighted by some respondents, an example being a respondent who indicated that "moving away from a Directive to a

[246] The results are generally in line with other impact assessments of regulatory compliance costs related to the due diligence and reporting obligations. An assessment of the economic impacts of introducing due diligence requirements for EU companies' supply chains finds, for example, that additional firm-level cost as percentages of revenues amount to 0.005% for large companies and 0.074% for SMEs. See European Commission (2020), Study on due diligence requirements through the supply chain, Final Report, 20 Febraury 2020.

Regulation would help reducing costs, while also increasing predictability and legal certainty" (see also section 8.3.3.1 for an estimation of cost savings of businesses).

8.3.3.3. Firm level impacts for specific types of operators

In the following sub-section, we consider the economic impacts for several types of operators which are of specific interest (such as SMEs) or may be specifically affected by the proposed measures under Option 3 (online marketplaces, online traders in general, and producers and distributors of food-imitating products).

Impacts on SMEs

The implementation of Option 3 would be expected to address current gaps in the product safety regime for non-harmonised products and thereby safeguard the continued free movement of goods in the Single Market[247]. This would likely contribute to positive spillover effects on consumer trust, demand, production and employment, compared to the baseline scenario. As concerns the benefits for SMEs, small companies generally estimate that a revision of the product safety requirements of the GPSD according to Option 3 would bring a variety of at least 'minor' to 'moderate' benefits. Option 3 is especially seen as a benefit due to its deterrent effect on rogue traders and as it would result in better information on unsafe products/measures taken by MSAs provided through Safety Gate/RAPEX. In the case of medium-sized companies, Option 3 is seen as a suitable contribution to a more level playing field among businesses. In addition, Option 3 is considered to be a significant benefit when it comes to reducing the occurrence of products presenting health and safety risks and also for contributing to a better functioning of the EU internal market. Finally, moderate benefits are expected regarding the potential to increase business revenue or consumer trust (see also Figure 24 above for a general overview).

As concerns costs for SMEs, the effects from Option 3 will generally have a larger relative cost impact on SMEs than on large companies[248]. Due to their size (e.g. in terms of turnover, profits and staff), SMEs generally bear a larger relative cost burden resulting from regulatory complexity and uncertainty. At the same time, and for the same reasons, SMEs can generally benefit more from policy measures that aim at a greater level of regulatory harmonisation in the EU (greater marginal benefit of reduced regulatory complexity compared to large companies) [249].

Option 3 would not entail stricter regulation for a particular type of SME, but may entail a higher relative cost burden for manufacturers than distributors. The total additional cost burden for SMEs in manufacturing and distribution sectors is reported in Table 61 (above), which shows estimates that are based on the full sample of companies' assessments of changes in costs. As indicated in the table, total costs for SMEs manufacturing, wholesale and retail of non-harmonised consumer products in the EU27 in the first year of implementation of Option 3 are estimated at EUR 111.2 million[250]. They would fall in subsequent years to EUR 99.9 million. Compared to the full sample results for the impact of Option 3 on businesses one-off and recurrent costs, SMEs would

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247 For a similar assessment, see SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final.

248 SMEs can be disproportionately impacted where new systems and processes need to be put in place to comply with general consumer safety requirements and requirements for the provison of information, since these costs are likely to be higher in relative terms for SMEs. See, e.g. VVA europe (2015), Implementation of the New Regulation on Market Surveillance: Indication of Origin, Final Report, 6 May 2016; European Commisison (2020), Study on due diligence requirements through the supply chain, Final Report, 20 Febraury 2020.

249 Higher relative cost impacts for SMEs compared to large companies are also reported in European Commission (2020), Study on due diligence requirements through the supply chain, Final Report, 20 February 2020.

250 Sum of the firm size categories 0 to 49 employees and 50 to 249 employees, see table above.

likely face higher compliance costs than large companies from the implementation of the proposed policy measures.

Even though the relative costs increases are generally higher for SMEs the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a greater level of regulatory harmonisation across the EU27 through the choice of a regulation. Also, the changes in SMEs costs are so small that Option 3 would not be expected to affecting operations considerably[251]. This consideration is also true for specific information obligations, such as the obligation for actors across the online supply chain to provide all safety information online that is also required to be provided with a product in 'brick-and-mortar' stores, and the related obligation for online platforms to make sure that third-party sellers, such as SMEs, provide this information. We expect these costs to be relatively low for companies selling consumer products on these platforms, including SMEs.

Impacts on online marketplaces

Option 3 would include to make legally binding most provisions of the voluntary Product Safety Pledge for online marketplaces (as in Option 2) and introduce a duty of care with respect to product safety, including the obligation to make sure that third party sellers on their platform provide safety information together with the product offer (without, however, being required to check the accuracy of the safety information provided). This could be expected to generally improve consumer safety for products purchased on online marketplaces. As concerns the benefits of policy measures considered under Option 3, platform respondents offered a mixed picture on the potential manifestation of benefits. While they mostly expected significantly increased costs, several platforms also tended to agree that the measures would improve consumer trust, provide better information on unsafe products/measures taken by MSAs through Safety Gate/RAPEX, provide greater legal certainty and less complexity, as well as having a deterrent effect on rogue traders and reducing the occurrence of products presenting health and safety risks in the Single Market.

When asked about the inclusion of online marketplaces as responsible economic operators, businesses generally argued that this would bring benefits for consumer safety. Some businesses also stated that obligations for online marketplaces need to go beyond the safety pledge provisions and be aligned with those obligations that need to be met by traditional ("offline") importers/distributors, including applying ex-ante and ex-post measures and meeting traceability requirements.

In our survey of business operators, five companies responded that operate as either retailers or manufacturers and at the same time operate online platforms or function otherwise as online intermediary. Four of them provided information about their consumer product safety-related compliance cost and information regarding the potential impacts from the implementation of Option 3. As concerns the cost impacts of Option 3, three platform respondents expect increases in recurrent costs, while one platform stated that recurrent costs would remain the same (see Table 62).

[251] This also implies that under any foreseeable scenario, the expected measures are not expected to leading to the closing down of either small or medium-sized businesses.

Table 62: Changes in costs to comply with safety requirements for consumer products – assessment by companies that also operate online marketplaces

	Change in costs to comply with safety requirements	
	Recurrent costs	One-off costs
Respondent 1	Increase costs significantly	No answer
Respondent 2	Costs would remain the same	No additional costs at all
Respondent 3	Increase costs significantly	No answer
Respondent 4	Increase costs significantly	Significant additional costs

A platform company provided a quantitative estimate for the expected impact on recurrent costs, stating that the company's overall consumer product safety-related costs would increase by 30%. As regards the impact on online platforms one-off costs, one platform respondent expects no additional costs, whereas another platform respondent expects significant additional costs.

As regards the Product Safety Pledge, the additional costs from Option 3 for online platforms would generally be relatively low for platforms that already signed the Products Safety Pledge. By contrast, non-signatory platforms would likely face additional compliance costs. In particular, some stakeholders were concerned that these compliance costs might specifically affect small platforms and create a deterrent effect on new market entrants, with negative effects on competition between platforms. This impact appears possible, but would also depend on the size of the additional costs. As most obligations under the Product Safety Pledge relate to 'notice and takedown' (i.e. imply a reactive approach), additional costs are likely to be limited. Due diligence obligations in terms of product safety might require more efforts, but would likely imply less efforts than those of distributors for fulfilling their obligations under the current regime.

Online marketplaces would also be affected by a requirement to safeguard that third-party sellers on the platform provide all safety information online that is also required "offline". We expect these costs to be low for both online platforms and businesses selling consumer products on these platforms, as this information is already available and the provision of already existing information should not result in significant additional costs[252] (see next section).

Impacts on other online sellers

Similar to online platforms, the new provisions for businesses across the online supply chain would require online sellers to provide all safety information online that is also required to be provided with a product in "brick-and-mortar" stores. It is already a common practice that sellers provide this type of information (e.g. "Not suitable for children under 3 years of age")[253]. Based on the understanding that the required information would not go beyond what is indicated on the packaging (which is the information typically also available in 'brick-and-mortar' stores), the provision of this information online in those cases where this is not yet done, should not create significant burdens for online sellers. Also, the provision of already existing information when listing

[252] In contrast, requiring online platforms to verify all safety information provided by third-party sellers could result in significant additional costs. However, this type of general monitoring obligation would be subject to the provisions of the new Digital Services Act, and therefore has not been considered here.

[253] For example, the search for 'not suited for children under the age of' led to approx 179 000 hits with Google on an EU website of a large international online marketplace, and 4 500 hits on a smaller national marketplace. On a specilised toy online shop, the number of hits was 79 000 (in the national language).

offers for consumer products on online platforms should not result in significant additional costs.

Impacts on producers of food-imitating products

To assess the impacts of Option 3 on the producers of food-imitating products, such as food-shaped shampoos or bath gels that could be confused with real food by vulnerable consumer groups such as children, two different sub-options have to be considered:

a) A ban of food-imitating products throughout the Union; or

b) Provisions that would better detail the requirements for food-imitating products (and possibly of child-appealing products in general[254]) and require the evaluation of the risks posed by the specific product, similarly to the requirements under the GPSD for other consumer products.

With respect to a), the economic impact of a ban would depend on the market size for food-imitating products. No data could be identified in this respect, with the general view being that this market is tiny. Therefore, the economic impacts of a ban of food-imitating products would likely be minor in a broader economic perspective. However, for the affected companies, which would need to shift their production or adapt to the sale of new products, the impact could, of course, be serious. It would therefore depend on the availability of evidence for major risks posed by food-imitating products for vulnerable consumer groups (such as children), to consider the proportionality of a ban (see also discussion below, impact on fundamental rights). For the present study, such evidence was not available (see section 4.6 above).

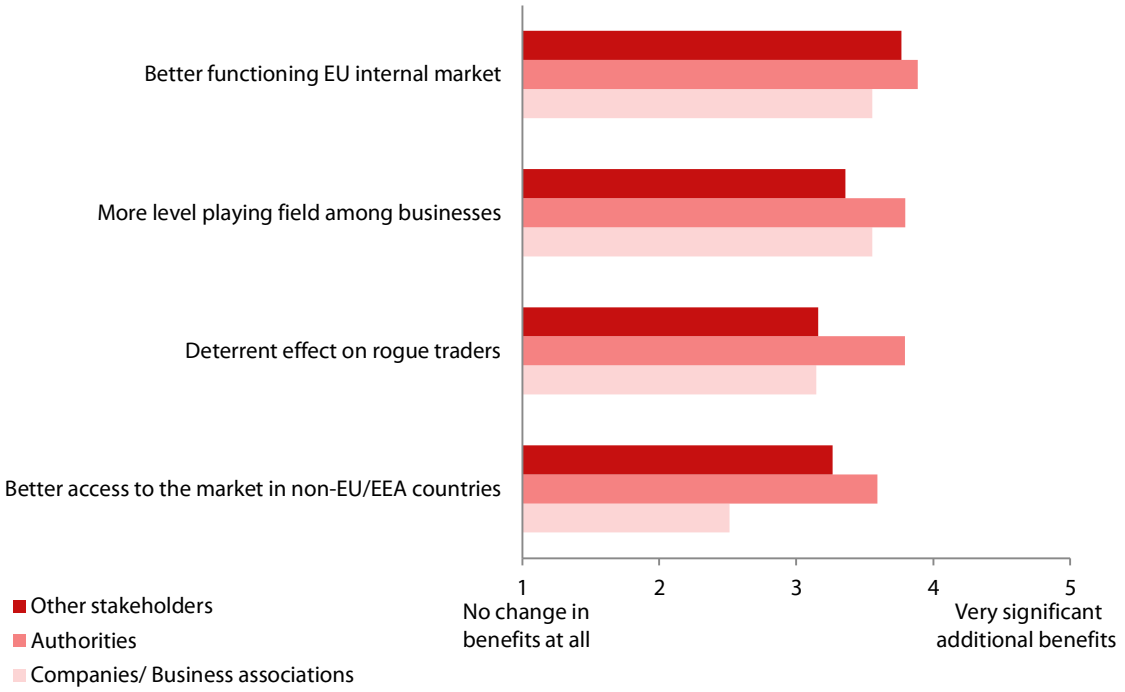
The alternative option b) is to better detail the requirements for food-imitating products (and possibly of child-appealing products in general) and require the evaluation of the risks posed by the specific product, similarly to the requirements under the GPSD for other consumer products. This would be in line with the current approach in the GPSD and would minimise the economic impact on producers of relevant products.

8.3.3.4. Macroeconomic impacts

The results of the consultation conducted for this study indicate that all stakeholder groups see important benefits of Option 3 in terms of a better functioning EU internal market and a more level playing field among businesses, partly through the deterrent effect on rogue traders. All these potential benefits were assessed as being 'moderate' to 'significant'. It is notable that a better access to non-EU/EEA markets due to higher product safety standards was considered a more significant benefit by MSAs and other stakeholders than by businesses.

[254] Child-appealing products are products that by their characteristics are attractive to children, without necessarily looking like food, e.g. colorful detergent pods or lighters looking like a weapon or a toy.

Figure 25: Where do you see the greatest additional benefits that would result from the implementation of Option 3? – Benefits for internal market and trade



These and other potential impacts of the implementation of Option 3 that are relevant in terms of trade and competition are discussed in the following sub-sections.

Impact on internal market and trade

As indicated in Part 1 of this study, the GPSD has been effective in achieving the free movement of products and level playing field in the internal market with respect to non-harmonised products. European integration has led to a decline in trade costs across EU countries and an increase in intra-EU competition respectively. Numerous studies outline the positive effects of the Single Market and European consumer safety legislation for (growth of) economic activity, economic integration, competition and prosperity[255]. At the same time, these studies highlight that the Single Market is still incomplete and, due to new regulatory initiatives at Member State level, at risk of being fragmented by new laws and regulations that follow Member States' approaches rather than harmonised EU rules.

Differences in horizontal regulations between Member States and differences in the national implementation of EU legislation, including product safety legislation, have a deterrent effect on trade, which is referred to as the impact of non-tariff barriers to trade (NTBs). NTBs have an economic effect on the quantities traded, with feedback effects on domestic production and prices. The World Bank, for example, estimated that the effects of several NTBs are almost twice as trade restrictive as tariffs[256]. The UN

[255] See, e.g., Veld, J. (2019), The economic benefits of the EU Single Market in goods and services, Journal of Policy Modeling 41 (2019) 803–818; Bruegel (2017), Making the best of the European single market, Policy Contribution, Issue 3/2017; ITC (2016), Navigating Non-Tariff Measures, International Trade Centre and European Commission, 2016; Civic Consulting for the European Parliament (2014), Contribution of the Internal Market and Consumer Protection to Growth, IP/A/IMCO/2014-04. December 2014.

[256] World Trade Report 2012, The trade effects of non-tariff measures and services measures, available at https://www.wto.org/english/res_e/booksp_e/anrep_e/wtr12-2d_e.pdf.

comes to similar conclusions[257]. For the EU, estimates indicate that in the internal market NTBs in goods and services sectors restrict intra-EU trade to a level about four times smaller than the intensity of trade between individual US states, which comprise a much more harmonised regulatory level-playing field for businesses and consumers.

It is generally difficult to distinguish between non-tariff measures (NTMs), which are legitimate and typically non-discriminatory measures to preserve legitimate public interests such as safeguarding consumer health, and NTBs, which have a discriminatory effect on foreign businesses. The dividing line between an NTM and an NTB is generally difficult to draw. A quantification of existing and potential NTBs from EU consumer safety regulation requires complex legal and economic analysis that goes beyond the scope of this analysis. However, increased regulatory fragmentation, triggered by new and different regulatory approaches for the treatment of, for example, software as a product, the safety of new technologies and the regulation of online sales channels could generate new barriers, which would in effect result in less trade between EU Member States. Less intra-EU trade would generally result in less economic opportunities, income losses, slowed-down economic and social convergence, and less consumer choice.

Given that Europe's digital transformation will continue, maintaining a large and creating more integrated markets for consumer products in the EU is particularly important for the preservation of the current state of the Single Market[258], making sure that both harmonised and non-harmonised consumer products can be traded across borders as freely as possible in the future. This could, however, be affected by the rise of new technologies, and in particular in relation to software that is subsequently embedded in a product after that product has been put on the market, and with self-learning software where technological development and uncertainty about the applicability of product safety law has produced an uneven level of protection between Member States (see Part 1, EQ4). Option 3 would address the safety of software for those products not covered by relevant harmonisation legislation, and thereby prevent Member States from resorting to national measures that could create an obstacle to the free movement of goods or services and lead to an uneven level playing field for businesses. Also, if Member States treated products with embedded self-learning software differently in terms of the assessment of their safety, this could produce similar effects. While the evaluation of the GPSD presented in Part 1 found no indication that this is currently the case, the clarification under Option 3 that stand-alone software is considered a product would safeguard that this is prevented in the future[259].

Also, the evaluation of the GPSD found that legal uncertainty concerning key concepts currently has negative effects in that it may prevent MSAs from taking action for perceived lack of competence or of the fulfilment of relevant requirements for taking action, in particular the lack of safety of a product; which may lead to a lack of enforcement of the GPSD, and to an uneven application of the GPSD by MSAs of different Member States which does not only impact on the level of consumer protection but also on the free movement of goods within the internal market (see above). While also guidance (as provided under Option 1) can address this uncertainty, a clarification in a new regulation will likely be more effective in safeguarding similar conditions in this respect in all Member States. A similar argument can be made with respect to the deterrence of rogue traders due to sanctions and penalties introduced under Option 3, which will also contribute to a more level playing field for economic operators across the EU.

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[257] UNCTAD (2013). The Economics Behind Non-tariff Measures: Theoretical Insights and Empirical Evidence, available at https://unctad.org/system/files/official-document/itcdtab58_en.pdf.

[258] European Commission (2020), Digital Economy and Society Index (DESI) 2020, available at https://ec.europa.eu/digital-single-market/en/digital-economy-and-society-index-desi.

[259] Note that this will also depend on the overall development of the EU legislative framework in this respect.

The revision of the GPSD under Option 3 would be expected to lead to a more aligned and clearer EU legislative framework for the safety of harmonised and non-harmonised consumer products, avoid implementation differences and reduce legal complexity, which could benefit businesses (see above, benefits for businesses). Generally, reduced costs and administrative burdens, including the need to keep informed, would level the competitive environment for companies from different countries within the EU and may at the same time help many European businesses to be more internationally competitive. At the same time, a more harmonised regulatory level playing field within the EU will also induce non-EU companies to market their products in the EU, with positive impacts on intra-EU competition. Under all options, including Option 3, the additional gains in EU companies' competitiveness are expected to be relatively small as companies' current compliance costs with consumer product safety legislation are already relatively low, accounting for relatively small shares of total revenues (for both distributors and manufacturers, although somewhat higher for manufacturers).

As concerns extra-EU exports, improved regulatory cooperation among Member State's MSAs and more aligned risk assessments could result in benefits, particularly less administrative costs and greater legal certainty. Respondents to the survey pointed out that Option 3 could facilitate coordination and mitigate potential contradictions which would help to prevent the inadvertent development of technical barriers to trade (TBTs), potentially creating trade facilitating effect. A more aligned product safety framework for harmonised and non-harmonised consumer products, as generally proposed under Option 3, could also improve the EU's ability to negotiate consumers safety standards in bilateral and multilateral negotiations, which would improve EU companies market access conditions in non-EU countries. In the medium to long-term the implementation of Option 3 could contribute to a narrowing of EU and non-EU approaches to consumer safety regulation, for which a reduction of intra-EU differences could pave the way.

Impact on competition and innovation

The impact on competition and innovation is difficult to assess ex-ante. As outlined above, the revision of the GPSD under Option 3 would be expected to lead to a more aligned and clearer EU legislative framework for the safety of harmonised and non-harmonised consumer products, which would reduce companies' compliance costs in this respect, while the addition of new regulatory requirements could to various extents counteract this effect. Due to the relatively low additional costs for businesses that would result from Option 3 (see analysis above), we do not expect distortions in competition and international trade for EU businesses, neither for competition within the Single Market nor with respect to non-EU competitors.

As concerns innovation, due to the limited impact on companies' compliance costs we do not expect significant impacts on EU companies' overall innovative capacities, i.e. higher budgets resulting from savings in compliance costs that translate to expanded research and business development activities. We nevertheless expect overall positive impacts on competition-driven innovation due to a greater degree of harmonisation and greater legal certainty. Additional effects are possible if the legal obligation to provide more product safety-related information to online traders, incl. online platforms, triggers the development and application of new information and traceability systems. Assuming database interoperability and frequent updates and exchanges of information with existing databases (e.g. EAN/GTIN barcodes, Safety Gate/RAPEX, CPNP for cosmetics and other databases for harmonised and non-harmonised products), a more inclusive and more consolidated European information domain for consumer products would help both businesses and MSAs to detect and mitigate risks timelier and more efficiently. Adding features such as customer registration systems for certain product categories and product recall information (warnings, procedural elements) could improve consumer safety in and beyond the EU and at the same time – to the extent that this incentivises innovative, IT driven solutions – minimise the related burden for companies that manufacture and/or sell consumer products in the EU, particularly SMEs.

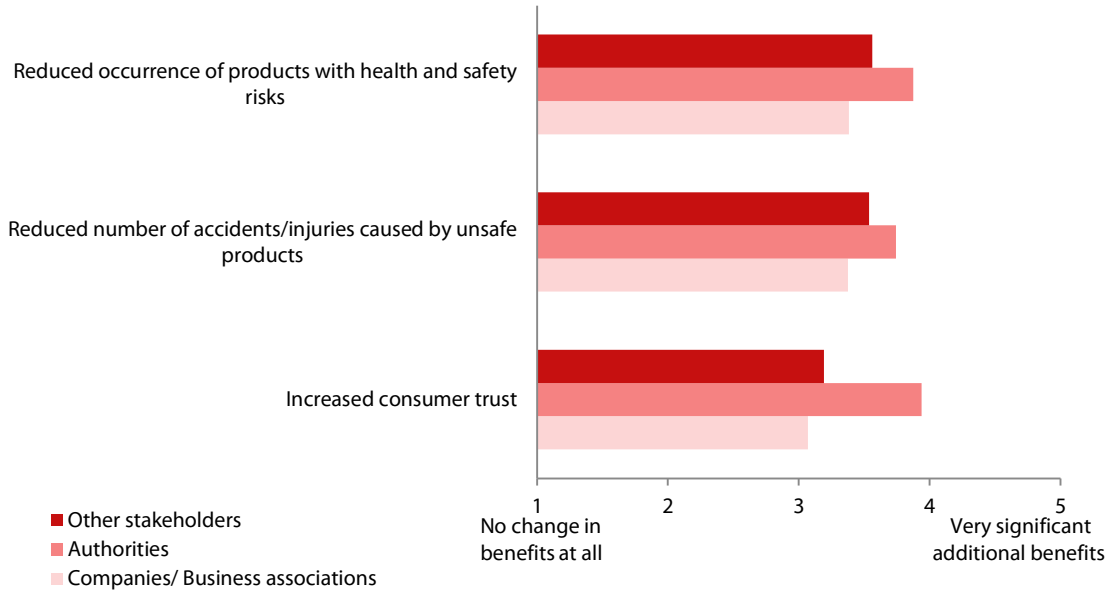
Additional macroeconomic effects

We do not expect significant additional macroeconomic effects. Generally, increased consumer trust would have a positive impact on consumption and economic activity respectively. At the same time, higher costs for businesses generally drive a wedge between supply and demand, which could have a depressing effect on the consumption of consumer products, with adverse feedback effects on production and imports respectively. However, since the additional costs from the implementation of Option 3 (one-off and recurrent costs) are relatively low for manufacturers, wholesalers, and retailers, the negative impacts on consumption in the EU is expected to be negligible (see also following section).

8.3.4. Impact on consumers and households

Stakeholder consider that Option 3 provides 'moderate' to 'significant' benefits for consumers. These include a reduced occurrence of unsafe products and a reduced number on injuries caused by them, as well as a resulting increase in consumer trust (see Figure 26).

Figure 26: Where do you see the greatest additional benefits that would result from the implementation of Option 3? – Benefits for consumers



In the following, we discuss several aspects of the impact on consumers in more detail, including the impact on consumer prices, consumer choice, and the overall impact on consumer safety and impacts on vulnerable consumers.

8.3.4.1. Impact on consumer prices

As indicated before, the implementation of Option 3 would generally result in increasing consumer product safety-related costs (one-off costs and recurrent costs) for companies operating in manufacturing as well as wholesale and retail sectors (incl. online platforms) in the EU. The estimated increases in product safety-related costs are generally lower for retail and wholesale sectors compared to manufacturing sectors. At the same time, the cost increases from Option 3 are only small compared to the baseline, taking into account that companies' overall product safety-related costs, including regulatory compliance costs, account for only very small shares of the turnover from non-harmonised products (see baseline estimates: median values of 0.59% for manufacturers and 0.14% for wholesale and retail companies). Some companies,

mainly in manufacturing sectors, may face higher costs due to firm- and product-specific characteristics. Some of the additional costs would be passed on to others, both up- and downstream the product value chain, and thereby impact consumer prices. A limited effect pertaining to the affordability of products is also possible. Purchase prices for some non-harmonised products might be affected (e.g. products that are most cheaply ordered through online platforms from traders in non-EU/EEA countries). With respect to these products, low-income consumers may have a price elastic response, i.e. reduce their purchases.

However, as most businesses report relatively low additional one-off and recurrent costs, the short and medium- to long-term impacts on consumer prices in the EU are expected to be negligible.

8.3.4.2. Impact on consumer choice

Some of the policy measures envisaged in Option 3 might have a deterrent effect on non-EU companies, including rogue traders, which could either withdraw from the EU or decide not to market their products in the EU in the first place (which is the intended effect, as long as unsafe products are concerned). This effect is mostly expected to be relevant for non-EU companies selling products to EU consumers that distribute their products directly via online retail channels and online marketplaces. The overall volume of sales of such products is, however, relatively small compared to the market size for consumer products that circulate in the EU (see Part 1 of this report). Reputable online sellers frequently apply measures (such as monitoring of Safety Gate/RAPEX notifications) to avoid sourcing of unsafe products and related business risks, as is the case for reputable 'brick-and-mortar' retailers. Also, it is already common practice to provide relevant consumer safety information online as well as offline. Accordingly, we do not expect a significant negative impact on consumer choice in the EU from the measures considered under Option 3.

8.3.4.3. Overall impact on consumer safety and impacts on vulnerable consumers

The implementation of Option 3 would result in greater benefits for consumers due to broader coverage and greater effectiveness of the GPSD in protecting consumers from unsafe products, particularly with respect to the mitigation of risks from new technologies and the coverage of products sold via online channels. New provisions for actors across the online supply chain are expected to improve consumer information regarding essential safety aspects of products offered online. Requiring online marketplaces to make sure that third party sellers provide this information could also contribute to better consumer information regarding product safety risks, although the practical impact on consumer safety would also depend on the use consumers make of this information.

In our quantitative analysis of the benefits of measures concerning online sales channels (Annex IV) we compare the baseline scenario with scenarios for the different policy options. Measures taken under Option 3 are likely to be more effective than previous options to address the challenges for product safety posed by online sales channels, through the introduction of due diligence obligations for platforms, the extension of certain obligations e.g., for fulfilment service providers and the sanctions and penalties incorporated in the new regulation replacing the GPSD. The scenario estimate for Option 3 therefore assumes that measures under this option contribute to aligning the level of product safety (in terms of the incidence of unsafe products) between the online sales channels and brick-and-mortar stores, and thereby to reduce the incidence of unsafe products on the market overall. Table 63 below provides the scenario estimates for the baseline and for Option 3, as well as the expected reduction of consumer detriment under this option.

Table 63: Expected consumer detriment due to unsafe non-harmonised products under scenario estimates for baseline and Option 3 (EU27, in EUR million per year)

Scenario	2025	2026	2029	2034
Option 0. 'Status quo': Baseline scenario not involving any new actions	20 873	21 237	20 078	21 941
Option 3. Full revision of the GPSD and recasting as Regulation	19 835	19 083	16 154	16 450
Expected reduction in consumer detriment under scenario for Option 3 compared to baseline (equivalent to consumer benefit)	**1 038**	**2 153**	**3 924**	**5 491**

Source: Civic Consulting. Notes: Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. The expected annual consumer benefit in the scenario estimate for Option 3 (i.e. the expected reduction in detriment compared to the baseline) increases over the years due to the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels due to enshrining provisions of the Product Safety Pledge in law, due diligence obligations for platforms, as well as sanctions and penalties (the deterrent effect of which is also expected to lead to a reduction in the incidence of unsafe products sold in *offline* sales channels). For details on the methodology for the analysis and the scenario assumptions regarding size of total retail, the share of online in total retail, and the respective incidence rates of unsafe products, see Annex IV.

Consumer detriment is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce. Table 63 shows that benefits in terms of reduced consumer detriment in the EU related to unsafe non-harmonised products are expected to amount to approximately EUR 1.0 billion in the first year of implementation, increasing to approximately EUR 5.5 billion per year over the next decade. These estimates are based on scenario assumptions, and should therefore be interpreted as an indication of the approximate size of benefits, rather than precise predictions. The extent to which these benefits materialise, will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of the platforms' duty of care and other measures are taken at EU level, including in the framework of the new Digital Services Act.

An additional benefit under Option 3 is the potentially reduced consumer detriment due to more effective recalls. In our quantitative analysis of benefits of measures in the field of recalls (Annex V), we compare consumer detriment in a baseline scenario with low recall effectiveness (current situation) to a scenario where recall effectiveness is improved. Table 35 in section 7.3.2 above provided the estimate for the baseline scenario. As indicated in this section, total consumer detriment under the baseline scenario with low recall effectiveness is about EUR 1.3 billion per year. Under the assumption that return rates of recalled products are doubled due to legislative measures and increased sanctions and penalties, this detriment is expected to be reduced to approximately EUR 0.9 billion per year (see Table 64).

Table 64: Consumer detriment due to recalls (improved effectiveness scenario), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products collected from consumers (EUR million)	Value of recalled products that remain with consumers (equivalent to consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1096	50%	548	548
Childcare articles and children's equipment	5.3	30	159	50%	80	80
Lighting chains	3.4	15	51	10%	5	46
Hobby/sports equipment	3.4	80	272	50%	136	136
Jewellery	1.2	10	12	10%	1.2	11
Decorative articles	1.1	5	5	0%	0	5
Laser pointers	0.8	5	4	0%	0	4
Furniture	0.7	150	98	50%	49	49
Lighters	0.4	0.3	0.1	0%	0	0.1
Gadgets	0.03	20	0.5	10%	0	0.5
Total	*34.6*		*1699*		*820*	***880***
Consumer benefit *(= reduction of detriment compared to baseline)*						***410***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124. b) See Table 125. Number of recalls and number of recalled items estimated on basis of data from Safety Gate/RAPEX and data on national recalls provided in the GPSD implementation study. For more details on the methodology, see Annex V.

It can be concluded that under a scenario of significantly improved recall effectiveness (as expected under Option 3), consumer detriment in the EU is reduced by approximately EUR 410 million per year compared to the baseline. This estimate is based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price[260]. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product causes damage to persons, other goods or the environment.

Option 3 could therefore be expected to substantially reduce consumer detriment due to unsafe products sold online and consumer detriment related to ineffective recalls. Thereby, it would be expected to have positive effects on consumer trust, which might translate in higher demand for consumer goods that are sold via online channels. Strengthened enforcement, a better deterrence of rogue traders by increased penalties, improved recalls and clarifications provided in a revised GPSD regarding the definition of safety and related risk assessments of consumer products (including in terms of food-imitating products, child-appealing products and risks for other vulnerable consumer

[260] A key element of the justification for this assumption is that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased by a consumer, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. For a detailed justification, see Annexes IV and V.

groups) could also generally increase the level of protection of EU consumers, including vulnerable consumer groups such as children, the elderly or disabled persons.

8.3.5. Impacts on Member States

8.3.5.1. Benefits for MSAs

The streamlining of provisions for harmonised and non-harmonised products could contribute to savings in terms of resources needed to conduct market surveillance activities for both harmonised and non-harmonised consumer products. As indicated in Figure 11 above, 16% of MSAs reported to currently incur additional costs due to the fact that the EU legal framework for product safety contains different provisions for market surveillance depending on whether the product is harmonised or non-harmonised. In contrast, 34% reported to have no additional costs due to this situation, and 50% did not know or did not answer. Therefore, the efficiency gains by MSAs due to aligning market surveillance provisions between harmonised and non-harmonised products under Option 3 are not expected to accrue to all authorities.

As outlined in the baseline (section 7.1.3 above), taking these results into account, current additional costs for MSAs due to legislative fragmentation are estimated to amount to 0.7 million EUR annually (total for the EU27). The proposed measures under Option 3 would fully align provisions for the market surveillance of harmonised and non-harmonised consumer products[261] so that this cost burden will be reduced accordingly. Option 3 would therefore result in estimated annual benefits (cost savings) for MSAs of 0.7 million EUR. Additional benefits include more aligned enforcement powers, which could, over time, reduce administrative burden from enforcement activities, while an arbitration mechanism that provides clarification regarding risk assessments in case of disputes between Member States' MSAs could lead to additional cost reductions for MSAs over time. As these benefits could not be quantified, and are not included in the quantitative estimate of cost savings, overall benefits for MSAs are expected to be considerably higher.

8.3.5.2. Costs of MSAs

As concerns the policy measures considered under Option 3, Member State MSAs would generally be impacted by a broadening of market surveillance responsibilities, new competences and a greater need for internal and external resources respectively. More specifically, the extended coverage of cybersecurity risks, risks from new technologies and the inclusion of stand-alone software would be expected to increase the need for professional staff and external expertise on the side of MSAs.

In the following sub-sections, we analyse recurrent and one-off costs under Option 3 in quantitative terms.

Recurrent costs of MSAs

Asked about the extent to which MSAs consider that the implementation of Option 3 would change their recurrent costs, nine MSAs reported that their recurrent costs would increase, nine MSAs reported that costs would remain the same and two MSAs reported that costs would likely decrease. MSAs did not comment on the nature of changes in recurrent costs. In total, 17 of the MSAs provided estimates regarding the percentage changes in recurrent costs if Option 3 was implemented, compared to current cost related to market surveillance of consumer products (see Table 65 for sample statistics).

Half of those MSAs that provided cost estimates do not expect increases in recurrent cost, which is reflected by a median cost estimate of 0.00%. At the same time, a

[261] As under Option 2, traceability requirements for non-harmonised products would also be aligned to those for harmonised products.

significant minority of MSAs expect cost increases (roughly one quarter of the respondents that provided quantitative assessments), which is reflected by the third quartile value (Q3) value of a 10% increase in recurrent costs. Assuming for one quarter of MSAs in the EU, Option 3 would bring an increase in recurrent costs of 10% of total annual staff-related costs (which, according, to the baseline estimate, account for more than 99% of consumer product-related market surveillance costs of MSAs), this would imply total additional costs in the EU27 of approx. EUR 6.7 million annually[262]. For the remaining MSAs we would assume that costs remain the same, in line with the distribution of the quantitative estimates. It should be noted that the actual percentage changes would differ for individual MSAs due to different national institutional market surveillance systems and organisational characteristics, e.g. the degree of centralisation, MSAs' product coverage and, after all, the actual assignment of new competences and enforcement requirements, e.g. market surveillance of software and new technologies embedded in consumer products, but also sanctions and penalties.

Table 65: MSAs' estimated changes in recurrent costs, Option 3

Sample statistics	Increase in recurrent costs
Number of responses	17
Min	-70.00%
Max	40.00%
Average	3.47%
Q1	0.00%
Q2 (median)	**0.00%**
Q3	10.00%
Q1 to Q3 (middle 50% of values)	0.00% - 10.00%

One-off costs of MSAs

Asked about the extent to which MSAs expect that the implementation of Option 3 would lead to changes in one-off costs, seven MSAs report "no additional costs", while 15 MSAs expect additional costs of which six MSAs expect "significant additional costs". Those MSAs that indicated additional one-off costs expected them in the following areas: costs related to "[d]ata systems for registration and inspectors for auditing quality systems", additional "implementing costs", "cost increases to adapt our procedures and staff training". One MSA stated it "supposed a significant increase in one-off costs in implementation of Option 3 e.g. due to necessity to adapt national legislation to new rules. It would be needed to prepare some national guidance's and new communication strategy and to strengthen cooperation at the national level. Other aspects would be e.g. organisation of trainings for MSA and all other stakeholders."

It should be noted that data on changes in one-off costs are scarce. Due to the low number of responses from MSAs that provided estimates, the data cannot be extrapolated to the EU level. However, the few cost estimates that were provided by MSA respondents indicate that the one-off adaption and implementation costs can considered to be relatively moderate.

8.3.5.3. Other effects on Member States

The proposed measures would align the enforcement powers of MSAs regarding non-harmonised products with their powers for certain categories of harmonised products

[262] This is the total amount for those MSAs that expect additional costs (i.e. sum across all MSAs that indicated increased costs).

under Regulation (EU) 2019/1020. Thereby, specific gaps such as legal difficulties to conduct mystery shopping for authorities in some Member States would be addressed, and the deterrence effect on rogue traders increased through penalties and sanctions. The efficiency of market surveillance processes with cross-border implications in the EU would be increased. For example, as elaborated in the evaluation of the GPSD (see Part 1 of this report), the number of Safety Gate/RAPEX notifications that were subject to disputes in the network due to divergent risk assessments of MSAs has been on average close to 30 per year in recent years. As a mechanism for arbitration would be created for cases of divergences in the product safety risk assessment between authorities, disputes due to divergent risk assessments of MSAs could be more efficiently settled.

8.3.6. Social impacts, impacts on fundamental rights and environmental impacts

Potential social or environmental impacts, as well as impacts on fundamental rights are discussed in the following sub-sections.

8.3.6.1. Social impacts

The implementation of Option 3 is expected to potentially have positive social impacts with regards to public health and safety and health systems. The introduction of additional requirements for traceability and product recalls including keeping supply chain records, making registration mandatory for certain products, notifying directly owners of recalled products are expected to improve the effectiveness of recalls. In addition, increased enforcement powers of Member States to impose penalties and sanctions in case of violations of the provisions of a revised GPSD, are anticipated to significantly improve market surveillance and enforcement. To the extent that the number of unsafe products on the market is reduced by these measures in the mid- to long term, this potentially could lead to a lower number of injury cases caused by consumer products in need of medical attention or hospitalization, hence lowering public health expenditure for the treatment of product related injuries. However, this potential impact is not straightforward, as the relationship between the incidence of unsafe products and product-related consumer injuries is complex and a variety of factors beyond product characteristics may contribute to the occurrence of such injuries[263]. Also, in a case study a responding market surveillance authority noted that it seems that unsafe products also often have a low quality, so they may break and are disposed of before they injure people (and are thereby rather an environmental concern as they contribute to wasteful over-consumption). On the other hand, also high-priced consumer goods (including cars) can be unsafe and subject to recalls. Better outreach to customers with respect to recalled products and related remedies could be expected to partly overcome behavioural biases which currently affect the effectiveness of recalls (see Part 1 of this study). This could reduce the extent to which recalled unsafe products continue to be used by consumers, with the related risk of injury. Based on our conservative estimation the current cost of health care utilisation for product-related injuries in the EU is approximately EUR 6.7 billion per year, with hospitalization accounting for the larger part of the total health care costs at about EUR 6.1 billion[264]. A revised GPSD may contribute thereby to lowering these health care costs for society.

8.3.6.2. Impacts on fundamental rights

As explained in detail in the relevant paragraphs focusing on the impacts on consumers and the environment, Option 3 is expected to improve consumer safety whilst also reducing environmental risks (see below). The implementation of a new regulation replacing the GPSD according to Option 3 shall hence have a positive impact on

[263] Part 1 of this report, EQ1.

[264] See Annex I regarding the costs of health care utilization for non-fatal product related injuries.

consumer protection and environmental protection in line with the Charter of Fundamental Rights of the European Union[265].

At the same time Option 3 imposes additional requirements for businesses, that will increase their compliance costs to a limited extent. The additional requirements imposed to economic operators do not affect the fundamental freedom to conduct a business[266] as they are necessary to pursue the general European Union interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be comparatively low compared to the businesses' turnover. On the other hand, measures also may include a ban of food-imitating products from the EU market (as sub-option). Such a ban would have a negative impact on the freedom to conduct a business[267], and for this restriction to be proportionate it would need to be justified with the objective of protection of consumers. A possible ban of food-imitating products aims at providing increased protection to vulnerable consumers such as children who may ingest such products by accident. However existing data on relevant accidents lack sufficiently registered information to distinguish whether the products causing the accident were food resembling[268]. At the same time "there are no studies that test whether or not products that could be mistaken food or are appealing to children, are more likely to be ingested by accident than those which do not. However, until there is more research available, the characteristics of a product can be used to estimate how child-appealing it might be. For instance, a product that is shaped like food, smells and tastes sweet and displays familiar cartoon characters in vivid colours in its packaging, is more likely to appeal to children and be confused with food, than a product that is just shaped like food and tastes sweet."[269] It follows that while the negative impact of banning food-imitating products for the relevant business sector is certain and significant, evidence to prove the intended benefits (better protection of children) would still be required to confirm proportionality. In the framework of the present study, such evidence could not be identified (see section 4.6 above).

8.3.6.3. Environmental impacts

Figure 27 presents stakeholder views on benefits related to environment of Option 3. While authorities see 'moderate' to 'significant' benefits regarding improved lifecycle/quality of products and a higher level of the protection of the environment due to the reduction of unsafe products that also have environmental impacts, companies/business associations and other stakeholders only see benefits that are (close to) 'moderate'.

[265] Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 37 on environmental protection and article 38 on consumer protection.

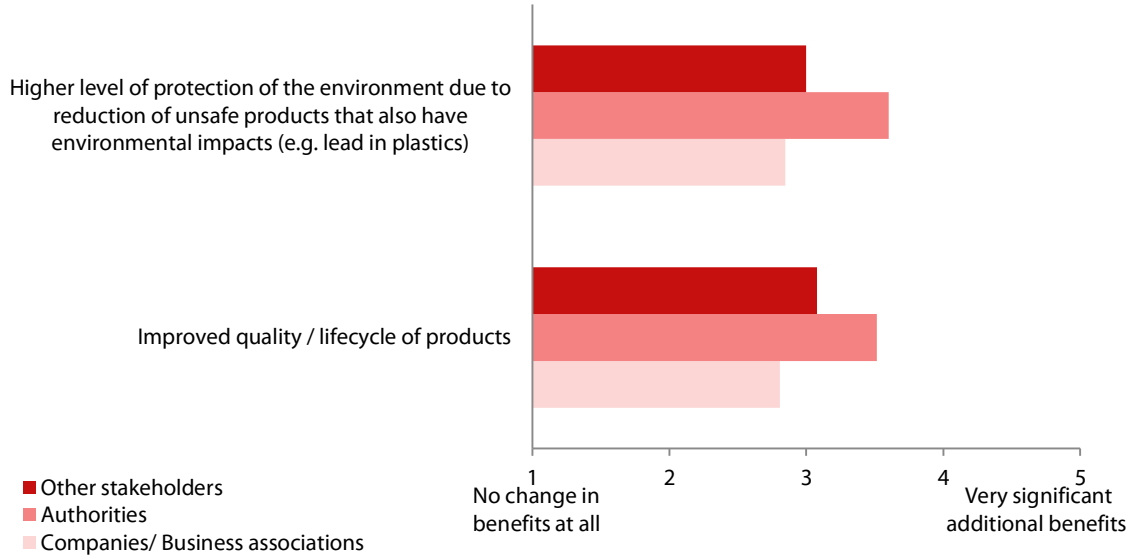
[266] Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 16.

[267] See Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 52 and Judgment of 13 April 2000, Kjell Karlsson and Others, Case C-292/97, EU:C:2000:202, paragraph 45.

[268] Scientific Committee on Consumer Safety, 'Opinion on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties', 22 March 2011, p. 8.

[269] See EU Commission (2012), '6.1. What characteristics increase the probability of confusing a product with food' in *Products that resemble food and appeal to children. Potential risks of accidental ingestion*, available at: https://ec.europa.eu/health/scientific_committees/opinions_layman/products-resembling-food/en/l-2/6-conclusion.htm#1. See also ibid. p 21-26.

Figure 27: Where do you see the greatest additional benefits that would result from the implementation of Option 3? – Benefits for environment



Compared to the corresponding assessments of Option 2, stakeholders expect increased benefits from the implementation of Option 3. Our analysis confirms that Option 3 can be expected to have positive environmental impacts, to the extent that it clarifies the application of the general safety requirement to products containing environmentally harmful substances that indirectly may also pose a risk to human health and safety. Hazardous chemicals that are often being found in consumer products such as clothes/textiles, furniture, electrical appliances, furnishings and surfaces, childcare articles, sports and playground equipment, have the potential to adversely affect human health but are also harmful for the environment[270]. Numerous studies have shown that chemical emissions from consumer products affect the quality of indoor environment[271] and are to a large extent responsible for the exposure to air toxics given that consumers spend up to 90% of their time indoors[272]. Chemicals in consumer goods are also an environmental concern when products are discarded as they may pollute waste and end up in the environment or even worse, continue their life cycle through recycling.

As the effects of the presence of hazardous chemicals in consumer goods to the health and safety of consumers cannot be easily disentangled from their impact to the environment, a revision of GPSD that would contribute to the effective mitigation of chemical risks of consumer products to the health and safety of consumers can be assumed to have proportionately the same extent of positive impact for the environment. As an indication, under the current provisions of the GPSD, for the period 2013-2019 approximately 25% of the products notified in Safety Gate/RAPEX,

[270] EU Commission (2017), Study for the for the strategy for a non-toxic environment of the 7th Environment Action Programme final report, p. 11-16; ANEC and BEUC (2020), Views for a modern regulatory framework on Product Safety: Achieving a higher level of consumer safety through a revision of the General Product Safety Directive, p. 1-19, at: https://www.anec.eu/publications/position-papers/856-beuc-and-anec-views-for-a-modern-regulatory-framework-on-product-safety-achieving-a-higher-level-of-consumer-safety-through-a-revision-of-the-general-product-safety-directive.

[271] McDonald B.C. et al. (2018), "Volatile chemical products emerging as largest petrochemical source of urban organic emissions", *Science* 359, p. 760-764; Nematollahi, N., Kolev, S. D. & Steinemann, A. (2019). "Volatile chemical emissions from 134 common consumer products", *Air Quality, Atmosphere & Health* 12(11), pp. 1259-1265; Abbatt J. P.D. & Wang C. (2020), "The atmospheric chemistry of indoor environments", *Environmental Science: Processes and Impacts* 22, pp. 25-48.

[272] Joint European Environmental Agency and Joint Research Centre Report (2013), 'Environment and Human Health', p. 40; European Environmental Agency (2020), 'Safeguarding people from environmental risks to health' in *State of the Environment Report 2020*.

presented a chemical substance risk with adverse health effects to consumers[273]. The relevant chemicals were often also harmful to the environment (e.g. lead and mercury).

The improved effectiveness of product recalls that is expected to occur under Option 3 could also be expected to have a positive effect on the environment given that unsafe consumer products including chemical substances with adverse environmental effects will be among the products that will be more effectively recalled.

8.3.7. Summary assessment

The summary assessment of the option is presented in Table 66 below.

[273] See above section 4.3 regarding extend of adaptation of GPSD to environmental issues with health impact.

Table 66: Summary assessment of Option 3 compared to baseline situation

Area	Assessment
Effectiveness in achieving the policy objectives	
Ensure general safety rules, including for product risks linked to new technologies	++
Address safety challenges in the online sales channels	+ / ++
Make product recalls more effective	++
Enhance market surveillance and ensure better alignment of rules	++
Address safety issues related to food-imitating products	+ (++ if ban)
Administrative simplification	
Reduction of regulatory complexity and uncertainty	+
Economic impact	
Benefits for businesses	+ Benefits of EUR 59 million/year
Cost of businesses (EU27)	Cost increase by < EUR 197 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	+
Impact on consumers and households	
Consumer prices	neutral
Consumer choice	neutral
Consumer safety and vulnerable consumers	++ Benefits of EUR 1 038 million within the first year of implementation, increasing over the years with the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels. Additional benefits of EUR 410 million/year due to improved recall effectiveness
Impact on Member States	
Benefits for MSAs	++ Benefits of > EUR 0.7 million/year
Costs for MSAs (EU27)	Costs increase by < EUR 7 million/year
Other effects on Member States	+
Social impacts, impacts on fundamental rights and environmental impacts	
Social impacts	neutral / +
Impacts on fundamental rights	+
Environmental impacts	+

Note: Magnitude of impact as compared with the baseline scenario: neutral = no significant difference to baseline situation; + = positive impact compared to baseline; ++ = significant positive impact compared to baseline. An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

8.4. Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

Option 4 provides for a new legal instrument including all elements described under Option 3 and also merging the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products, so that one single set of rules would apply to market surveillance rules for both harmonised and non-harmonised products.

Table 67: Main policy actions related to Option 4: New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

Specific policy objectives	Description of policy actions
Ensure general safety rules, including for product risks linked to new technologies	This option would provide for a new legal instrument including all elements described under Option 3 and also merging the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products, so that one single set of rules for market surveillance would apply to harmonised and non-harmonised consumer products
Address safety challenges in the online sales channels	
Make product recalls more effective	
Enhance market surveillance and ensure better alignment of rules	
Address safety issues related to food-imitating products	

In the following analysis related to Option 4, we first assess the extent to which the suggested policy actions under Option 4 are likely to achieve the specific policy objectives listed above. We then present stakeholder views in this respect. Subsequently, we elaborate on the economic impacts, including on companies, consumers and households, as well as impacts on Member States. Finally, we analyse the expected social impacts, impacts on fundamental rights and environmental impacts of this option.

8.4.1. Effectiveness in achieving the policy objectives

8.4.1.1. Assessment by specific policy objective

The extent to which the option is expected to address the specific policy objectives is assessed in Table 68 below. The table is largely similar to the table presented regarding Option 3, as the policy measures foreseen are identical, and differences between the two options only concern the choice of legal instrument for the market surveillance rules. Differences with the assessment of Option 3 are underlined.

Table 68: Assessment of Option 4: New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

Specific policy objectives	Areas	Achievement of specific objectives (differences with the assessment of Option 3 are underlined)	Assessment
Ensure general safety rules, including for product risks linked to new technologies	*Certainty regarding coverage of new risks*	The revision of the definition of safety in the GPSD is expected to clarify that the covered risks arising from the product to the safety and physical/mental health of persons include not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect health. For harmonised products, there is relevant work ongoing in relation to the Radio Equipment Directive, the Machinery Directive, and the Low Voltage Directive. A similar provision in the GPSD will avoid any gaps in product coverage that may remain in this respect. This will create legal certainty for business operators and MSAs.	Legally binding clarifications will avoid uncertainty. The choice of a Regulation will avoid implementation differences in MS
	Certainty regarding coverage of software	A change in the definition of product in the GPSD will clarify that safety risks stemming from software updates and stand-alone software interacting with products are in the scope of the Regulation. This means that gaps regarding the coverage of software updates and stand-alone software interacting with products by the GPSD will be closed, and related uncertainty and diverging approaches in Member States avoided.	Gaps related to coverage of software by GPSD closed
Address safety challenges in the online sales channels	*Safety of products sold on online platforms*	The coverage of all online platforms by legal obligations similar to those in the Product Safety Pledge will improve accessibility of platforms for notice-and-take-down procedure, and increase consumer safety regarding products sold on platforms that are currently not covered by the Pledge. While safety risks for EU consumers due to products sold on online platforms could be partly reduced (and likely more so than under Option 2, as online platforms would have a duty of care), their mitigation will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of the platforms' duty of care and the further development of the EU legal framework, most notably the new DSA.	Safety risks for EU consumers due to products sold on online platforms could be partly reduced (and more so than under Option 2), with the effectiveness also depending on other factors
	Information of consumers on essential safety aspects	As businesses selling online to consumers will have to provide all safety information online that are also required 'offline', and marketplaces will be required to make sure that third party sellers provide this information, consumer information regarding essential safety aspects can be expected to be improved.	Achievement of objectives can be expected
Make product recalls more effective	*Reaching out to consumers affected by recalls*	As in Option 2, the clarification/creation of a legal basis for economic operators to use any available customer contact details at their disposal to directly notify the owners of recalled products – without the need of consumer consent – will contribute to effectively reaching out. The requirements for businesses to disseminate recall announcements on their website/social media and other appropriate channels to ensure the widest possible reach, would also contribute to this aim, although this is (especially regarding websites) frequently already done. The option that economic operators with product registration systems (e.g. for warranty or technical support) should offer consumers the possibility to register their contact details specifically to receive possible safety notifications and the possibility to set out (through implementing acts) further requirements for product registration and to determine categories of products subject to mandatory supply-side registration can further improve the outreach to consumers affected by recalls. The challenge for mandatory supply-side registration of products – which is expected to be limited to high-risk products as a measure of last resort – is to balance the related administrative burdens with the expected benefits in terms of consumer	The option can be expected to facilitate the use of available customer data and the increased collection of customer data for high-risk product categories, while avoiding that outreach measures are prevented by data protection concerns

		safety. It will therefore require a careful analysis of data on risks and injuries on a case-by-case basis, to safeguard the proportionality of the measure.	
	Information provided in recall notices	Binding requirement for economic operators to use a template for recall notices (annex of the Regulation) can be expected to lead to better and clearer information on recalled products, if enforced adequately.	Improvement in the information provided in recall notices is expected to be achieved
	Monitoring of recall effectiveness	Several requirements for businesses are foreseen in this area under Option 3, such as registering voluntary recalls in an EU public database and monitoring recall effectiveness; the possibility of MSAs to pre-approve proposed remedies and communication strategy before the recall for a dangerous product goes public; the possibility of MSAs to request monitoring data on the effectiveness of a product recall from economic operators. These measures are expected to increase the effectiveness of recalls, if appropriately implemented by MSAs.	Improvement in the effectiveness of recalls is expected to be achieved, also depending on implementation
	Remedies for consumers affected by recalls	Under this option, consumers' right to an effective, cost-free and timely remedy would be set out, so that existing, limited remedies for consumers affected by recalls will be improved and related detriment compensated.	Reduction of consumer detriment due to recalls expected
Enhance market surveillance and ensure better alignment of rules	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	Creating a single set of market surveillance rules that would apply to harmonised and non-harmonised consumer products will simplify the EU legal framework greatly. It can also be expected to improve traceability through clarification of related requirements and the requirement of an EU representative. It can be expected that the objective to create uniform requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products will be fully achieved. Whether the traceability of consumer products will improve in practice will also depend on enforcement of these requirements, and the extent to which measures will be taken to avoid that the obligation for an EU representative is not circumvented by rogue traders, including those that access EU consumers through online platforms.	Fully uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products expected to be achieved
	Deterrence effect	Under this option, stronger enforcement powers (in addition to the ones in Chapter V of Regulation (EU) 2019/1020 on market surveillance and compliance of products) will be incorporated in the GPSD, such as penalties and sanctions.	Deterrence effect likely to be achieved, depending on the maximum levels of penalties and sanctions foreseen
	Diverging risk assessments by Member States' MSAs	According to Option 3, in case Member States have diverging assessments of the risk posed by a notified product (a major point of criticism by stakeholders), a mechanism could be triggered where either a group of Member States or the Commission are called to arbitrate. This could apply for the close to 30 cases each year in which Safety Gate/RAPEX notifications are subject to dispute by notifying Member States, and formalise procedures that currently require informal agreement	Risk assessments are likely to become more harmonised, achieving the desired effect
	Simplification of standardisation procedures	Simplification of standardisation procedures at the Commission level under the GPSD can be expected to increase the efficiency of the process, and possibly reduce the time for the overall standardisation process.	Simplification of standardisation procedures is expected to be achieved
Address safety issues related to food-imitating products	*Addressing risks of food-imitating products*	The provisions of the Food-imitating Products Directive will be integrated in the new Regulation. Specific types of products that could be confused with real food by vulnerable consumer groups such as children, could be banned throughout the Union. A ban would simplify enforcement of safety regarding food-imitating products, as there will be no need to conduct risk assessment for each specific product. However, consumer harm due to food-imitating products would need to be evidenced to safeguard the proportionality of the measure (again, two sub-options are possible, see Option 3).	While a ban would be an effective measure to achieve objective, the degree to which it is justified by evidence of consumer harm is unclear. Also, a ban might not be proportionate

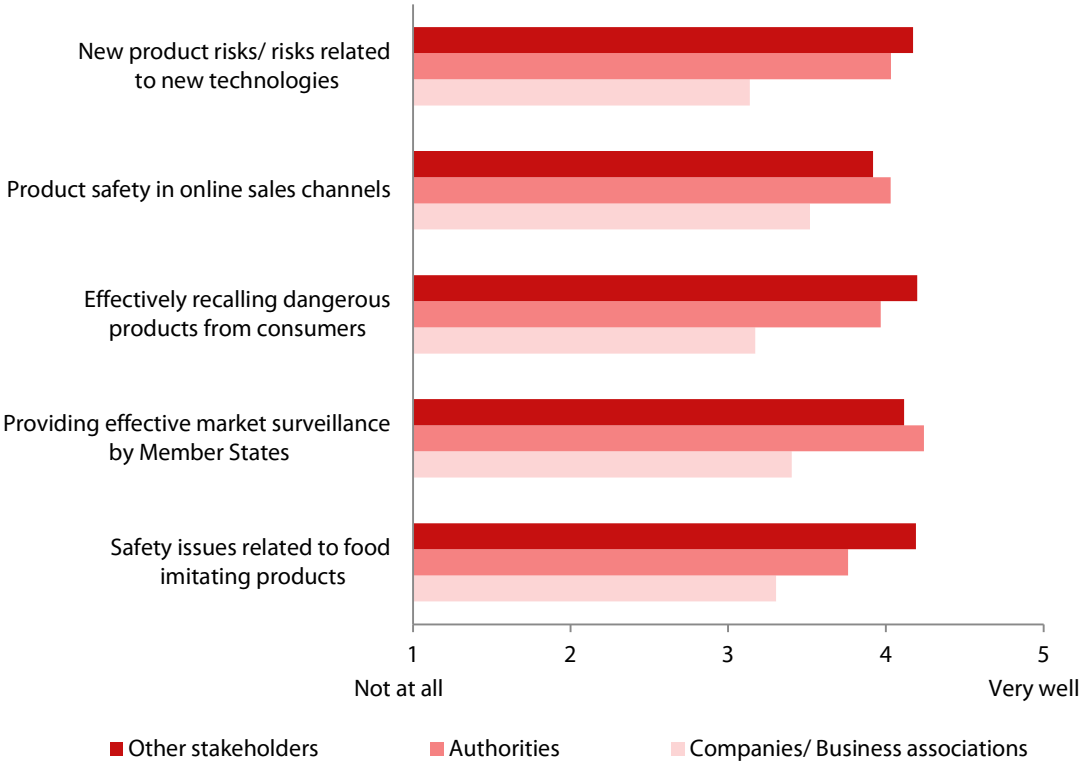
8.4.1.2. Stakeholder views on Option 4

In the stakeholder survey, we asked businesses/business associations, MSAs and other stakeholders to what extent they consider Option 4 to effectively address five challenges, reflecting the five policy objectives of a possible revision of the GPSD:

- Ensure general safety rules, including for product risks linked to new technologies
- Address safety challenges in the online sales channels
- Make product recalls more effective
- Enhance market surveillance and ensure better alignment of rules
- Address safety issues related to food-imitating products

All stakeholder groups considered that Option 4 addressed all challenges at least moderately well. MSAs and other stakeholders were most positive, and found on average that this option well addressed all challenges with averages of 4 and 4.1 respectively (on a scale of 1 to 5). However, companies and business associations were less positive (with an average assessment of 3.3 across all five challenges). Overall, the average assessment across all stakeholder groups was 3.8. This is similar to Option 3, in line with the fact that both options provide identical policy measures, but are implemented with differing legislative approaches.

Figure 28: In your view, to what extent would Option 4 effectively address the following challenges for product safety? Please assess.



8.4.2. Potential for administrative simplification

Due to the inclusion of all elements from Option 3, Option 4 would for the most part have similar implications on administrative costs of businesses and MSAs as Option 3 (see benefits of businesses and MSAs). In addition, a single set of rules to apply for market surveillance and compliance of harmonised and non-harmonised consumer

products in the EU could, overall, result in even less legal complexity. This could translate to simplifications for businesses and MSAs in countries where current national law implements the GPSD and harmonised product legislation in different legal instruments. Where all product safety legislation is already transposed into a single product safety law, comprising relevant EU legislation for both harmonised and non-harmonised products (which is the case in some countries), simplifications through a new EU legal instrument that includes all elements described under Option 3 and also merges the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products are likely to be very limited.

On the other hand, Option 4 would include some additional administrative requirements for specific types of operators (identical to Option 3, and not repeated here).

8.4.3. Economic impacts

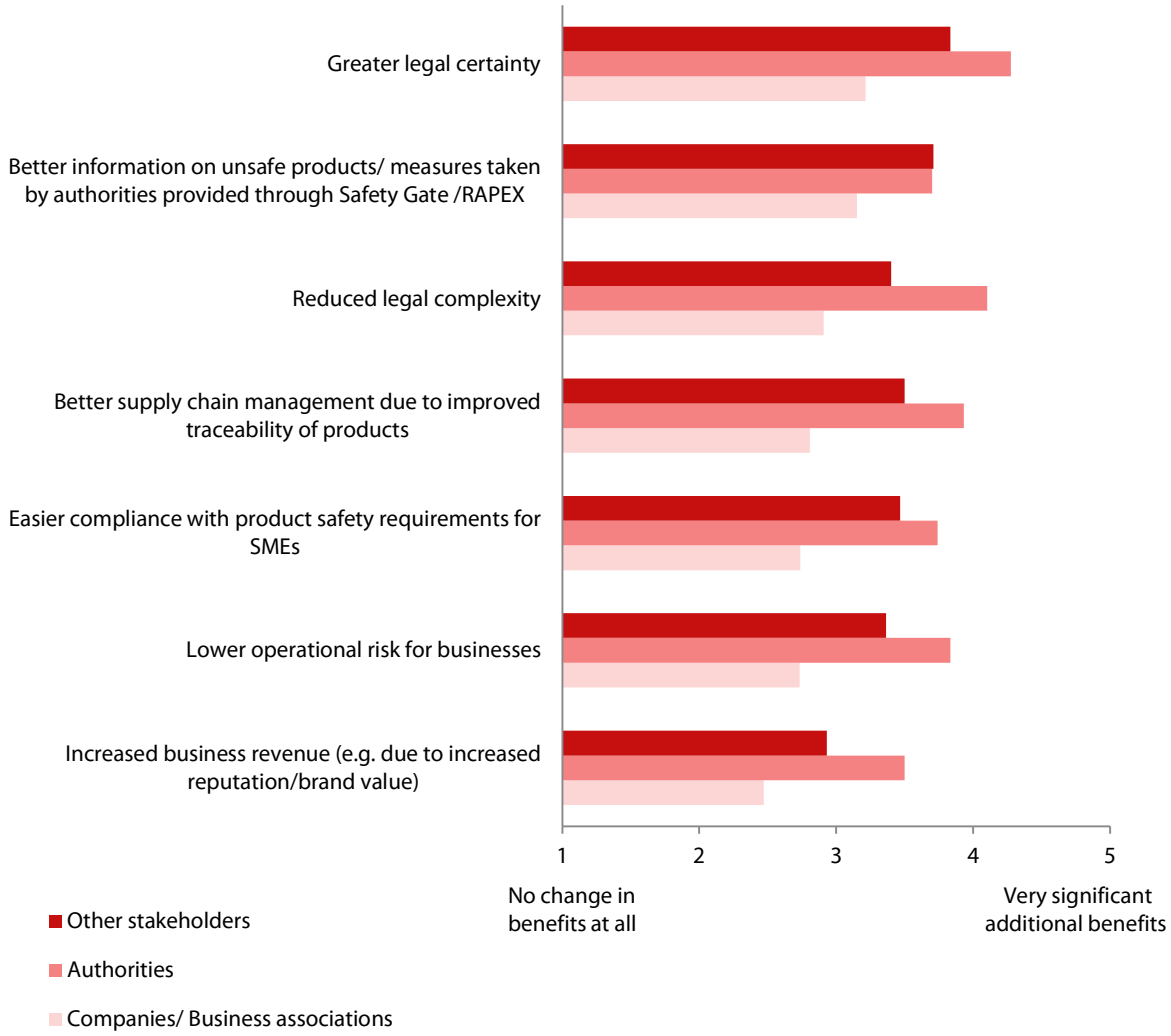
The following section outlines the economic impacts for businesses that are likely to result from the implementation of Option 4, focusing first on benefits and costs to be expected.

8.4.3.1. Benefits for businesses

As outlined in the baseline, businesses currently incur additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). These are estimated to amount to 119 million EUR annually (see section 7.1.3 above, Table 28). As Option 4 foresees the adoption of a new regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020, implementation differences under Option 4 would be avoided at the legislative level (due to the direct applicability of the new regulation in Member States). However, as is the case under Option 3, it can be expected that some differences in the national interpretation of rules will remain. Accordingly, we do not expect a full reduction of businesses' additional costs that currently accrue due to implementation differences in Member States, but assume a 50% reduction of businesses' additional costs, similar as in Option 3 (see Table 56 above). Option 4 would therefore also be expected to result in benefits for businesses (cost savings compared to the baseline) of 59 million EUR annually, of which 34 million EUR would be saved by EU SMEs and 26 million EUR saved by EU large businesses respectively.

The results of the stakeholder survey regarding benefits of Option 4 for businesses are presented in Figure 29 (some of the benefits are also relevant for MSAs).

Figure 29: Where do you see the greatest additional benefits that would result from the implementation of Option 4? – Direct benefits for businesses



MSAs expect on average considerably more benefits that would result from an implementation of Option 4 than businesses/business associations and other stakeholders. Overall, MSAs assessed a value of 3.9, or very close to 'significant' benefits. MSAs especially expect 'significant' benefits from greater legal certainty and reduced legal complexity (values of 4.3 and 4.1 respectively). Also other stakeholders see this option bringing 'moderate' to 'significant' benefits (average 3.5). Businesses are more sceptical, and see slightly less than 'moderate' benefits on average (2.9). It is notable that the expected benefits of Option 4 are considered to be slightly higher across stakeholder groups, than benefits of Option 3 (with 0.1 to 0.2 assessment levels difference).

8.4.3.2. Costs of businesses

Due to the inclusion of all elements from Option 3, Option 4 would have similar implications on businesses' administrative procedures as Option 3. At the same time, many businesses appear to expect additional costs from Option 4 and the aim to have one single set of rules that would apply to harmonised and non-harmonised products. This is reflected by the expected increases in businesses' recurrent as well as one-off costs, which go beyond the expected costs under Option 3.

Recurrent costs

Businesses' survey responses indicate that implementing Option 4 would overall increase companies' recurrent regulatory compliance costs. As is the case in the previously assessed option, the largest increases would be borne by manufacturers of consumer products, which compared to distributors have to adjust different stages of the value-adding process to new regulatory requirements.

Comments made by businesses indicate that respondents were generally uncertain about the precise implications of Option 4. Respondents often referred to Option 3 with regard to potential implications for their businesses. At the same time, respondents' estimates for changes in recurrent costs indicate that many businesses expect higher costs from Option 4, reflecting a pattern among businesses to rather err on the side of caution with regard to additional costs from the new regulatory obligations from Option 4 (see detailed discussion below).

Similar to the approach described before, our estimation of changes in EU businesses' recurrent costs is based on company respondents' estimates regarding the extent to which recurrent costs to comply with safety requirements for consumer products would increase. We applied the estimated changes in recurrent (annual) costs to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (see section 7 for the baseline estimates). The sample statistics are provided in Table 69 below.

Table 69: Sample statistics of businesses' estimated change in recurrent costs in product safety-related costs under Option 4 (as percentage of recurrent costs to comply with safety requirements for consumer products)

Sample statistics	Full sample of business respondents, change of recurrent costs
Count	22
Min	-5.00%
Max	100.00%
Average	22.55%
Q1	0.00%
Q2 (median)	**5.00%**
Q3	47.50%
Q1 to Q3 (middle 50% of values)	0.00% - 47.5%

Applying the sample median of 5.00% (see Table 69) as best estimate for the extent to which recurrent costs would increase under Option 4 to the estimated annual consumer product safety-related costs of EU businesses, results in additional annual cost of EUR 186.2 million for EU manufacturers, EUR 46.5 million for EU wholesalers and EUR 63.6 million for EU retailers (see Table 70).

Table 70: Estimated changes in EU businesses' annual recurrent costs, EU total under Option 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	42.7	54.8	88.7	**186.2**

Total wholesale sectors	17.1	11.8	17.6	**46.5**
Total retail sectors	33.6	6.4	23.7	**63.6**
Total additional recurrent costs	***93.4***	***72.9***	***130.0***	***296.3***

One-off costs

Businesses need additional staff time for the implementation of new policy measures. Businesses are also confronted with additional non-staff costs, e.g. costs arising from external support for changes to IT systems, staff training etc. The estimation of EU businesses' total one-off costs is based on individual respondents' estimates for the total additional staff needed and the total additional non-staff costs that arise from familiarisation and implementation efforts under Option 4. Based on the respondents' estimates, we calculated staff costs in Euro terms and added other costs, using the approach described before. The total one-off costs for each company were divided by the EU turnover for consumer products, i.e. we expressed companies' total additional one-off costs resulting from activities to comply with safety requirements for consumer products under Option 4 as a share of the related turnover. Sample statistics are provided in Table 71.

Table 71: Sample statistics of businesses' estimated one-off costs under Option 4 as percentage share of annual EU turnover from consumer products (total of additional staff and additional non-staff costs)

Sample statistics	Full sample of business respondents, one-off costs
Count	17
Min	0.00%
Max	2.75%
Average	0.53%
Q1	0.00%
Q2 (median)	**0.0016%**
Q3	0.08%
Q1 to Q3 (middle 50% of values)	0.00% - 0.08%

Applying the sample median of 0.0016% to the estimated annual turnover for manufacturing, wholesale and retail of consumer products in the EU results in additional one-off cost of EUR 9.8 million for EU manufacturers, EUR 10.6 million for EU wholesalers and EUR 14.4 million for EU retailers (see Table 72).

Table 72: Estimated changes in EU businesses' one-off costs, EU total under Option 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Total manufacturing sectors	2.3	2.9	4.7	**9.8**
Total wholesale sectors	3.9	2.7	4.0	**10.6**
Total retail sectors	7.6	1.4	5.4	**14.4**

Total additional one-off costs	***13.8***	***7.0***	***14.0***	***34.8***

Total costs

Absolute changes in one-off and recurrent costs within the first year of the implementation of Option 4 as well as absolute changes in annual recurrent costs after the first year of the implementation of Option 4 are outlined in Table 73 (below). Total costs of businesses in the EU27 in the first year of implementation are estimated at EUR 331.1 million, equivalent to 0.03% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in subsequent years to EUR 296.3 million.

Table 73: Changes in EU companies' costs within and after the first year of implementation of Option 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	45.0	57.7	93.4	**196.0**
Total wholesale sectors	21.0	14.5	21.6	**57.0**
Total retail sectors	41.2	7.8	29.0	**78.0**
Total additional costs	***107.2***	***79.9***	***144.0***	***331.1***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	42.7	54.8	88.7	**186.2**
Total wholesale sectors	17.1	11.8	17.6	**46.5**
Total retail sectors	33.6	6.4	23.7	**63.6**
Total additional costs	***93.4***	***72.9***	***130.0***	***296.3***

Note: Estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in recurrent and one-off costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

Costs from Option 4 are therefore expected by businesses to be higher compared to Option 3 (which provides identical policy measures). A possible explanation for this is that businesses tend to provide cautious estimates with regard to additional costs from new regulatory obligations that might arise if one single set of rules would apply to harmonised and non-harmonised products. Some respondents highlighted that changing Regulation (EU) 2019/1020 so quickly could have considerable implications on costs. For example, a company stated that the impacts of Option 4 would be the same as under Option 3, but "adding the disruption of well-functioning legal frameworks and muddying the waters between harmonized and non-harmonized products". Another respondent pointed out that "such integration of different legal instruments so soon after the revision of the market surveillance regulation will lead to disruption in company structures and procedures without any guarantee of additional benefits. We also expect the revision to take much longer, therefore delaying the positive effects of the revised legislation".

8.4.3.3. Firm level impacts for specific types of operators

Other than the increased costs discussed in the previous section, impacts on SMEs, online marketplaces, online traders in general, and producers and distributors of food-imitating products, are expected to be similar to the impacts under Option 3.

8.4.3.4. Macroeconomic impacts

Impacts on internal market, trade, competition and innovation are expected to be identical to the impacts under Option 3.

8.4.4. Impact on consumers and households

Impacts on consumers and households are expected to be identical to the impacts under Option 3.

8.4.5. Impacts on Member States

8.4.5.1. Benefits for MSAs

Option 4 would generally result in the same benefits as Option 3 regarding savings in terms of the resources needed to conduct market surveillance activities for both harmonised and non-harmonised consumer products, and related improvements in efficiency due to aligning the legal framework.

8.4.5.2. Costs for MSAs

In the following sub-sections, we analyse recurrent and one-off costs of MSAs under Option 4.

Recurrent costs

Asked about the extent to which MSAs consider that the implementation of Option 4 would change their recurrent costs, nine MSAs reported that their recurrent costs would increase, 10 MSAs reported that costs would remain the same and two MSAs reported that costs would likely decrease. Most MSAs did not comment on the nature of changes in recurrent costs.

In total, 15 of the MSAs provided estimates regarding the percentage changes in recurrent costs if Option 4 was implemented, compared to current cost related to market surveillance of consumer products (see Table 74 for sample statistics).

Table 74: MSAs' estimated changes in recurrent costs, Option 4

Sample statistics	Increase in recurrent costs
Number of responses	15
Min	-80.0%
Max	50.0%
Average	4.0%
Q1	0.0%
Q2 (median)	**0.0%**
Q3	5.0%
Q1 to Q3 (middle 50% of values)	0.0% - 5.0%

More than half of those MSAs that provided cost estimates do not expect increases in recurrent cost, which is reflected by a median cost estimate of 0.00%. At the same time, a significant minority of MSAs expect cost increases (roughly one quarter of the respondents that provided quantitative assessments), which is reflected by the third quartile value (Q3) value of a 5.0% increase in recurrent costs. Assuming that for one quarter of MSAs in the EU, Option 4 would bring an increase in recurrent costs of 5% of total annual staff-related costs, this would imply total additional costs of MSAs in the

EU27 of approx. EUR 3.3 million annually. For the remaining MSAs, we expect that costs remain the same, in line with the distribution of the quantitative estimates. As indicated before, actual percentage changes would differ for individual MSAs due to different national institutional market surveillance systems and organisational characteristics, e.g. the degree of centralisation, MSAs' product coverage and, after all, the actual assignment of new competences and enforcement requirements.

One-off costs

Asked about the extent to which MSAs expect that the implementation of Option 4 would lead to changes in one-off costs, five MSAs report "no additional costs", while eight MSAs expect additional costs of which five MSAs expect "significant additional costs", without further explanation. An MSA that expects significant additional one-off costs explained that this is "due to [the] necessity to adapt national legislation to new rules. It would be needed to prepare some national guidance, new communication strategy and to strengthen cooperation at the national level. Other aspects would be e.g. organisation of trainings for MSA and all other stakeholders."

Empirical quantitative data on changes in one-off costs from Option 4 are rare. Due to the low number of responses from MSAs that provided numerical estimates (two MSAs) and different institutional characteristics, these data cannot be extrapolated to the EU level. However, the few numbers that were provided by MSA respondents indicate that the one-off adaption and implementation costs are considered to be relatively low.

8.4.5.3. Other effects on Member States

The proposed measures would align the enforcement powers of MSAs regarding non-harmonised products with their powers for certain categories of harmonised products under Regulation (EU) 2019/1020 in the form of one unified set of rules. As is the case under Option 3, specific gaps such as legal difficulties to conduct mystery shopping for authorities in some Member States would be addressed, and the deterrence effect on rogue traders increased through penalties and sanctions. The efficiency of market surveillance processes with cross-border implications in the EU would be increased. As a mechanism for arbitration would be created for cases of divergences in the product safety risk assessment between authorities, disputes due to divergent risk assessments of MSAs could be more efficiently settled.

8.4.6. Social impacts, impacts on fundamental rights and environmental impacts

As the measures implemented under Option 4 are identical to the measures implemented under Option 3, the two options are expected to have identical impacts in a social or environmental perspective, as well as on fundamental rights.

8.4.7. Summary assessment

The summary assessment of the option is presented in Table 75 below.

Table 75: Summary assessment of Option 4 compared to baseline situation

Area	Assessment
Effectiveness in achieving the policy objectives	
Ensure general safety rules, including for product risks linked to new technologies	++
Address safety challenges in the online sales channels	+ / ++
Make product recalls more effective	++
Enhance market surveillance and ensure better alignment of rules	++
Address safety issues related to food-imitating products	+ (++ if ban)
Administrative simplification	
Reduction of regulatory complexity and uncertainty	+ / ++
Economic impact	
Benefits for businesses	+ Benefits of EUR 59 million/year
Cost of businesses (EU27)	Costs increase by < EUR 332 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	+
Impact on consumers and households	
Consumer prices	neutral
Consumer choice	neutral
Consumer safety and vulnerable consumers	++ Benefits of EUR 1 038 million within the first year of implementation, increasing over the years with the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels. Additional benefits of EUR 410 million/year due to improved recall effectiveness
Impact on Member States	
Benefits for MSAs	++ Benefits of > EUR 0.7 million/year
Costs for MSAs (EU27)	Costs increase by < EUR 4 million/year
Other effects on Member States	+
Social impacts, impacts on fundamental rights and environmental impacts	
Social impacts	neutral / +
Impacts on fundamental rights	+
Environmental impacts	+

Note: Magnitude of impact as compared with the baseline scenario: neutral = no significant difference to baseline situation; + = positive impact compared to baseline; ++ = significant positive impact compared to baseline. An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

8.5. Effects of the COVID-19 crisis in the context of the policy options and their expected impacts

As mentioned before, our analysis of the impact of COVID-19 is based on macroeconomic data and a series of interviews conducted with companies producing/selling (also) non-harmonised consumer products (see section 7.4). Next to discussing the baseline situation (i.e. current impacts on their companies), we also explored the views of interviewees on the policy options and potential effects of COVID-19 in this respect, as well as expectations concerning relevant long term, structural changes. In terms of structural changes that would need to be considered for changes in the EU legislative framework in general, interviewees expected:

- A change in consumer behaviour towards more quality products that are also more eco-friendly;
- Energy efficiency will be an important topic and people will likely buy more sustainable and environmentally friendly products;
- Promoting the reuse, refurbishment and recycling of used products may need to be addressed by the GPSD;
- A stronger focus on hygiene is expected, and the safety of these products will have a more prominent role for consumers.

Furthermore, in the short-term, interviewees expected practical difficulties in conducting market surveillance for authorities due to COVID-19 restrictions. An interviewee noted that COVID-19 had led to a reduction in controls. Accordingly, this interviewee considered that the need for a clearer GPSD has increased as it would help conducting market surveillance more effectively in the 'new normal' with less visits of inspectors.

Interviewees also expected in the medium-term to long-term that reduced public budgets (due to potential austerity measures after the pandemic) would mean that the downward trend in market surveillance capacities in Member States that they had noted after the financial crises would continue. According to their view, this would increase the need for a less complex legal framework and a (resulting) more efficient market surveillance, more efficient recall procedures, and increased support through EU programmes.

Concerning the impacts of the options for a possible revision of the GPSD, interviewees emphasised the overall impact of COVID-19 on the baseline situation, i.e. the increased importance of e-commerce, including with third countries, which was expected to put additional demands on authorities in terms of online market surveillance. Safety of products sold online is therefore expected by interviewees to become more important, which would make Options 3 and 4 (and especially the suggested changes regarding online sales and online marketplaces) more relevant. All interviewees stressed the importance of having a common set of rules in the EU, and of reducing administrative burdens, e.g. to explore differences in legislation between countries. Interviewees also emphasised that good guidance would help in decision-making of companies.

Based on the interviews and the analysis presented in previous sections, it can therefore be concluded that the COVID-19 crisis has increased the need for reducing existing, and avoiding additional administrative burdens, while the expected growing importance of online sales channels has emphasised the need to address related challenges for product safety.

8.6. Comparison of options

In this section, we present the results of the impact assessment, by horizontally comparing all four options, considering stakeholder views on the options, the expected achievement of objectives, administrative simplification, economic impacts, impacts on consumers and households, impacts on Member States as well as social impacts, impacts on fundamental rights and environmental impacts.

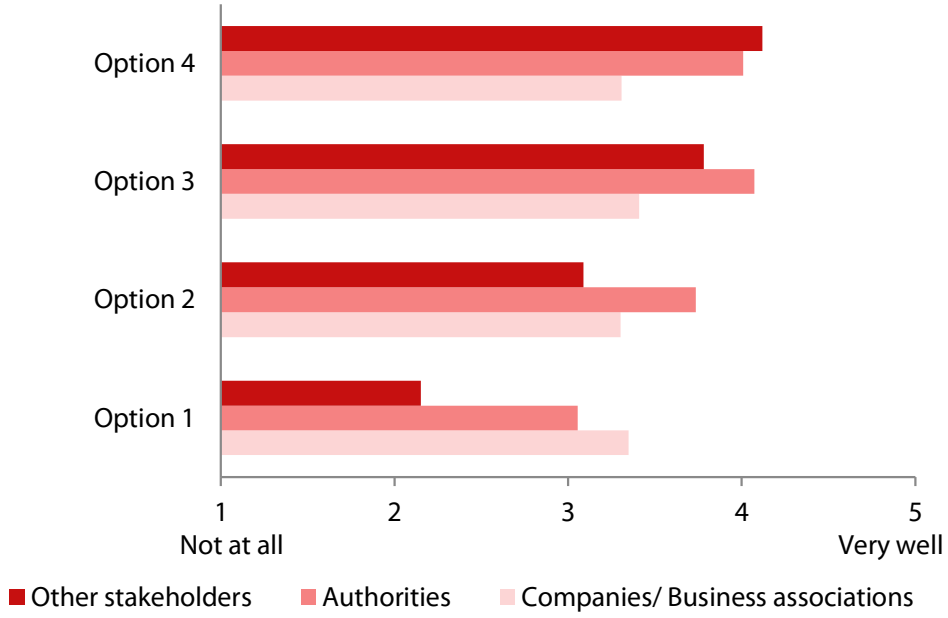
8.6.1. Stakeholder views on options

For each of the four options discussed in sections 8.1 to 8.4, we presented the assessment by stakeholders regarding the extent to which the option would effectively address each of the following five challenges for product safety (on a scale of 1 to 5, from 'not at all' to 'very well'):

- Ensure general safety rules, including for product risks linked to new technologies
- Address safety challenges in the online sales channels
- Make product recalls more effective
- Enhance market surveillance and ensure better alignment of rules
- Address safety issues related to food-imitating products

Figure 30 below combines the assessments provided by each stakeholder group for each option (i.e. presents a total score, calculated as average of the assessments regarding the five listed challenges).

Figure 30: In your view, to what extent would Option [...] effectively address the following challenges for product safety? – Average across all challenges, by stakeholder group

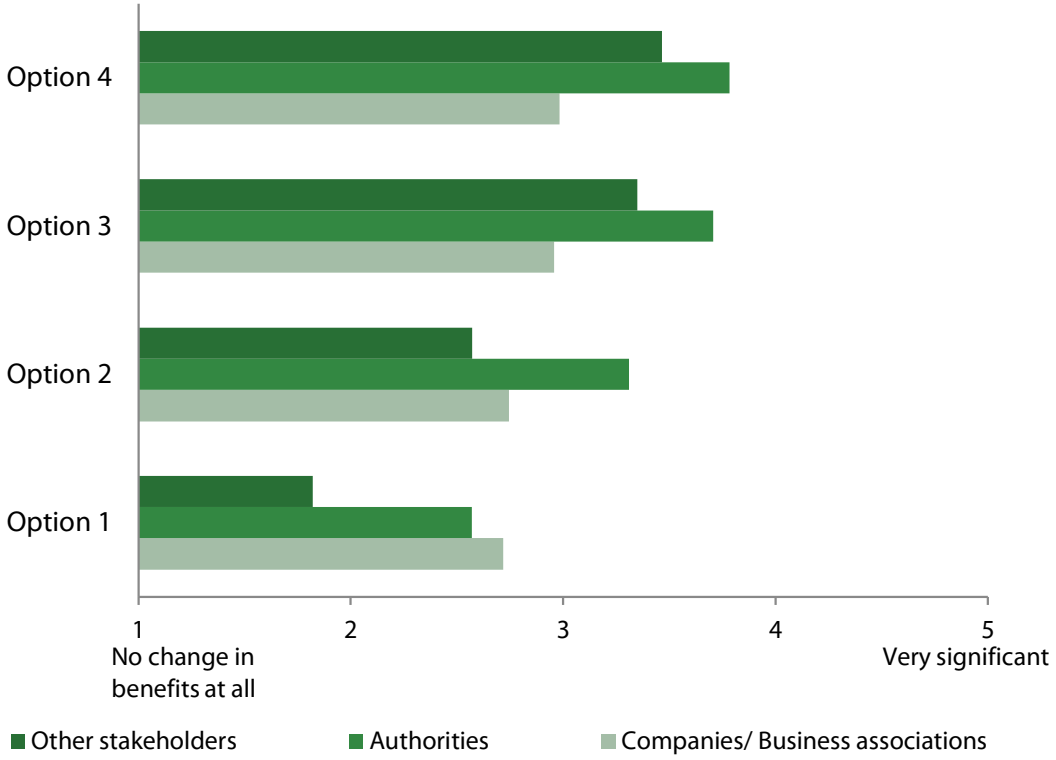


As Figure 30 illustrates, authorities and other stakeholders assessed Options 3 and 4 as being most effective, and considered them to well address the challenges (for authorities, this assessment was similar for both options, other stakeholders assessed Option 4 as slightly more effective). In contrast, average assessments by companies/business associations do not show a considerable variation between the options, and consider all four options to slightly better than 'moderately well' address

the challenges. When considering the views of companies (including SMEs) and business associations separately, the picture is, however, slightly different. Companies overall, as well as SMEs as specific sub-group, assessed Options 3 and 4 as being most effective, and considered them to 'moderately' to 'well' address the listed challenges. In contrast, average assessments by business associations consider Options 1 and 2 to be most effective. As a result, the overall assessment of business stakeholders (when put together) does not show a considerable variation between the options. For more details, see Figure 33 in Annex IX.

The picture is relatively similar when considering the summary assessment of the three stakeholder groups regarding the expected benefits that would result from the implementation of each option, compared to the baseline (Figure 31).

Figure 31: Where do you see the greatest additional benefits that would result from the implementation of Option […]? – Average across all benefit categories, by stakeholder group



Again, Options 3 and 4 are seen as providing most benefits. Authorities see the highest level of benefits for these options (close to 'significant'), whereas other stakeholders assess these benefits on average between 'moderate' and 'significant'. Companies/business associations find the benefits of Options 3 and 4 to be 'moderate' on average, but still clearly more beneficial than Options 1 and 2[274]. The reasons for these differences between the assessment of the four options are that all stakeholder groups, including businesses, see higher benefits under Options 3 and 4 especially regarding the following benefit dimensions (listed according to average ranking, highest on top)[275]:

[274] In general, business associations tend to see less benefits across all options, than companies overall, as well as SMEs as specific sub-group.

[275] Listed are all benefits which in our surveys achieved an average assessment regarding Options 3 and 4 above 'moderate' (3) in all three stakeholder groups.

- Better functioning EU internal market
- Reduced occurrence of products with health and safety risks
- Greater legal certainty
- More level playing field among businesses
- Reduced number of accidents/injuries caused by unsafe products
- Better information on unsafe products/ measures taken by authorities provided through Safety Gate /RAPEX
- Deterrent effect on rogue traders

8.6.2. Achievement of objectives

In sections 8.1 to 8.4 we have assessed the extent to which the options can be expected to achieve the specific policy objectives, based on the results of the evaluation of the GPSD (Part 1 of this report) and considering the problem analysis presented in section 4. The following Table 76 summarises the results of the assessment.

Table 76: Summary assessment of Options 1 to 4 – effectiveness in achieving policy objectives

Area	Option 1	Option 2	Option 3	Option 4
Ensure general safety rules, including for product risks linked to new technologies	neutral / +	+	++	++
Address safety challenges in the online sales channels	neutral	neutral / +	+ / ++	+ / ++
Make product recalls more effective	neutral	neutral / +	++	++
Enhance market surveillance and ensure better alignment of rules	neutral	++	++	++
Address safety issues related to food-imitating products	+	+	+ (++ if ban)	+ (++ if ban)

Table 76 above shows that Option 1 is unlikely to be adequate to address the problems identified, although uncertainty for businesses and MSAs will be reduced due to guidance provided by the Commission, and the coverage of online platforms is expected to increase through the promotion of Product Safety Pledge. However, safety risks for consumers due to products sold on online platforms are expected to continue. Option 1 would be expected to achieve the last policy objective, namely to address safety issues related to food-imitating products by aligning of the regime of the Food-imitating Products Directive with the GPSD regime and providing clarifications regarding the risks that have to be taken into account.

Option 2 is likely to be partially adequate to address the identified problems. Gaps will remain regarding the coverage of stand-alone software, and implementation differences in Member States will likely remain. While safety risks for EU consumers due to products sold on online platforms could be partly reduced, their mitigation will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs, and the further development of the EU legal framework, most notably the new Digital Services Act (DSA).

In contrast, Option 3 is mostly adequate to address the problems identified. Gaps regarding the coverage of stand-alone software will be closed, and implementation

differences will be avoided through the choice of a Regulation. However, while safety risks for EU consumers due to products sold on online platforms could be partly reduced (and likely more so than under Option 2, as online platforms would have a duty of care), their mitigation will also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of the platforms' duty of care and the further development of the EU legal framework, most notably the new DSA. Option 3 would be similar to Option 1 and 2, if the regime of the Food-imitating Products Directive will be aligned with the GPSD regime, i.e. constitute of a risk assessment that considers the character of a product (including features that imitate food or are specifically child-appealing). The safety objective would most clearly be achieved through a ban of food-imitating products, but questions of proportionality of this measure remain (see below).

Finally, Option 4 is also considered to be mostly adequate to address problems, with the same reasoning that is provided for Option 3, due to the fact that the suggested policy measures under Option 3 and 4 are identical. Differences between both options mostly concern the legislative approach chosen, which affects administrative simplification rather than achievement of objectives (see following section).

8.6.3. Administrative simplification

Table 77 summarises the results of the assessment presented in sections 8.1 to 8.4 regarding administrative simplification, i.e. the extent to which the proposed measures have the potential to reduce regulatory complexity and uncertainty, thereby reducing administrative burdens.

Table 77: Summary assessment Options 1 to 4 – administrative simplification

Area	Option 1	Option 2	Option 3	Option 4
Reduction of regulatory complexity and uncertainty	neutral / +	neutral / +	+	+ / ++

Under Option 1, a slight reduction of regulatory complexity and uncertainty can be expected through the provision of guidance. Also, no new administrative requirements are foreseen that would affect specific types of operators or recall procedures. However, administrative burdens due to the current fragmentation of the legal regime for market surveillance of harmonised and non-harmonised products (experienced by 16% of MSAs that responded) and also due to differences in the implementation GPSD in Member States (experienced by 42% of companies that responded to our cost survey) would continue to remain[276].

The picture is relatively similar concerning Option 2, with some reduction of regulatory complexity and uncertainty to be expected, especially if a regulation was chosen as legal instrument. Implementation differences between MS would be expected to remain if a directive was chosen as legal instrument. Only very limited additional administrative requirements for specific operators are foreseen.

Under Options 3 and 4, the reduction of regulatory complexity and uncertainty is considered to be more significant, as all identified regulatory gaps would be closed.

[276] See Figure 11. Companies had been asked as follows: "The EU legal framework for product safety contains different provisions for market surveillance depending on whether the product is harmonised or non-harmonised. To what extent do you [currently] incur additional costs due to this situation?" The figure of 42% refers to those respondents that reported to incur minor to significant additional costs.

General requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products, and implementation differences in Member States would be reduced, which is likely to contribute to reduced regulatory complexity and thereby to reduced administrative burdens for businesses. On the other hand, Options 3 and 4 would include some additional administrative requirements for specific types of operators: This includes the requirement for online sellers to provide all safety information online that is also required to be provided with a product in "brick-and-mortar" stores, and several requirements that aim at improving the effectiveness of recalls. These refer e.g. to the possibility to set out further requirements for product registration, the requirement for businesses to register voluntary recalls in an EU public database, the use of a template for recall notices and consumers' right to an effective, cost-free and timely remedy. While these requirements likely lead to related administrative burdens, they would mostly affect those companies that have brought unsafe products on the market and therefore have to recall products from consumers. As currently the limited effectiveness of recalls leads to considerable consumer detriment, these additional measures and the related administrative burdens appear to be proportionate.

Option 4 would largely be similar to Option 3 in terms of reduction of regulatory complexity and uncertainty. However, as one single set of rules would apply to harmonised and non-harmonised products, simplification could be expected to be more significant. This could translate to simplifications for businesses and MSAs in countries where current national law implements the GPSD and harmonised product legislation in different legal instruments. Where all product safety legislation is already transposed into a single product safety law, comprising relevant EU legislation for both harmonised and non-harmonised products (which is the case in some countries), simplifications through a new EU legal instrument that includes all elements described under Option 3 and also merges the market surveillance provisions of the GPSD and Regulation (EU) 2019/1020 on the market surveillance and compliance of products are likely to be very limited.

8.6.4. Economic impacts

The following table (Table 78) summarises the results of the assessment presented in sections 8.1 to 8.4 regarding the economic impacts for companies, and potential macroeconomic impacts.

Table 78: Summary assessment of Options 1 to 4 – economic impacts

Area	Option 1	Option 2	Option 3	Option 4
Benefits for businesses (EU27)	neutral / +	neutral / + (Benefits of EUR 59 million/year, if Regulation)	+ Benefits of EUR 59 million/year	+ Benefits of EUR 59 million/year
Cost of businesses (EU27)	neutral	Costs increase by < EUR 37 million/year	Costs increase by < EUR 197 million/year	Costs increase by < EUR 332 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral	neutral / +	+	+

As indicated in the table above, benefits for businesses are expected to be minor under Option 1, mostly related to reduction of uncertainty due to guidance. Benefits of Option 2 depend on whether the new legal instrument is a Directive or a Regulation. If a revised GPSD under Option 2 would be recast as a Regulation, implementation differences would be avoided at the legislative level (due to the direct applicability of the new regulation in Member States). In this case, benefits for businesses (cost savings compared to the baseline) of 59 million EUR annually are expected. In case that a revised GPSD would remain a Directive, we would still consider it likely that implementation differences would be somewhat reduced (as certain aspects would be clarified in the wording of the new Directive), but less so than if it was implemented as Regulation. Benefits for businesses under Options 3 and 4 in terms of avoidance of implementation differences between Member States are similar to Option 2 (if implemented as a Regulation), i.e. are expected to lead to savings of EUR 59 million/year.

Other benefits are also expected under Options 3 and 4, as all legislative gaps identified in the problem analysis are closed and related uncertainty is avoided. The measures taken regarding online sales (including through platforms) contribute to safeguarding a level playing field for businesses and the deterrence of rogue traders, which are expected to have concrete benefits at firm level, especially in those areas where consumer trust and safety are affected by unsafe products entering the EU through direct online B2C transactions. These benefits can, however, not be quantified.

As Options 2 to 4 include legislative measures, they will lead to adaption and compliance costs for businesses. Our estimates regarding these costs are provided in Table 79 for all four policy options.

Table 79: Changes in EU companies' annual costs within and after the first year of implementation of Options 1 to 4, EU27, in million EUR

	Option 1	Option 2	Option 3	Option 4
First year of implementation (total of one-off and recurrent costs)				
Manufacturing sectors	0	20.7	17.0	196.0
Wholesale sectors	0	6.9	33.6	57.0
Retail sectors	0	9.4	46.0	78.0
Total additional costs (EU27)	***0***	***36.9***	***196.6***	***331.1***
Subsequent years (recurrent costs only)				
Manufacturing sectors	0	18.6	111.7	186.2
Wholesale sectors	0	4.7	27.9	46.5
Retail sectors	0	6.4	38.2	63.6
Total additional costs (EU27)	***0***	***29.6***	***177.8***	***296.3***
Equivalent to the share of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products (first year of implementation):				
Share in turnover	***0%***	***0.004%***	***0.02%***	***0.03%***

Note: for detailed results and methodology, see sections 8.1 to 8.4. Note that the estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in recurrent and one-off costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

The table shows that changes in compliance costs for EU companies are not expected under Option 1, and only expected to a minor extent under Option 2. Under Option 2, compliance costs are EUR 36.9 million in the first year (which also includes one-off costs for adaptation to the new legislation), equivalent to 0.004% of turnover of EU companies

for manufacturing, wholesale and retail of non-harmonised consumer products. Costs are going down to EUR 29.6 million in subsequent years, in which no further familiarisation costs and costs from adapting to regulatory changes (e.g. for external advice) accrue.

Compliance costs of businesses are expected to increase under Option 3 to an EU total of EUR 196.6 million in the first year (and EUR 177.8 million in subsequent years), equivalent to 0.02% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. Businesses expect that implementing Option 3 would increase companies' recurrent regulatory compliance costs. Companies that are manufacturers generally expect more significant changes than wholesalers and retailers. It is plausible that manufacturers would be more affected by regulatory changes than distributors, as they might have to adjust different stages of the value-adding process to new regulatory requirements, e.g. consider relevant steps in the manufacturing process, but also sales and aftersales procedures. In their comments, respondents explained why they expected higher costs than under Option 2. For example, a respondent stated that risk of financial penalty would require more accuracy, with the effect being that "bureaucratic costs will increase", or, as another respondent put it, the "need for mechanisms to ensure compliance" would increase costs. Others referred to the potential costs of mandatory registration schemes, also depending on the implementation details. As pointed out before, respondents frequently highlighted the considerable uncertainty in their estimates, as implementation details were not yet known. Expected costs savings of companies due to further harmonisation and the use of a Regulation as legislative instrument were also highlighted by some respondents, an example being a respondent who indicated that "moving away from a Directive to a Regulation would help reducing costs, while also increasing predictability and legal certainty" (see above).

Finally, under Option 4 compliance costs of businesses are expected to increase to an EU total of EUR 331.1 million in the first year (and EUR 296.3 million in subsequent years), equivalent to 0.03% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. A possible explanation for the difference in the assessment of costs provided by businesses in our cost survey regarding Option 3 and Option 4 (which provide identical policy measures) is that businesses tend to provide cautious estimates with regard to additional costs from new regulatory obligations that might arise if one single set of rules would apply to harmonised and non-harmonised products. Some respondents highlighted that changing Regulation (EU) 2019/1020 so quickly could have considerable implications on costs. For example, a company stated that the impacts of Option 4 would be the same as under Option 3, but "adding the disruption of well-functioning legal frameworks and muddying the waters between harmonized and non-harmonized products". Another respondent pointed out that "such integration of different legal instruments so soon after the revision of the market surveillance regulation will lead to disruption in company structures and procedures without any guarantee of additional benefits. We also expect the revision to take much longer, therefore delaying the positive effects of the revised legislation".

The four options also differ with respect to their impact on SMEs, online marketplaces, online traders in general, and producers and distributors of food-imitating products. Under all options, the effects of additional compliance costs (under Option 2 to 4) will have a larger relative cost impact on SMEs than on large companies. Due to their size (e.g. in terms of turnover, profits and staff), SMEs bear a larger relative cost burden resulting from regulatory complexity and uncertainty. At the same time, and for the same reasons, SMEs can generally benefit more from policy measures that aim at a greater level of regulatory harmonisation in the EU (greater marginal benefit of reduced regulatory complexity compared to large companies). Even though the relative costs increases are higher for SMEs, the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a greater level of regulatory harmonisation across the EU27 through the choice of a regulation (possibly

under Option 2, and clearly under Options 3 and 4). Also, the changes in SMEs costs are so small that the implementation of any of the options would not be expected to significantly affect operations. This consideration is also true for specific information obligations under Options 3 and 4, such as the obligation for actors across the online supply chain to provide all safety information online that is also required to be provided with a product in 'brick-and-mortar' stores, and the related obligation for online platforms to make sure that third-party sellers, such as SMEs, provide this information. We expect these costs to be relatively low for companies selling consumer products on these platforms, including SMEs.

Impacts on online platforms are expected to a minor degree under Option 2 for those platforms that are not yet signatories of the Product Safety Pledge. Under Options 3 and 4 higher impacts on online platforms are expected, due to the introduction of due diligence obligations in terms of product safety. While these might require more efforts for online marketplaces, they would likely imply less efforts than those of distributors for fulfilling their obligations under the current regime. Similar to online platforms, the new provisions for businesses across the online supply chain would require online sellers to provide all safety information online that is also required to be provided with a product in "brick-and-mortar" stores (under Options 3 and 4). It is already a common practice that sellers provide this type of information (e.g. "Not suitable for children under 3 years of age"). Based on the understanding that the required information would not go beyond what is indicated on the packaging (which is the information typically also available in 'brick-and-mortar' stores), the provision of this information online in those cases where this is not yet done, should not create significant burdens for online sellers. Also, the provision of already existing information when listing offers for consumer products on online platforms should not result in significant additional costs.

Finally, if a ban of food-imitating products throughout the Union would be introduced, the economic impact would depend on the market size for food-imitating products. No data could be identified in this respect, with the general view being that this market is tiny. Therefore, the economic impacts of a ban of food-imitating products would likely be minor in a broader economic perspective. However, for the affected companies, which would need to shift their production or adapt to the sale of new products, the impact could, of course, be serious. It would therefore depend on the availability of evidence for major risks posed by food-imitating products for vulnerable consumer groups (such as children), to consider the proportionality of a ban (see also discussion below, impact on fundamental rights). For the present study, such evidence was not available.

With respect to macroeconomic impacts, the impacts are expected to be mostly limited, with most (positive) impacts to be expected under Options 3 and 4. Both options would be expected to lead to a more aligned and clearer EU legislative framework for the safety of harmonised and non-harmonised consumer products as well as reduced legal complexity, which could overall significantly reduce the part of companies' compliance costs that results from different legal requirements for harmonised and non-harmonised consumer products in the EU. Reduced costs and administrative burdens would level the competitive environment for companies from different countries within the EU and may at the same time help many European businesses to be more internationally competitive. At the same time, a more harmonised regulatory level playing field within the EU will also induce non-EU companies to market their products in the EU, with positive impacts on intra-EU competition. However, the additional gains in EU companies' competitiveness are expected to be relatively small as companies' current compliance costs with consumer product safety legislation are already relatively low, accounting for small shares of total revenues (for both distributors and manufacturers, although somewhat higher for manufacturers). Moreover, additional regulatory requirements, for which most businesses that replied to the survey expect additional one-off costs and higher recurrent costs, would level potential cost reductions (e.g. recall procedures, registration systems etc.).

8.6.5. Impact on consumers and households

None of the four options is expected to significantly affect consumer prices or consumer choice, as shown in Table 80 below. Reasons include that the estimated increases in compliance costs are small compared to baseline costs, and companies' overall product safety-related costs, including regulatory compliance costs, account for only very small shares of the turnover from non-harmonised products (see baseline estimates: median values of 0.59% for manufacturers and 0.14% for wholesale and retail companies). It is possible that some of the additional costs under the options with the highest compliance costs (Options 3 and 4) could be passed on to other companies, both up- and downstream the product value chain, and thereby impact consumer prices. However, as most businesses report relatively low additional one-off and recurrent costs, the short and medium- to long-term impacts on consumer prices in the EU are expected to be negligible. A similar argument can be made for consumer choice under all options.

Table 80: Summary assessment of Options 1 to 4 – impact on consumers and households

Area	Option 1	Option 2	Option 3	Option 4
Consumer prices	neutral	neutral	neutral	neutral
Consumer choice	neutral	neutral	neutral	neutral
Consumer safety and vulnerable consumers	neutral	+	++	++

Regarding consumer safety and the protection of vulnerable consumer groups, the four options differ, however. Options 3 and 4 are expected to provide a higher level of protection, as elaborated in section 8.6.2 (achievement of policy objectives). Benefits of the options have also been assessed in quantitative terms regarding the benefits of measures concerning online sales channels, and the benefits of measures in the field of recalls.

According to our analysis of benefits of measures concerning online sales channels (Annex IV), Option 1 is not expected to lead to a reduction of unsafe products in the online sales channels, due to the limited scope and voluntary character of the measures taken. We would expect some reduction of the incidence of unsafe products in online sales channel with implementation of Option 2 (due to enshrining provisions of the Product Safety Pledge in law, covering some additional platforms). Options 3 and 4 are likely to be more effective than previous options to address the challenges for product safety posed by online sales channels, through the introduction of due diligence obligations for platforms, the extension of certain obligations e.g., for fulfilment service providers and the sanctions and penalties incorporated in the new regulation replacing the GPSD. The scenario estimates for Options 3 and 4 therefore assume that the measures taken contribute to aligning the level of product safety (in terms of the incidence of unsafe products) between the online sales channels and brick-and-mortar stores, and thereby contribute to reducing the incidence of unsafe products on the market overall[277]. Table 81 below provides the scenario estimates for the expected reduction in consumer detriment due to unsafe products under Option 1 to 4.

[277] For a full set of scenario assumptions, see Annex IV.

Table 81: Expected benefits for consumers under scenario estimates for Options 1 to 4 – EU27, in EUR million per year

Year	Option 1	Option 2	Option 3	Option 4
2025	0	333	1 038	As Option 3
2026	0	704	2 153	
2029	0	821	3 924	
2034	0	1 031	5 491	

Note: Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. The expected annual consumer benefits in the scenario estimates for Options 2, 3 and 4 (i.e. the expected reduction in detriment compared to the baseline) increases over the years due to the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels due to enshrining provisions of the Product Safety Pledge in law (Options 2, 3 and 4), due diligence obligations for platforms (Options 3 and 4), as well as sanctions and penalties (Options 3 and 4) - the deterrent effect of which is also expected to lead to a reduction in the incidence of unsafe products sold in offline sales channels. For details on the methodology for the analysis and the scenario assumptions regarding size of total retail, the share of online in total retail, and the respective incidence rates of unsafe products, see Annex IV.

Measures taken under Option 2 are expected to reduce consumer detriment in the EU due to unsafe non-harmonised products by EUR 333 million in the first year, increasing to EUR 1 031 million per year in the course of the next decade. The reason for this increase is that overall consumer detriment is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce. The table shows that benefits in terms of reduced consumer detriment in the EU due to unsafe non-harmonised products under Options 3 and 4 are expected to amount to approximately EUR 1.0 billion in the first year of implementation, increasing to approximately EUR 5.5 billion per year over the next decade. The extent to which these benefits materialise, will however, also depend on the continued surveillance of platforms (to notify unsafe products) by MSAs and others, which are unlikely to have the capacity to reach a full coverage of products sold. This will also depend on the resources allocated to MSAs and to the enforcement of the platforms' duty of care and other measures are taken at EU level, including in the framework of the new Digital Services Act.

An additional potential benefit of policy measures is the reduced consumer detriment due to more effective recalls. In our analysis of benefits of measures in the field of recalls (Annex V), we compare consumer detriment in the baseline scenario with low recall effectiveness (current situation) to a scenario where recall effectiveness is improved. Table 82 below provides our scenario estimates.

Table 82: Expected benefits for consumers under Option 1 to 4: reduction in consumer detriment due to ineffective recalls – EU27, in EUR million per year

Year	Option 1	Option 2	Option 3	Option 4
Reduction of consumer detriment compared to baseline	0	205	410	As Option 3

Note: Based on scenario estimates, see Annex V.

Measures under Option 1 in the area of product recalls are not expected to lead to a significantly higher recall effectiveness, and therefore are not expected to reduce related detriment. Option 2 could be expected to provide limited improvements in terms of return rates of recalled, unsafe products, leading to a reduction of consumer detriment of EUR 205 million. Finally, Options 3 and 4 could be expected to substantially reduce consumer detriment due to unsafe products sold online and consumer detriment related to ineffective recalls. Under a scenario of significantly improved recall effectiveness (as expected under Options 3 and 4), consumer detriment in the EU is reduced by more

than EUR 400 million per year. These estimates are based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price[278]. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product causes damage to persons, other goods or the environment.

Therefore, Options 3 and 4 (and to a limited degree Option 2) would be expected to have positive effects on consumer trust, which might translate in higher demand for consumer goods that are sold via online channels. Strengthened enforcement, a better deterrence of rogue traders by increased penalties, improved recalls and clarifications provided in a revised GPSD regarding the definition of safety and related risk assessments of consumer products (including in terms of food-imitating products, child-appealing products and risks for other vulnerable consumer groups) could also generally increase the level of protection of EU consumers, including vulnerable consumer groups such as children, the elderly or disabled persons.

8.6.6. Impacts on Member States

Table 83 below summarises the results of the assessment presented in sections 8.1 to 8.4 regarding impact on Member States, focusing on the costs and benefits for market surveillance authorities and other effects.

Table 83: Summary assessment Options of 1 to 4 – impacts on Member States

Area	Option 1	Option 2	Option 3	Option 4
Benefits for MSAs (EU27)	neutral / +	+ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year
Costs for MSAs (EU27)	neutral	Costs increase by < EUR 7 million/year)	Cost increase by < EUR 7 million/year)	Costs increase by < EUR 4 million/year)
Other effects on Member States	neutral	neutral / +	+	+

Benefits for market surveillance authorities are expected to mostly arise from the alignment of the provisions for market surveillance of harmonised and non-harmonised products. This leads to improvements in efficiency of market surveillance, and related cost savings, which are estimated at EUR 0.7 million per year across the EU[279]. As all Options other than Option 1 would involve greater alignment of the legislative framework for harmonised and non-harmonised products, the expected benefits are similar in monetary terms under Options 2, 3 and 4. However, streamlined standardisation procedures and an arbitration mechanism that provides clarification regarding risk assessments in case of disputes between Member States' MSAs could lead

[278] A key element of the justification for this assumption is that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased by a consumer, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. For a detailed justification, see Annexes IV and V.

[279] As indicated in Figure 13 in section 7.1.3, 16% of MSAs reported to currently incur additional costs due to the fact that the EU legal framework for product safety contains different provisions for market surveillance depending on whether the product is harmonised or non-harmonised. Therefore, savings are not expected to accrue to all MSAs.

to additional cost reductions for MSAs over time (under Options 3 and 4), which could not be quantified in monetary terms.

Cost for MSAs are expected to increase slightly under all options, except Option 1. Under the other options, estimates of total additional costs across the EU are between EUR 3.3 million/year (Option 4) and EUR 6.6. million/year (Options 2 and 3). It is possible that the minor difference in terms of costs between these three options is due to the differences in the extent of alignment brought by legislative change, with Option 4 being most far reaching and leading to a single set of rules that would apply to harmonised and non-harmonised products, leading to most efficiency gains.

8.6.7. Social impacts, impacts on fundamental rights and environmental impacts

The following summary table concerns the results of the assessment of social impacts, impacts on fundamental rights and environmental impacts (see Table 84).

Table 84: Summary assessment Options of 1 to 4 – social impacts, impacts on fundamental rights and environmental impacts

Area	Option 1	Option 2	Option 3	Option 4
Social impacts	neutral	neutral / +	neutral / +	neutral / +
Impacts on fundamental rights	neutral	neutral / +	+	+
Environmental impacts	neutral	neutral / +	+	+

As shown in the table, Option 1 is not expected to have significant social impacts, impacts on fundamental rights and environmental impacts, due to the limited scope and voluntary character of the measures foreseen.

The implementation of Option 2 is expected to potentially have some positive social impacts with regards to public health and safety and health systems, to the extent that the number of unsafe products on the market is reduced by the measures and this would lead to a reduction in consumer detriment due to product-related injuries and related health care costs for society. However, this impact is far from being sure (see below). Measures under Option 2 would also be expected to reduce product-related environmental risks to some extent, and hence ensure a somewhat higher level of consumer protection and a higher level of environmental protection in line with the Charter of Fundamental Rights of the European Union.

Most social impacts, impacts on fundamental rights and environmental impacts are to be expected under Options 3 and 4. The introduction of additional requirements for traceability and product recalls including keeping supply chain records, making registration mandatory for certain products, notifying directly owners of recalled products are expected to improve the effectiveness of recalls. In addition, increased enforcement powers of Member States to impose penalties and sanctions in case of violations of the provisions of a revised GPSD, are anticipated to significantly improve market surveillance and enforcement. To the extent that the number of unsafe products on the market is reduced by these measures in the mid- to long term, this potentially could lead to a lower number of injury cases caused by consumer products in need of medical attention or hospitalization, hence lowering public health expenditure for the treatment of product related injuries. However, this potential impact is not straightforward, as the relationship between the incidence of unsafe products and product-related consumer injuries is complex and a variety of factors beyond product

characteristics may contribute to the occurrence of such injuries[280]. Better outreach to customers with respect to recalled products and related remedies could be expected to partly overcome behavioural biases which currently affect the effectiveness of recalls (see Part 1 of this study). This could reduce the extent to which recalled unsafe products continue to be used by consumers, with the related risk of injury. Based on our conservative estimation the current cost of health care utilisation for product-related injuries in the EU is approximately EUR 6.7 billion per year, with hospitalization accounting for the larger part of the total health care costs at about EUR 6.1 billion[281]. A revised GPSD may contribute thereby to lowering these health care costs for society.

Options 3 and 4 are also expected to reduce product-related environmental risks, to the extent that the application of the general safety requirement to products containing environmentally harmful substances that indirectly may also pose a risk to human health and safety is clarified. Hazardous chemicals that are often being found in consumer products such as clothes/textiles, furniture, electrical appliances, furnishings and surfaces, childcare articles, sports and playground equipment, have the potential to adversely affect human health but are also harmful for the environment[282]. Chemicals in consumer goods are also an environmental concern when products are discarded as they may pollute waste and end up in the environment or even worse, continue their life cycle through recycling. The improved effectiveness of product recalls that is expected to occur under both options could also be expected to have a positive effect on the environment given that unsafe consumer products including chemical substances with adverse environmental effects will be among the products that will be more effectively recalled.

The implementation of a new regulation replacing the GPSD according to Option 3 or 4 shall hence have a positive impact on consumer protection and environmental protection in line with the Charter of Fundamental Rights of the European Union[283].

At the same time Options 3 and 4 impose additional requirements for businesses, that will increase their compliance costs to a limited extent. The additional requirements imposed to economic operators do not affect the fundamental freedom to conduct a business[284] as they are necessary to pursue the general European Union interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be comparatively low compared to the businesses' turnover. On the other hand, measures also may include a ban of food-imitating products from the EU market (as sub-option). Such a ban would have a negative impact on the freedom to conduct a business[285], and for this restriction to be proportionate it would need to be justified with the objective of protection of consumers. A possible ban of food-imitating products aims at providing increased protection to vulnerable consumers such as children who may ingest such products by accident. However existing data on relevant accidents lack sufficiently registered information to

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280 Part 1 of this report, EQ1.

281 See Annex I regarding the costs of health care utilization for non-fatal product related injuries.

282 EU Commission (2017), Study for the for the strategy for a non-toxic environment of the 7th Environment Action Programme final report, p. 11-16; ANEC and BEUC (2020), Views for a modern regulatory framework on Product Safety: Achieving a higher level of consumer safety through a revision of the General Product Safety Directive, p. 1-19, at: https://www.anec.eu/publications/position-papers/856-beuc-and-anec-views-for-a-modern-regulatory-framework-on-product-safety-achieving-a-higher-level-of-consumer-safety-through-a-revision-of-the-general-product-safety-directive.

283 Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 37 on environmental protection and article 38 on consumer protection.

284 Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 16.

285 See Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, article 52 and Judgment of 13 April 2000, Kjell Karlsson and Others, Case C-292/97, EU:C:2000:202, paragraph 45.

distinguish whether the products causing the accident were food resembling[286]. It follows that while the negative impact of banning food-imitating products for the relevant business sector is certain and significant, evidence to prove the intended benefits (better protection of children) would still be required to confirm proportionality. In the framework of the present study, such evidence could not be identified (see section 4.6 above).

8.6.8. Overview of options

Table 85 on the following pages provides an overview of the impacts of Options 1 to 4, compared to the baseline situation.

[286] Scientific Committee on Consumer Safety, 'Opinion on the potential health risks posed by chemical consumer products resembling food and/or having child-appealing properties', 22 March 2011, p. 8.

Table 85: Summary assessment of Options (compared to baseline situation)

Area	Option 1	Option 2	Options 3	Option 4
Effectiveness in achieving the policy objectives				
Ensure general safety rules, including for product risks linked to new technologies	neutral / +	+	++	++
Address safety challenges in the online sales channels	neutral	neutral / +	+ / ++	+ / ++
Make product recalls more effective	neutral	neutral / +	++	++
Enhance market surveillance and ensure better alignment of rules	neutral	++	++	++
Address safety issues related to food-imitating products	+	+	+ (++ if ban)	+ (++ if ban)
Administrative simplification				
Reduction of regulatory complexity and uncertainty	neutral / +	neutral / +	+	+ / ++
Economic impact				
Benefits for businesses	neutral / +	neutral / + Benefits of max. EUR 59 million/year (less if Directive)	+ Benefits of EUR 59 million/year	+ Benefits of EUR 59 million/year
Cost of businesses	neutral	Costs increase by < EUR 37 million/year	Costs increase by < EUR 197 million/year	Costs increase by < EUR 332 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral	neutral / +	+	+
Impact on consumers and households				
Consumer prices	neutral	neutral	neutral	neutral
Consumer choice	neutral	neutral	neutral	neutral
Consumer safety and vulnerable consumers	neutral	+ Benefits of EUR 330 million within the first year of implementation,	++ Benefits of EUR 1 038 million within the first year of	++ Benefits of EUR 1 038 million within the first year of

		increasing over the years with the expected growth in online retail and a reduction of the incidence of unsafe products in online sales channels to a limited extent. Additional benefits of EUR 205 million/year due to somewhat improved recall effectiveness	implementation, increasing over the years with the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels. Additional benefits of EUR 410 million/year due to improved recall effectiveness	implementation, increasing over the years with the expected growth in online retail and a gradual reduction of the incidence of unsafe products in online sales channels. Additional benefits of EUR 410 million/year due to improved recall effectiveness
Impact on Member States				
Benefits for MSAs	neutral / +	++ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year	++ Benefits of > EUR 0.7 million/year
Costs for MSAs	neutral	Costs increase by < EUR 7 million/year	Costs increase by < EUR 7 million/year	Costs increase by < EUR 4 million/year
Other effects on Member States	neutral	neutral / +	+	+
Social impacts, impacts on fundamental rights and environmental impacts				
Social impacts	neutral	neutral / +	neutral / +	neutral / +
Impacts on fundamental rights	neutral	neutral / +	+	+
Environmental impacts	neutral	neutral / +	+	+

Note: Magnitude of impact as compared with the baseline scenario: neutral = no significant difference to baseline situation; + = positive impact compared to baseline; ++ = significant positive impact compared to baseline. An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

8.7. Potential complementary measures to increase achievement of objectives and reduce administrative burdens

Based on the results of the evaluation of the GPSD (see Part 1 of this report), as well as the complementary consultation, research and analysis conducted for the impact assessment (Part 2), several potential complementary measures to increase achievement of objectives and reduce administrative burdens were identified. These are:

- Create single contact point in Member States for consumer product safety;
- Consider the status of customs authorities as market surveillance authorities in their own right;
- Support exchange of best practices for business operator-based market surveillance approaches;
- Improve collection of data on non-fatal injuries and mortality data;
- Introduce a reporting system for product related accidents, modelled on the reporting systems in Australia, Canada and the US;
- Continue to improve priority setting for market surveillance activities and to align risk assessment methodologies across the EU;
- Further explore how product-related chemical risks can be reduced through EU measures;
- Update the European Commission's Blue Guide to include the GPSD, so as to provide uniform guidance regarding EU product safety legislation;
- Consider e-labelling solutions for product safety related information.

The following sub-sections discuss each potential measure. At the end of the section, we separately discuss potential costs and benefits of each measure in tabular format.

Create single contact point in Member States for consumer product safety

The organisation of market surveillance at national level is complex in many EU Member States, and in some cases the fragmentation of responsibilities in terms of product sectors and level of government is considerable, often related to administrative structures and traditions (see also EQ2, Part 1 of this report). For this reason, Regulation (EU) 2019/1020 requires in Article 10 the appointment of single liaison offices in Member States that at least will be responsible for representing the coordinated position of market surveillance authorities and for communicating the related national strategies. A revised GPSD could clarify that these single liaison offices are required to offer a single contact for consumer product safety, both regarding harmonised and non-harmonised consumer products, which provides access for representatives of businesses' and consumers' interest regarding all issues concerning consumer product safety, at least in terms of signposting to the responsible authority. This would help relevant stakeholders to have easily identifiable contact points in each Member State, the absence of which has reportedly been a problem in some Member States in the past.

Consider the status of customs authorities as market surveillance authorities in their own right

In most EU/EEA countries, customs authorities conduct controls in cooperation with market surveillance authorities, without being market surveillance authorities themselves. This means that the typical procedure is as follows: If customs decides to suspend the release of a product imported to the EU for free circulation on the EU market based on the check of the product's characteristics, it notifies the relevant market surveillance authority. The market surveillance authority performs an inspection within a short time following 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. 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. In most Member States, MSAs have a working agreement with customs and a list of priority products, countries of origin etc., which is agreed every year between customs and the authorities.

In several countries, however, a different approach is chosen. In these countries, customs is designated as a market surveillance authority in its own right (as is the case in Finland, France and Latvia). In France, while surveillance of consumer products on the French market is mainly carried out by officials of the Directorate-General for Competition, Consumer Affairs and Fraud Prevention (DGCCRF), this responsibility lies with the Directorate-General for Customs and Indirect Taxation (DGDDI) in the case of products imported from non-EU countries. 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. Also, in Finland, customs has the power to decide on whether the import, export or transit of certain products is allowed. This possibility of customs taking own product safety-related decisions was indicated by the interviewed authorities to be a major advantage, safeguarding quicker and more efficient decisions.

It could therefore be considered by Member States whether to follow this model, or otherwise to allow for more efficient processes for product safety checks at the border and related product testing in laboratories to address the challenges posed by an increasingly globalised consumer product market. Non-legislative measures accompanying a possible revision of the GPSD (e.g. in the framework of the CASP) could support this process.

Support exchange of best practices for business operator-oriented market surveillance approaches

In several countries, business operator-based market surveillance approaches have been introduced. For example, in the Netherlands the MSA responsible for consumer products (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, to improve efficiency of the process. The target group for proactive surveillance in the country – identified with the use of the matrix – is a core group of around 3 000 enterprises that are 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 reportedly EU importers with large commercial volumes of a huge range of different types of high-risk products from non-EU/EEA countries. Operator-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. Another form of operator-oriented surveillance is called system surveillance. This involves using audits to check a company's quality system, 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 frequent surveillance. The responsible authority also helps companies to develop such systems (compliance assistance). The surveillance is intended to encourage business compliance with the product safety legislation. 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. System surveillance

reportedly yields good results at companies that want and are able to invest in compliance and that also trade in many different types of product groups[287].

As business operator-oriented market surveillance approaches are reported to be more efficient than purely product-based approaches, best practices in this respect could be elaborated and non-legislative measures accompanying a possible revision of the GPSD (e.g. in the framework of the CASP) could support this process.

Improve collection of data on non-fatal injuries and mortality data;

The analysis of data on non-fatal injuries from the European Injury Database (IDB) and mortality data provided by the WHO for this study has identified major weaknesses in the collection of this data, which are widely known and have been analysed multiple times in the past[288]. However, already the existing data can provide important input to standardisation efforts, and for setting priorities for the improvement of consumer safety in non-work and non-transport contexts. One potential measure is therefore to gradually improve the collection of data on non-fatal injuries in emergency departments of selected hospitals in EU Member States. The currently available data for the (most relevant) IDB-FDS is based on reporting from about 100 hospitals, which is similar to the sample size in existing systems in other jurisdictions (such as the US NEISS system). Data processing at EU level and a simple-to-use open access interface for queries would need to be safeguarded, as well as accompanying measures to improve approaches for data collection, including by safeguarding representativeness of the data collected. An important complementary source of relevant insights is mortality data, which is considered to be the best available epidemiological data, due to its coverage of all cases of fatalities in the EU and existing reporting systems. However, granular mortality data (which would allow e.g. to identify the number of mortalities due to electrical current in a home setting), is currently not easily accessible, and key information, such as whether an accident happened at home or in a work setting, is often missing. A potential measure would therefore be to improve mortality reporting, to provide simple and open access to granular mortality data by Eurostat, and to improve the International Classification of Diseases so as to allow a better identification of consumer product related accidents. These measures would be expected to be cost-effective in a medium to long-term, as the preventable detriment to EU consumer due to consumer products is estimated at EUR 11.5 billion per year (see Annex I), and the required input at EU level is comparatively very minor, while allowing for more targeted product safety measures (both in terms of market surveillance and standardisation). More targeted measures would also be expected to reduce regulatory and administrative burdens on business operators.

Introduce a reporting system for product-related accidents, modelled on the reporting systems in Australia, Canada and the US

Currently, there is no mandatory reporting system for product-related accidents in Europe, as is the case e.g. in Australia, Canada and the US:

- A key data source of the Australian Competition and Consumer Commission (ACCC) to determine the annual product safety priorities is a mandatory injury reporting process. Under Australian Consumer Law, suppliers are required to report any product-related death, serious injury or serious illness associated with a consumer product in Australia, and there is a related mandatory injury report form on the ACCC website. Both serious injuries that are documented

[287] See GPSD implementation study, country report Netherlands. Note that the quoted information is based on several reports by the MSA to the EC, and was updated based on the interviews conducted.

[288] Most recently in Radovnikovic, A. et al. (2020), 'Assessment of the opportunities for increasing the availability of EU data on consumer product related injuries', *Injury Prevention*.

and serious injuries that are alleged by consumers to have happened have to be reported[289];

- Under the Canada Consumer Product Safety Act (CCPSA), industry must report health or safety incidents involving consumer products to Health Canada. Forms for industry and for consumers to report an incident involving a consumer product or cosmetic are available on the website of the Government of Canada[290];
- The US Consumer Product Safety Commission (CPSC) collects reports of harm or potential harm about dangerous or potentially unsafe consumer products. Each report is reviewed by its staff of investigators and consumer product safety experts to determine what actions should be taken to protect the public. For this purpose, the CPSC provides a Consumer Product Safety Information Database, which is a publicly searchable database where submitters (consumers and businesses) can report to the CPSC a harm or risk of harm related to the use of a consumer product or other product or substance within the jurisdiction of the CPSC. Forms for this purpose for consumers and businesses are available on the website saferproducts.gov.

In all three countries, the accident reporting system is considered to be a cornerstone of the product safety system. It is a key data source to determine the annual product safety priorities and surveillance activities. The accident reports are also an important data source for targeted product safety enquiries. In our interviews with business operators, specific accident information from the US system, which is partly publicly accessible, was considered a valuable source for assessing product-related risks for manufacturers and distributors. The data would also complement the baseline injury data collected from hospitals[291]. A revised GPSD could therefore foresee a mandatory reporting process, with a web interface (reporting forms for businesses and consumers) integrated into the Safety Gate portal, with the follow-up to the reported cases being conducted in the Member State in which the accident occurred.

Establishing a mandatory accident reporting system in the EU can be expected to be a cost-effective supplement to the existing EU framework established by the GPSD, as the resulting information will provide essential information to complement injury data from hospitals and mortality data. The data would allow both the EC and Member States' authorities to focus market surveillance and standardisation on those issues that matter most in terms of EU consumers' safety and health.

Continue to improve priority setting for market surveillance activities and to align risk assessment methodologies across the EU

To provide assistance to the EU Member States' product safety authorities, the Commission funds Coordinated Activities on the Safety of Products (CASP), which enable MSAs of EU/EEA countries to cooperate in reinforcing the safety of products placed on the European markets. CASP projects can focus, e.g. on the analysis of a single product or a group of products (product specific activities) or on the exchange of best practices on market surveillance (horizontal activities). It could be considered to develop and formalise this framework further to conduct on a regular basis joint accident

[289] See www.productsafety.gov.au/contact-us/for-retailers-suppliers/mandatory-injury-report#product-details

[290] See www.canada.ca/en/health-canada/services/consumer-product-safety/advisories-warnings-recalls/report-incident-involving-consumer-product.html

[291] A major difference between accident reporting and injury data collected at emergency departments of hospitals is that the latter type of data does provide insights whether product was involved in an injury, but typically does not allow to decide whether there was a causal relationship, or not. At the same time, this data provides a general overview of consumer injuries (baseline), which allows for measures to be taken to improve consumer safety in a non-work and non-traffic setting. In contrast, a product accident reporting system can provide information on potential causal relationships, and also collect details on the injury mechanism. Both datasets are therefore complementary, and existing systems in non-EU jurisdictions, such as the US, use both data sources as input for specific product safety investigations.

investigations related to priority consumer products, e.g. identified on basis of improved injury data and accident reports (see above). This would support evidence-based market surveillance and other measures to improve product safety in the EU. For this purpose, specific lead bodies/authorities in the Member States could be designated by the European Commission for product categories or risk types relevant for non-harmonised products. These bodies/authorities would function as EU centres of expertise for the specific product categories or risk types, similar to the role of EU reference laboratories and reference centres in other policy areas[292]. Their role could also include to clarify technical and methodological questions regarding specific risk assessment methods and related tests (including in the area of chemicals), which could lead to more harmonised approaches across Member States[293].

Further explore how product-related chemical risks can be reduced through EU measures

As elaborated in detail in Part 1 of this report, the revised RAPEX guidelines clarify that in certain cases, the Commission may validate notifications that are submitted without a detailed and individual risk assessment, if a product contains a chemical substance either banned or in a concentration above the limit established by European legislation. The existence of threshold values for chemicals in EU legislation therefore greatly facilitates the notification of dangerous products and thereby enhances the relevance of the GPSD for environmental issues with health impact. As the number of substances for which the EU legislative framework establishes limit values or requirements that can be referred to in risk assessments is limited, it could be explored how product-related chemical risks can be further reduced through EU measures, including with respect to product categories that are not covered by specific EU product legislation, such as clothing and textiles, furniture, childcare articles and sports and playground equipment, including through the standardisation process. Also, a revised GPSD could foresee a possibility to set additional requirements regarding traceability of chemicals for certain sensitive categories of products such as child-care articles (e.g. through implementing acts).

Update the European Commission's Blue Guide to include the GPSD, so as to provide uniform guidance regarding EU product safety legislation

The so-called 'Blue Guide' explains EU product rules and helps businesses and MSAs to apply these rules across different sectors and throughout the EU. It is also used by business and consumer associations, standardisation bodies and conformity assessment bodies. It was last updated in 2016[294]. Currently, the Blue Guide does not cover the GPSD, and refers to separate guidance in this respect. However, it would be helpful for operators and authorities if the interaction of the harmonised legislation with a potentially revised GPSD would be considered in a future revision, to support better understanding of business operators and authorities regarding the overall EU product safety framework.

Consider e-labelling solutions for product safety related information

The GPSD requires business operators to inform consumers of any risks associated with the products they supply, as well as to provide traceability information. Also, harmonised legislation contains product-related information requirements. In our interviews with business operators and market surveillance authorities, the option was raised to make more use of e-labelling solutions for product safety related information.

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[292] E.g. in the policy areas of food safety, animal health and animal welfare. See Civic Consulting (2011), Evaluation of the EU-RLs in the field of food and feed safety and animal health and live animals.

[293] The new Regulation (EU) 2019/1020 already provides in Article 21 for Union testing facilities that include among their tasks to "provide independent technical or scientific advice". It would be possible to clarify that these Union testing facilities would also function as EU centres of expertise related to non-harmonised products, thereby contributing to more uniform testing and risk assessment, and possibly coordinating relevant accident investigations in their respective areas.

[294] 'Blue Guide' on the implementation of EU products rules (2016/C 272/01)

To minimise costs for companies in general and SMEs in particular, e-labelling could become a useful solution to raise synergies from displaying consumer safety-relevant product information while increasing product traceability. Electronic labelling could consist of displaying compliance information directly on the screen of devices or on barcodes. A recent study on the costs and benefits of e-labelling highlighted that physical marking presents several challenges to companies, such as:[295]

- *High costs of compliance*. Under the current legislation, indicating compliance with the relevant product safety requirements is considered to be costly. An analysis of the market focusing on three industries in the ICT sector suggested that physical labels cost companies over 797 million EUR per year[296];
- *Monitoring and updating*. For companies, it is cumbersome to track and update labelling requirements, especially in case of changes to labels for products that are distributed in several Member States;
- *Implementation difficulties*. Labelling may sometimes be technically difficult to implement, especially for smaller products.

Compliance information can be shown electronically in various ways, including a label displayed on screen, or a QR code. E-labelling could make labelling less expensive for companies, but also facilitate and increase access to up-to-date product-safety related information. Depending on which option is chosen for a possible revision of the GPSD, new traceability requirements and mandatory recall procedures may create new obligations for the collection and sharing of product-related information. It could therefore be considered to further explore as accompanying measure to the possible revision of the GPSD the introduction of e-labelling and related database(s) for product and consumer relevant information to lower compliance costs for labelling and for fostering related innovations, including regarding traceability information. This initiative could link to the ongoing plans of the Commission to launch a European Circular Dataspace, which aims at mobilising the potential of digitalisation of product information, introducing for example digital product passports[297]. Digital product passports are intended to provide information on a product's origin, durability, composition, reuse, repair and dismantling possibilities, and end-of-life handling[298].

Table 86 below provides an overview of the expected costs and benefits of the complementary measures discussed in this section.

Table 86: Expected costs and benefits of complementary measures

Area	Costs	Benefits	Mainly responsible
Create single contact point in Member States for consumer product safety	Minor, for clarification of responsibility of single liaison office	Better access to authorities regarding safety of consumer products	Member States
Consider the status of customs authorities as market surveillance authorities in their own right	Minor, as resources would mainly be reallocated	More efficient customs controls and laboratory access	Member States

[295] See, e.g., VVA (2018), Study for the introduction of an e-labelling scheme in Europe - Cost Benefit Analysis, available at https://www.digitaleurope.org/wp/wp-content/uploads/2019/01/Study%20for%20the%20introduction%20of%20an%20e-labelling%20scheme%20in%20the%20EU%20-%20CBA%20-%20final%20report%2021062018.pdf.

[296] Ibid.

[297] See https://ec.europa.eu/commission/presscorner/detail/en/QANDA_20_419

[298] See Commission Communication on a European strategy for data, COM(2020) 66 final.

Area	Costs	Benefits	Mainly responsible
Support exchange of best practices for business operator-based market surveillance approaches	Minor	More efficient market surveillance of operators	Member States, supported by EC
Improve collection of data on non-fatal injuries and mortality data	Initial estimate of 5 to 10 FTE at EU level for processing of data and improving system, plus costs for reporting of data from selected hospitals in MS[a)]	Better targeted consumer safety measures. Baseline for monitoring of product safety. Improved standardisation due to better access to injury data	EC, Member States
Introduce a reporting system for product related accidents, modelled on the reporting systems in Australia, Canada and the US	Estimate of between EUR 0.8 million and EUR 2.4 million in the first year of operation, increasing with the number of reports filed (total of costs for businesses and for authorities for processing of reported cases)[b)]	Better targeted product safety measures. Complementary data for monitoring of product safety. Improved standardisation due to better access to accident data	Companies, Member States, EC
Continue to improve priority setting for market surveillance activities and to align risk assessment methodologies across the EU	Additional costs depend on scope of implementation. Could be neutral (using existing CASP), or require limited additional funds, if specific EU centres of expertise for specific product categories/ risk types were designated	Better targeted product safety measures. More effective reduction of consumer injuries and accidents. Better aligned risk assessment methodologies across the EU, reducing administrative burdens for companies that are currently caused by discrepancies in risk assessments	EC, Member States
Further explore how product-related chemical risks can be reduced through EU measures	Additional measures at EU level (beyond standardisation) would be subject to specific assessment of impacts	Additional EU threshold values for harmful substances in non-harmonised product categories that are not otherwise regulated may improve sustainability and consumer health	EC
Update a future edition of the European Commission's Blue Guide to include the GPSD, so as to provide uniform guidance regarding EU product safety legislation	Minor	Integration of a possibly revised GPSD into a future edition of the Blue Guide would support better understanding of business operators and authorities regarding the overall EU product safety framework	EC
Consider e-labelling solutions for product safety related information	Minor to significant, depending on specific measures	E-labelling for product safety information could improve access to this information for consumers and authorities, while reducing administrative burdens for companies	Companies, supported by EC measures

Source: Civic Consulting. Notes: a) In addition, minor costs for setting up publicly searchable database system at EU level. b) For a detailed estimate, see Annex III. According to the estimate, a mandatory reporting system for product related injuries and fatalities in the EU could be expected to cost between EUR 0.8 million and EUR 2.4 million in the first year of its operation, with a gradual increase until the estimated maximum costs of EUR 8 million to EUR 24 million are reached in year 10, depending on the number of reports filed. In addition, minor costs for setting up webforms for reporting of accidents and related database system at EU level.

Annex I: Detriment due to product-related injuries and fatalities in the EU

Injuries and premature deaths associated with consumer products create consumer detriment and potentially loss of trust in the Single Market. These losses are predictable and to the extent they are attributed to unsafe products they could be largely prevented through improved product safety. The cost of injuries and fatalities, is the most significant component of this detriment[299]. With the aim to better assess the size of the problem generated by the presence of unsafe consumer products on the EU market, this section focuses on the estimation of the cost of injuries and premature death related to products.

To develop the methodology for this assessment, we first analysed relevant approaches in non-EU/EEA countries. Annex IIa provides this contextual information by presenting some of the approaches that have been used so far to estimate the cost of product related non-fatal injuries and fatalities, focusing on research conducted in the US, Australia and Canada.

We then reviewed the data available in an EU context, focusing first on the data available in the European Injury Database (IDB). The following assessment describes the available data in the IDB, and then calculates on basis of data extracted from the IDB the resulting detriment for consumers and society, considering health care utilization costs, productivity losses and loss of quality of life. Subsequently, we discuss the data on fatalities that can be used for estimating detriment due premature death extracted from the WHO Mortality Database (WHO-MDB), describe our approach in this respect, and present results of the calculation. We finally provide an overview of results, bringing together the estimates of the detriment caused by non-fatal injuries and premature death.

All the data retrieved and the calculations presented in the following subsections refer to the European Union of 27 Member States. The monetary values are expressed in EUR 2017; in cases where 2017 values have not been available, monetary values were inflated to 2017 values using Eurostat's Labour Cost Index[300].

Due to the complex nature of the analysis, the research team was supported by a EuroSafe[301] expert for the extraction and interpretation of IDB data, who also provided advice concerning the injury and fatality categories to be selected for the analysis. In each step, we will explain the approach chosen for monetization, clarify the underlying assumptions and be transparent, wherever choices in terms of methodology and data have to be made, about the reasons of the choices made. We thereby follow a conservative approach, so that the resulting estimates constitute the minimum detriment suffered by EU consumers and society.

The cost of non-fatal product related injuries in the EU

For the calculation of the cost of non-fatal product related injuries in the EU, we use the European Injury Database (IDB) as a source of data on product-related injuries. Our approach for the calculation of cost of non-fatal product-related injuries closely follows

[299] Other components include costs of the unsafe product itself and costs caused by the unsafe product to other goods.

[300] Eurostat, Labour cost index by NACE Rev. 2 activity - nominal value, annual data [lc_lci_r2_a]. NACE_R2: Industry, construction and services (except activities of households as employers and extra-territorial organisations and bodies). Extracted 16/06/2020.

[301] EuroSafe's mission is to prevent home and leisure accidents by working in partnership with industry, governments, research institutes and health and safety practitioners to help reduce the greatest risks. Members are organisations or individuals working in the field of injury prevention and safety promotion, see www.eurosafe.eu.com.

the rationale of the US injury cost model (see Annex IIa) in that we calculate the total cost by combining estimates on the cost of:

- Healthcare utilization;
- Productivity loss; and
- Loss of quality of life.

After presenting the data in the IDB and its limitations, we describe the number of product-related injuries in the EU as extracted from the IDB, before calculating the detriment related to each of the above listed cost types.

Data available in the European Injury Database (IDB)

The European Injury Database (IDB) is managed by EuroSafe and was hosted by the European Commission until 2019[302]. The European IDB was set up by DG SANTE (back then DG SANCO) in 1999 to serve as a point of access to the product-related injury data collected by Member States in the context of the program on a European Home and Leisure Accident Surveillance System (EHLASS)[303]. Since then, through several other European Commission projects that aimed to facilitate injury collection and exchange of injury data on an EU-level, the IDB has expanded to contain information on intentional and unintentional injuries that are treated in hospitals and emergency departments across Europe. Similar to NEISS, the IDB aims to provide information on the circumstances and consequences of non-fatal injuries to facilitate their prevention and improve safety. Different from the NEISS however, the IDB does not contain data on product related injuries only, but also keeps record of injuries occurring in the workplace, at home, at school, during leisure and sports as well as injuries occurring as a result of road traffic accidents, interpersonal violence and self-harm.

The data are collected from the emergency departments of a number of selected hospitals, which, based on their size (small, medium, large) and type (e.g. general hospitals, children hospitals, university hospitals) are assumed to constitute a representative sample for the respective Member State[304]. The data are voluntarily contributed by the Member States participating in the IDB, which were 15 out of 28 Member States in 2016[305].

Two levels of datasets exist in the IDB: the full dataset indicated as IDB-FDS and the minimum dataset referred to as IDB-MDS. The IDB-FDS provides more detailed information with regards to the circumstances of the injury and the products involved, in comparison to the IDB-MDS, which includes limited information pertaining to the injury. The differences in the structure and the information contained in these datasets is crucial for the estimation of the costs of product-related injuries.

More specifically the IDM-FDS comprises 19 core data elements, which apart from demographic data as for instance the age and gender of patient, include information such as intent, place of occurrence, mechanism of injury, activity when injured and, most importantly, the product/object/substance involved in the incident[306]. It also includes a free text narrative field. This structure enables distinguishing between different risk categories. For example, home and leisure injuries can be differentiated from all other cases by taking into account the elements of intent, activity and place of occurrence when injured. By selecting unintentional injuries and by excluding from them

[302] See footnote 199.

[303] EUROSAFE (2016), 'EU Injury Database: operating manual', p. 11.

[304] EUROSAFE (2017), 'Injuries in the European Union 2013-2015, supplementary report to the 6th edition of 'Injuries in the EU', p. 9.

[305] Ibid., p. 26.

[306] EUROSAFE (2016), IDB-FDS Data dictionary, p. 7-8 ff.

transport, occupational and cases with unspecified activity it is possible to arrive at home and leisure injuries. Consequently, by using the data element of product/object/substance involved in the injury, it is in principle possible to identify the type of product.

The IDB-MDS as a simplification of IDB-FDS includes less data elements in comparison to IDB-FDS, covering basic information about injuries. IDB-MDS includes data elements such as intent, place of occurrence, mechanism of injury and activity when injured but it does not contain information regarding the product involved in the injury. It is therefore again possible to differentiate e.g. home and leisure injuries in the same way as with IDB-FDS by selecting unintentional injuries and excluding from them occupational injuries, transport injuries and cases with unspecified activity, however it is not possible to ascertain whether a consumer product was involved in the generation of the injury[307]. IDB-MDS was designed to maximize data collection on injuries, hence data conversion tables from other coding systems (e.g. ICD-10) to IDB-MDS are available[308]. However, despite the availability of more data, the IDB-MDS is less suitable for the calculation of the cost of product related injuries as it does not provide information on product involvement. However, it provides information that can be used to extrapolate the number of injuries recorded in the IDB-FDS to the EU level. For the following analysis, therefore both datasets have been applied.

Query used to extract data from the IDB

As we are interested only in injury incidents related to a product, we focus the analysis on accidental, non-intentional injuries and exclude transport injury events and work-related injuries. From the remaining injury incidents, we select the ones that are related to any object/product, except for food, drinks and pharmaceutical substances[309]. As IDB data has also been used as an indicator for the European Commission's Consumer Market Scoreboard, we select the same product groups used by the Consumer Market Scoreboard to define consumer products as represented in the IDB[310].

Table 87 below includes categories and codes, which relate to products that are contained in the relevant data element. A further breakdown of the codes is possible enabling better differentiation of the type of product involved.

[307] EUROSAFE (2016), IDB-MDS Data dictionary.

[308] EUROSAFE (2016), 'EU Injury Database: operating manual', chapter 7.

[309] Also excluded were the following objects: means of transport, mobile machinery, weapons, medical devices, and laboratory equipment, and other non-product agents such as animals and other persons.

[310] See European Commission (2014), 'Consumer Markets Scoreboard. Making markets work for consumers', 10th edition, p. 60-61.

Table 87: Selected IDB-FDS data elements

OBJECT/SUBSTANCE/PRODUCT INVOLVED IN THE INJURY OVERVIEW OF SELECTED (PRODUCT-RELATED) CODES OF FIRST AND SECOND LEVEL			
05 Furniture/ furnishing	05.01 Bed, bedding or bedding accessories		09.09 Carrying equipment, luggage
	05.02 Chair, sofa		09.98 Other specified personal use item
	05.03 Table, stand, cupboard, shelf or partition		09.99 Unspecified personal use item
	05.04 Decoration, decorating item	10 Equipment mainly used for sports/recreational activity	10.01 Ball used in sport
	05.05 Garden furniture		10.02 Hand-held sports equipment
	05.06 Household linen		10.03 Equipment/structure for playing sports and exercise
	05.98 Other specified furniture/furnishing		10.04 Equipment with wheels or designed for movement mainly used for sports/recreational activity
	05.99 Unspecified furniture/furnishing		10.05 Underwater diving equipment
06 Infant or child product	06.01 Baby or child article		10.98 Other specified equipment mainly used for sports/recreational activity
	06.02 Toy		10.99 Unspecified equipment mainly used for sports/recreational activity
	06.03 Playground equipment	11 Tool, machine, apparatus mainly used for work-related activity	11.01 Machinery or fixed plant
	06.98 Other specified infant or child product		11.02 Powered hand tool/equipment
	06.99 Unspecified infant or child product		11.03 Unpowered hand tool/equipment
07 Appliance mainly used in household	07.01 Cooking or kitchen appliance		11.04 Pressure-based equipment
	07.02 Cleaning or laundering appliance or tool		11.05 Other unpowered equipment
	07.03 Lighting appliance		11.98 Other specified tool, machine, apparatus mainly used for work-related activity
	07.04 Heating or cooling appliance		11.99 Unspecified tool, machine, apparatus mainly used for work-related activity
	07.05 Sewing appliance or equipment	14 Building, building component, or related fitting	14.01 Building fitting
	07.06 Entertainment appliance		14.02 Door, window, or related fitting/feature
	07.98 Other specified household appliance		14.03 Floor or related fitting/feature
	07.99 Unspecified household appliance		14.04 Wall or related fitting/feature
08 Utensil or container	08.01 Cooking or food processing utensil		14.98 Other specified building, building component, or related fitting
	08.02 Crockery, kitchen container		14.99 Unspecified building, building component, or related fitting
	08.02 Crockery, kitchen container	15 Ground surface or surface conformatio	15.01 Ground surface
	08.03 Cleaning utensil or container		15.02 Body of water
	08.04 Food storage or related utensil or container		15.98 Other specified surface conformation
	08.98 Other specified utensil or container		15.99 Unspecified surface conformation
	08.99 Unspecified utensil or container	17 Fire, flame, or smoke	17.01 Fire, flame
09 Item	09.01 Clothes, footware, or related products		17.02 Smoke
	09.02 Clothing accessory or personal decoration item		17.98 Other specified fire, flame or smoke
	09.03 Personal grooming utensil		17.99 Unspecified fire, flame or smoke injury
	09.04 Toiletries, cosmetics, or related product	18 Hot object/substance nec	18.01 Hot liquid
	09.05 Communication or related utensil or accessory		18.02 Hot air or gas
	09.06 Arts and crafts supplies		18.98 Other specified hot object/substance
	09.07 Personal aid		18.99 Unspecified hot object/substance
	09.08 Tobacco or related product		

Source: IDB-FDS data dictionary

For the purpose of focusing on just the injuries that were related to a product, we exclude all cases in which the object/substance is unspecified. The remaining cases form the group of injury incidents related to products in the sense that a product was directly linked to the injury event. Annex IIb contains in detail the selection criteria and the filters that are sequentially applied in IDB-FDS to arrive at this group.

It should be noted however that while injuries that related to a product can be ascertained, the IDB-FDS cannot provide information with regards to whether the injury was actually caused by the product design or the lack of product safety. In the following analysis of IDB data we therefore refer to product-related injuries. A reference to 'injury' in this section refers to non-fatal injuries. Only a small number of fatal injuries are recorded in the IDB, and these cases have been excluded for the analysis.

Incidence of product-related injuries in the EU

To estimate the number of injuries related to different product groups we use the number of injuries recorded in the IDB-FDS between 2013-2017. The period spanning from 2013 to 2017 has been selected on the grounds of data availability given that systematic collection of relevant injury data occurred after countries signed up for a Joint Action for Injury Monitoring in Europe (JAMIE) in 2010, with the number of data-supplying countries reaching a peak of responses in 2013 and remaining stable in the

following years until 2017 when funding for IDB was discontinued[311]. Table 88 presents the estimated total number of injuries in the EU27 on average per year between 2013-2017 that were related to different product groups by age of the injured. differentiating between children (0 to 14 years), working age population (15 to 64 years) and older (65+ years). The results show that approximately 50% of all the injuries recorded are related to products.

Table 88: Product-related injuries by age group (EU27, annual average 2013-2017)

Product group	Age			Total[a)]
	0-14	15-64	65+	
05 FURNITURE/FURNISHING	531 053	397 615	368 649	1 297 317
06 INFANT OR CHILD PRODUCT	475 147	49 634	4 421	529 202
07 APPLIANCE MAINLY USED IN HOUSEHOLD	60 262	109 525	37 568	207 355
08 UTENSIL OR CONTAINER	65 380	372 591	38 766	476 737
09 ITEM MAINLY FOR PERSONAL USE	70 955	155 348	165 954	392 257
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY	845 582	748 078	26 657	1 620 339
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	44 995	488 280	139 885	673 181
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	1 165 403	2 190 528	1360 322	4 716 406
15 GROUND SURFACE OR SURFACE CONFORMATION	231 290	492 657	237 998	962 163
17 FIRE, FLAME, OR SMOKE	5 575	28 095	5 009	38 679
18 HOT OBJECT/SUBSTANCE NEC	45 278	44 973	5 946	96 197
A. TOTAL PRODUCT-RELATED INJURIES	**3 540 920**	**5 077 323**	**2 391 176**	**11 009 833**

Source: Civic Consulting, based on IDB-FDS and IDB-MDS data provided by EuroSafe in July 2020. All data extrapolated to EU27 a) Including cases in which age was not specified (19 cases in category).

As explained in the previous sections, not all European countries provide systematic records of injury incidents in the IDB-FDS. To overcome this problem, we use the IDB-MDS, which contains more entries of recorded injuries, and Eurostat population data to extrapolate the FDS data. The method for extrapolation is elaborated in detail in Annex IIc. All tables only present the extrapolated results for the EU27. Given the lack of complete detailed data in the IDB-FDS, this estimation is the best possible approximation of the incidence of product-related injuries taking into account the data available. We find that approximately 11 million product-related injuries occurred in the EU27 per year, during the period 2013-2017. Even though substantial, this number is an underestimation of the actual product-related injuries that occurred, given that IDB only includes injuries that are registered in emergency departments, and does not include injuries treated by consumers themselves or doctors without previous visit to an emergency department. Nevertheless, since health care is required and productivity loss is generally experienced for injuries of at least a certain severity, we consider the estimate appropriate for the calculation of injury costs that is analysed in the next paragraphs.

Table 89 shows the incidence of product-related injuries based on their place of occurrence.

311 EUROSAFE (2013), 'Injuries in the European Union, Report on Injury Statistics 2008-2010', Amsterdam, p. 5; EUROSAFE (2017), 'Injuries in the European Union 2013-2015, supplementary report to the 6th edition of 'Injuries in the EU', p. 26.

Table 89: Product-related injuries by place of occurrence (EU27, annual average 2013-2017)

Product group	Place of occurrence				Total
	Home and residential home	School and education area	Sports area	Other place/ missing	
05 FURNITURE/FURNISHING	1 053 808	9 125	72 044	162 339	1 297 317
06 INFANT OR CHILD PRODUCT	162 426	25 329	96 785	244 662	529 202
07 APPLIANCE MAINLY USED IN HOUSEHOLD	174 600	806	6 033	25 917	207 355
08 UTENSIL OR CONTAINER	369 869	1 895	8 799	96 175	476 737
09 ITEM MAINLY FOR PERSONAL USE	219 399	24 174	14 505	134 179	392 257
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY	192 001	877 967	181 330	369 041	1 620 339
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	464 432	4 138	9 147	195 464	673 181
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	2 976 044	331 560	341 186	1 067 616	4 716 406
15 GROUND SURFACE OR SURFACE CONFORMATION	223 450	43 383	55 362	639 969	962 163
17 FIRE, FLAME, OR SMOKE	25 133	22	152	13 372	38 679
18 HOT OBJECT/SUBSTANCE NEC	81 082	174	436	14 505	96 197
A. TOTAL PRODUCT-RELATED INJURIES	**5 942 245**	**1 318 573**	**785 777**	**2 963 238**	**11 009 833**

Source: Civic Consulting, based on IDB-FDS and IDB-MDS data provided by EuroSafe in July 2020. All data extrapolated to EU27.

The results confirm, in line with previous studies, that most of the injuries that are related to products occur at home as opposed to sports and athletics areas and school and educational areas[312].

Health care utilization

Health care utilization costs include the costs of hospitalization/hospital admission, the costs of treatment in a hospital emergency department, as well as the costs of being treated in a non-hospital setting e.g. at a doctor's office or as an outpatient. To calculate the cost of health care corresponding to the product-related injuries, it is necessary to retrieve data regarding the consequences of the injuries in terms of the required medical attention as well as the unit costs for each type of health care. The data contained in the IDB-FDS enable us to identify between three different groups of product-related injuries in terms of the type of treatment required:

- Patients with product-related injuries that are sent home after treatment;
- Patients with product-related injuries that are either treated and referred to a general practitioner for further treatment or treated and referred for further treatment as an outpatient;
- Patients with product-related injuries that are treated and admitted to hospital or transferred to another hospital.

[312] EuroSafe, Injuries in the European Union, Report on injury statistics 2010-2012, Amsterdam, 2014. EuroSafe, Policy Briefing 12, Safety of Consumer Products and Services, 2009.

Table 90 below shows the number of injuries falling under each of the three groups of health care treatment. More than half of the average number of product-related injuries occurring annually in the EU (6.8 million) concern cases that are sent home after treatment, while 3.9 million injury incidents are admitted to hospitals or referred for further treatment elsewhere (general practitioners, outpatient clinics) after receiving treatment. We exclude from the calculation, injuries that are treated in a different way and injuries for which the treatment is not indicated (roughly 0.3 million cases).

Table 90: Product-related injuries per type of treatment received (EU27, annual average 2013-2017)

Product group	Treatment				Total
	Sent home after treatment	Treated and referred to general practitioner or as an outpatient for further treatment	Treated and admitted to hospital or transferred to another hospital	Other/ Unknown/ No treatment	
05 FURNITURE/FURNISHING	762 953	232 749	239 414	62 200	1 297 317
06 INFANT OR CHILD PRODUCT	265 069	134 985	89 075	40 073	529 202
07 APPLIANCE MAINLY USED IN HOUSEHOLD	136 771	42 360	22 802	5 423	207 355
08 UTENSIL OR CONTAINER	378 624	62 331	30 164	5 619	476 737
09 ITEM MAINLY FOR PERSONAL USE	181 069	105 649	91 667	13 873	392 257
10 EQUIPMENT MAINLY USED FOR SPORTS/ RECREATIONAL ACTIVITY	952 472	477 390	140 473	50 004	1 620 339
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	427 800	118 259	118 607	8 515	673 181
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	3 167 784	581 101	884 783	82 737	4 716 406
15 GROUND SURFACE OR SURFACE CONFORMATION	475 800	199 951	265 570	20 842	962 163
17 FIRE, FLAME, OR SMOKE	17 837	5 858	13 830	1 154	38 679
18 HOT OBJECT/SUBSTANCE NEC	58 781	16 508	20 363	544	96 197
A. TOTAL PRODUCT-RELATED INJURIES	**6 824 959**	**1 977 140**	**1 916 748**	**290 986**	**11 009 833**

Source: Civic Consulting, based on IDB-FDS and IDB-MDS data retrieved by EuroSafe in July 2020.

To arrive at the costs of health care utilization we use the approach as described in the following box:

Health care utilisation costs for a given injury type can be estimated by multiplying the average cost of treatment by the number of cases, as indicated below:

$$HeathCareUtil_{EU} = \sum [NrInjuries_{EU,Cat} \times AvgTreatmentCost_{EU,Cat}]$$

Where:

$HealthCareUtil_{EU}$ is the total cost of health care utilisation at the EU level;

$NrInjuries_{EU,Cat}$ is the number of product-related injuries by treatment category;
$AvgTreatmentCost_{EU,Cat}$ is the average cost of treatment for the given injury in a given MS, by treatment category.

For assessing average treatment costs, we use unit cost values for health service delivery from the WHO-CHOICE project, which are provided for different world regions in 2010 international dollars[313]. More specifically the WHO-CHOICE unit cost database contains data on the average cost per inpatient bed day by hospital level and per outpatient visit. The costs take into account personnel (doctor) expenses, facilities expenses, food and overnight costs, while excluding the cost of drugs and diagnostic tests. These data enable us to assign a monetary value to each type of treatment.

After converting the two types of costs into EUR 2010 using the OECD purchasing power parity (PPP) exchange rate[314], we inflate them to EUR 2017 using Eurostat's Labour Cost Index. Based on these conversions the average cost per inpatient bed hospital day is EUR 531.67 while the average cost per outpatient visit amounts to EUR 51.88. We use these values to estimate respectively the cost of the three groups of treatment; each of the group is assigned a value as presented in Table 91.

Table 91: Health care utilization costs by treatment type (in Euro 2017)

	Sent home after treatment	Treated and referred to general practitioner or as an outpatient for further treatment	Treated and admitted to hospital or transferred to another hospital
Costs per unit	€51.88 (per treatment)	€103.76 (per treatment)	€531.67 (per bed day)

Source: Civic Consulting based on WHO-CHOICE estimates of cost for inpatient and outpatient health service delivery, EURO A area. Costs per unit are averages of costs for primary, secondary and tertiary hospitals.

As shown in table above, the outpatient unit cost is used for the injuries that are sent home after treatment, while for the injuries that are referred for further treatment to another doctor or to an outpatient clinic, we apply double this value given that the injured will make at least one additional visit as an outpatient for treatment. The unit cost for injuries that are treated and referred to a general practitioner or to an outpatient clinic for further treatment is a prudent cost estimate, given that no relevant benchmark data could be identified for the EU. The average cost for an inpatient bed day is then multiplied by the number of injuries that have been admitted to hospital or transferred to another hospital, and by the average length of stay of patients admitted due to product-related injuries as retrieved from the IDB-FDS (6 days). Our results for the health utilization costs are depicted in Table 92.

[313] WHO Economic Analysis and Evaluation Team (2010), 'WHO-CHOICE estimates of cost for inpatient and outpatient health service delivery', pp. 1-60, available at: https://www.who.int/choice/cost-effectiveness/inputs/country_inpatient_outpatient_2010.pdf.

[314] OECD (2020), Purchasing power parities (PPP) (indicator), available at: doi: 10.1787/1290ee5a-en (accessed on 06 July 2020).

Table 92: Costs of health care utilization for product-related injuries (EU27, annual extrapolated average 2013-2017) per type of treatment received

Product group	Treatment Costs (€)			Total (€)
	Sent home after treatment	Treated and referred to general practitioner or as an outpatient for further treatment	Treated and admitted to hospital or transferred to another hospital	
05 FURNITURE/FURNISHING	39 582 512	24 150 394	763 736 215	827 469 121
06 INFANT OR CHILD PRODUCT	13 751 963	14 006 189	284 151 835	311 909 986
07 APPLIANCE MAINLY USED IN HOUSEHOLD	7 095 746	4 395 295	72 740 091	84 231 132
08 UTENSIL OR CONTAINER	19 643 240	6 467 524	96 222 565	122 333 328
09 ITEM MAINLY FOR PERSONAL USE	9 393 954	10 962 250	292 419 333	312 775 537
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY	49 414 866	49 534 635	448 112 306	547 061 806
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	22 194 544	12 270 669	378 359 631	412 824 845
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	164 346 743	60 295 763	2 822 482 257	3 047 124 763
15 GROUND SURFACE OR SURFACE CONFORMATION	24 684 835	20 747 148	847 175 421	892 607 403
17 FIRE, FLAME, OR SMOKE	925 385	607 884	44 116 483	45 649 752
18 HOT OBJECT/SUBSTANCE NEC	3 049 589	1 712 922	64 958 916	69 721 427
A. TOTAL PRODUCT-RELATED INJURIES	**354 083 375**	**205 150 672**	**6 114 475 052**	**6 673 709 099**

Source: Civic Consulting, based on IDB-FDS and IDB-MDS data retrieved by EuroSafe in July 2020.

Our estimation indicates that the total health care utilization cost for product-related injuries in the EU is approximately EUR 6.7 billion per year. As expected, hospitalization costs account for the larger part of the total health care costs, reaching about EUR 6.1 billion. While the annual cost of EUR 6.7 billion is significant, it should however be regarded as a conservative estimate given that the WHO-CHOICE unit costs exclude the cost of medicine and diagnostic tests. If these costs were also included in the assessment, the total cost of health care for product-related injuries would considerably increase.

Productivity losses

The cost of productivity losses is considered for this assessment to correspond to the value of missed time from work. We focus on losses in terms of paid employment, hence productivity losses concerning non-paid work such as household work, work losses of family/friends due to time spent transporting, visiting, caring etc., as well as employer cost are not considered. The cost of productivity losses is calculated first by estimating the number of work days lost as a consequence of the injury related to a product and then multiplying this number by the EU average gross daily earnings. Product related injuries for which the type of treatment is not indicated or recorded are not taken into account for the assessment of productivity losses.

The detailed approach for determining productivity losses is provided in the following box:

The cost of **productivity losses** for a given treatment category are calculated as the cost of missed work. The calculation can be expressed as:

$$ProdLoss_{EU} = \sum [NrInjuries_{EU,Cat} \times WAPop_{EU} \times LMP_{EU} \times Wage_{EU} \times DaysLost_{Cat}]$$

Where:

ProdLoss$_{EU}$ is the total cost of productivity losses in the EU;

NrInjuries$_{EU,\ Cat}$ is the number of product-related injuries in a given treatment category;

WAPop$_{EU}$ is the proportion of the injured persons that are of working age;

LMP$_{EU}$ is the labour market participation rate in the EU for working age population;

Wage$_{EU}$ is the average daily wage in the EU; and

DaysLost$_{Cat}$ is the average number of days of work lost for a given treatment category.

The number of work days lost differs based on the severity of the injury and the required subsequent treatment. Table 93 presents the assumptions used for this calculation. They are partly based on a conservative minimum estimate, and partly reflect available estimates on the average work days lost per type of injury, which have been used for assessing productivity losses for patients that were hospitalized due to a product-related injury.

Table 93: Average work days lost per type of treatment

	Sent home after treatment	Treated and referred to general practitioner or as an outpatient for further treatment	Treated and admitted to hospital or transferred to another hospital
Lost work days	1[a)]	2 [a)]	15.6[b)]

Source: Civic Consulting based on IDB-FDS data. a) No benchmark data could be identified. Assumed as conservative minimum estimate. b) Calculated by Civic Consulting based on average days lost per case due to workplace non-fatal injury, by nature of injury, for people working in the last 12 months in Great Britain (three year average 2016/17-2018/19). Source: Labour Force Survey (LFS), https://www.hse.gov.uk/statistics/dayslost.htm, detailed data file: ;https://www.hse.gov.uk/statistics/lfs/lfsinjnat.xlsx. The average work days lost was calculated by multiplying for each type of injury the average loss in work days with the share of this type of injuries in the hospitalised cases. For types of injury where no data was available, the average days lost for 'other type of injury' was used (8.8 days), except for 'Traumatic amputation, where the value for fracture/broken bones was used (23.1).

The monetary value of a day missed from work is estimated based on the EU27 average annual gross earnings for year 2017 divided by the number of working days for the same year[315]. Based on this calculation, the average daily wage for EU27 in 2017 is EUR 132.10.

[315] For gross annual earnings see Eurostat, *Annual net earnings [earn_nt_net].* Extracted June 2020. For the number of working days per year see ECB, *Annual working days for EU-27 in 2017.* Extracted June 2020.

Finally, productivity losses in terms of paid employment are experienced only by persons that are active in the labour market. We therefore use for the calculation the labour market participation rate for the age group 15 to 64 years, which is 72.8% for 2017[316].

Table 94 below shows our estimation of the costs of productivity losses due to product-related injuries (per type of treatment). As described in the previous box the total costs of productivity loss is calculated by adding up the productivity losses for each of the three types of treatment (see Table 93 above). The productivity losses per type of treatment are calculated by multiplying the number of injuries in this category by the proportion of the injured persons that are working age and employed, and by the average daily earnings as well as the average number of workdays lost per injury.

Table 94: Cost of productivity losses due to product-related injuries per type of treatment (EU27, 2017)

Product group	Costs of productivity losses (€)			Total (€)
	Sent home after treatment	Treated and referred to general practitioner or as an outpatient for further treatment	Treated and admitted to hospital or transferred to another hospital	
05 FURNITURE/FURNISHING	33 839 101	20 646 179	165 451 157	219 936 437
06 INFANT OR CHILD PRODUCT	11 756 557	11 973 895	61 556 921	85 287 373
07 APPLIANCE MAINLY USED IN HOUSEHOLD	6 066 155	3 757 539	15 757 970	25 581 664
08 UTENSIL OR CONTAINER	16 793 011	5 529 088	20 845 070	43 167 169
09 ITEM MAINLY FOR PERSONAL USE	8 030 894	9 371 630	63 347 941	80 750 466
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY	42 244 783	42 347 174	97 076 318	181 668 275
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	18 974 123	10 490 199	81 965 524	111 429 845
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	140 500 079	51 546 865	611 445 347	803 492 292
15 GROUND SURFACE OR SURFACE CONFORMATION	21 103 073	17 736 743	183 526 918	222 366 733
17 FIRE, FLAME, OR SMOKE	791 112	519 680	9 557 126	10 867 918
18 HOT OBJECT/SUBSTANCE NEC	2 607 094	1 464 378	14 072 303	18 143 776
A. TOTAL PRODUCT-RELATED INJURIES	**302 705 983**	**175 383 370**	**1 324 602 595**	**1 802 691 948**

[316] For the labour market participation rate see data on the active population in the labour market (both sexes) in 2017 from Eurostat, *Employment and activity by sex and age - annual data [lfsi_emp_a].* Extracted June 2020.

Source: Civic Consulting based on IDB-FDS data, Eurostat data on Annual net earnings [earn_nt_net] and Employment and activity by sex and age - annual data [lfsi_emp_a], ECB data on Annual working days for EU-27 in 2017 and estimates on average days lost per injury.

Our results indicate that productivity losses are higher for product-related injuries for which hospitalization has been necessary, while the large number of less serious product related injuries explains why the productivity losses for injuries that were sent home after treatment are also quite high. More specifically, productivity losses are estimated at approximately EUR 1.3 billion for cases of injuries that required hospitalization while the productivity losses of less serious injuries are estimated at about EUR 0.5 billion. The total cost of productivity losses resulting from product-related injuries amounts to approximately EUR 1.8 billion on average per year.

Loss of quality of life

Apart from the health care costs and the loss in productivity that are incurred as a result of an injury, the reduction in quality of life that may be experienced due to an injury, is also an important cost that needs to be assessed. Especially in cases of severe injuries, the loss in quality of life can far exceed the rest of all the costs incurred. To estimate the impact of the injury in terms of reduced life quality we use the Quality Adjusted Life Year (QALY), a measure that integrates evaluation of the quality and quantity of life[317]. The QALY was initially developed to undertake cost effectiveness analyses of health care interventions but it can also represent the consequences of different injuries in terms of loss of quality of life[318]. The impact of each injury can be expressed in terms of a QALY loss. Each injury is assessed based on QALY-weight with 1.0 representing perfect health and 0.0 representing death. Multiplying the weight representing the QALY loss due to an injury with the value of a QALY can provide a monetary estimation of the loss of quality of life as a result of the injury.

For calculating the cost due to reduced quality of life, we use the following approach[319].

Loss of quality of life will be considered for serious injuries, which are considered to be those for which hospitalisation was required, according to the following equation.

$$LossQualityLife_{EU} = \sum [NrInjuries_{EU,Hosp,Inj} \times LossQALY_{Inj} \times ValueQALY_{EU}]$$

Where:

LossQualityLife$_{EU}$ is the monetised total loss of quality of life of patients hospitalised due to product-related injuries in the EU;

NrInjuries$_{EU,Hosp,\ Inj}$ is the number of hospitalised cases for each main type of injury related to products in the EU;

LossQALY$_{Inj}$ is the Quality Adjusted Life Year loss for each main type of injury;

ValueQALY$_{EU}$ is the monetary value assigned to a Quality Adjusted Life Year.

According to the injury data presented above, the total average number of hospitalized cases that result from product-related injuries is approximately 1.9 million per year.

317 Adler, Matthew D. "QALY's and Policy Evaluation: A New Perspective." *Yale Journal of Health Policy, Law, and Ethic*s 6, (2006), Hammitt, James K. "QALYs Versus WTP." *Risk Analysis* 22, no. 5 (2002): 985-1001.

318 See Drummond, Michael F., Mark Sculpher, George W. Torrance, Bernie J. O'Brien, and Greg L. Stoddart. *Methods for the Economic Evaluation of Health Care Programmes*. 3rd ed. Oxford, New York: Oxford University Press, 2005; Brazier, John, Julie Ratcliffe, Joshua A. Salomon, and Aki Tsuchiya. Measuring and Valuing Health Benefits for Economic Evaluation. Oxford; New York: Oxford University Press, 2007.

319 See Karapanou, Vaia. *Towards a Better Assessment of Pain and Suffering Damages for Personal Injuries. A proposal based on Quality Adjusted Life Years.* Cambridge, Antwerp, Portland: Intersentia, 2014.

Table 95 lists the ten most frequently occurring injuries among hospitalized cases, which account for 89% of all injury cases where patients were admitted to a hospital.

Table 95: Type of injury for hospitalized cases

Type of injury	Number of hospitalized cases	Share of hospitalized cases
Fracture	1 024 668	53.5%
Contusion, bruise	210 579	11.0%
Concussion	188 844	9.9%
Open wound	107 130	5.6%
Injury to muscle and tendon	52 813	2.8%
Luxation, dislocation	41 510	2.2%
Burns, scalds	37 590	2.0%
Distortion and sprain	18 011	0.9%
Traumatic amputation	16 791	0.9%
Abrasion	5 684	0.3%
All other injury types	*186 927*	*9.8%*
Unspecified/missing	*26 200*	*1.4%*
Total hospitalised	**1 916 748**	**100%**

Source: Civic Consulting based on IDB-FDS data retrieved by EuroSafe in July 2020. Number of hospitalised cases extrapolated to EU27.

For each of the injuries we have identified the corresponding QALY-weight that expresses the impact of the injury in terms of the quality of life of individuals. The Center for the Evaluation of Value and Risk in health (CEVR), which is part of the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center, has compiled an archive of such estimates, the Cost-Effectiveness Analysis (CEA) registry, which comprises more than 10 300 QALY-weights[320]. We have searched the CEA-registry using the list of the most frequent injuries as search terms to arrive at the relevant QALY-weights[321]. We subtract these QALY-weights from 1.00, assuming the injured had perfect health before the injury to isolate potential effects of other pre-existing health conditions, and arrive at the loss experienced in the quality of life due to the injury. Table 96 below presents QALY losses for the most frequent injuries resulting from products. Note that for contusion, distortion, and abrasion we assume a QALY loss of 0 given that these injuries are temporary and least serious in terms of inconvenience experienced, hence we assume they do not affect the quality of life in a given year. We assign the same value to other types of injury, in line with the conservative approach chosen for elaborating this estimate[322].

[320] Center for the Evaluation of Value and Risk in Health. The Cost-Effectiveness Analysis Registry [Internet]. (Boston), Institute for Clinical Research and Health Policy Studies, Tufts Medical Center. Available from: www.cearegistry.org Accessed in July 2020.

[321] The listed QALY losses indicate the extend of the loss that is experienced from a representative occurrence of the respective injury (main scenario). However, given that milder and more severe occurrences of these injuries are possible e.g. minor burns vs third-degree burns, we also perform a sensitivity analysis estimating the loss of quality of life using lower and higher QALY–weights to indicate respective gravity of losses (see sensitivity analysis, below).

[322] Due to data limitations, we also do not consider losses in the quality of life in the year following the year of the injury (which is relevant for serious injuries, such as amputations).

Table 96: QALY losses per type of injury

Type of injury	QALY losses
Traumatic amputation	0.4
Concussion	0.2
Open wound	0.3
Luxation, dislocation	0.2
Fracture	0.13
Injury to muscle and tendon	0.1
Burns, scalds	0.1
Contusion, bruise	0
Distortion and sprain	0
Abrasion	0
All other injury types	0
Unspecified/missing	0

Source: Cost-Effectiveness Registry, see https://cevr.tuftsmedicalcenter.org/databases/cea-registry, retrieved in July 2020. Note that for the cases of contusion, distortion, abrasion a QALY loss of 0 is assumed given that these injuries are temporary and least serious in terms of experience inconvenience.

To estimate the monetary value of the loss of quality of life due to the injury we have to assign a monetary value to a QALY. Numerous studies exist in which the monetary value for one QALY has been estimated using the willingness to pay (WTP) for a small gain in QALYs. Table 97 presents some of the existing estimates.

Table 97: Estimates for the willingness to pay per QALY

Source	WTP for a QALY estimate
Hirth et al. (2000)	$265 345 (median estimate of 35 studies) (in 1997 dollars)
Bobinac et al. (2014)	€114 665 (in EUR 2010)
Ryan and Svensson (2014)	€118 839 (in EUR 2010)
European Value of a QALY	€68 000 (in EUR 2010)
World Health Organization (2010)	€55 000
European Commission (2016)	€31 391 (in EUR 2012)
European Agency for Safety and Health at Work (2019)	€41 096 (in EUR 2013)
Civic Consulting based on VSL estimates provided in EU Commission's Better Regulation Toolbox	€101 706 (low estimate) €123 500 (medium estimate) €145 294 (high estimate) (in EUR 2017)

Source: Hirth, Richard A., Michael E. Chernew, Edward Miller, A. Mark Fendrick, and William G. Weissert (2000). "Willingness to Pay for a Quality-Adjusted Life Year: In Search of a Standard." *Medical Decision Making* 20, no. 3 (7): 332-342; Bobinac A, van Exel J, Rutten FF, Brouwer WB. (2014). "The value of a QALY: individual willingness to pay for health gains under risk", PharmacoEconomics 32:75–86; Ryen, L., & Svensson, M. (2014). "The Willingness to Pay for a Quality Adjusted Life Year: A Review of the Empirical Literature*", Health Economics, 24(10), 1289–1301;* Huang L., Frijters P., Dalziel K., Clarke P. (2018). "Life satisfaction, QALYs, and the monetary value of health", *Social Science & Medicine* 211: 131-136; EuroVaQ, *European Value of a Quality Adjusted Life Year Final Publishable Report*, 2010. http://research.ncl.ac.uk/eurovaq/EuroVaQ_Final_Publishable_Report_and_Appendices.pdf; The WHO Regional Office for Europe, (2010), "Best practice in estimating the cost of alcohol – Recommendations for future studies", 1-65; European Commission, Commission Staff Working Document: Impact Assessment Accompanying the document Council Directive amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead, SWD(2016) 290 final; European Agency for Safety and Health at Work (2019), "The value of occupational safety and health and the societal costs of work-related injuries and diseases", 1-116; Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245; ECHA (2016), Reference willingness-to-pay values for monetizing chemicals health impacts, pp. 1-8.

Another approach that has been used to estimate the WTP for a QALY involves taking advantage of the existing literature on the Value of Statistical Life (VSL). The VSL expresses the value of lost life expectancy both in terms of lost earnings as well as in terms of lost enjoyment and quality of life, while the Value of Statistical Life Year (VSLY) expresses the present value of a lost life year. The extensive literature on the VSL(Y) investigates how many resources people are willing to spend on reducing the probability of fatal accidents. These readily available WTP values can be used to derive a monetary value per QALY if certain assumptions are made. More specifically, if full quality of life is assumed over the remaining life expectancy, the monetary value for a QALY can be derived by dividing the VSL by the number of life years left, applying a discount factor to express it in current values and excluding the cost of lost productivity. This approach, the validity of which was also confirmed by an expert of the European Chemicals Agency (ECHA)[323], is also consistent with the VSL approach that is used below to calculate the cost of premature death.

We follow this approach to derive the monetary value for one QALY, using the VSL range of estimates between €3.5 million (lower estimate) and €5 million (higher estimate) included in the Commission's Better Regulation Toolbox[324]. After expressing them in EUR 2017 using the labour cost index we convert them to VSLY estimates by applying a discount factor of 4%[325] and a remaining life expectancy of 35 years, which is commonly considered as the remaining life expectancy of an adult at the time of injury[326]. Finally, considering that the resulting values based on the VSL are upper bound estimates that tend to overestimate the value per QALY by a factor of two on average, we divide the estimated amounts by two[327]. Our resulting range of willingness to pay estimates per QALY are listed at the bottom of Table 97.

Using this approach, we apply a medium estimate of EUR 125 000 per QALY across the EU to reach an estimation of the loss of the quality of life due to product-related injuries while retaining the low and high estimates for later sensitivity analysis. As mentioned before, we focus on serious injuries which are the most likely to have inflicted loss in the quality of life of the injured consumers, namely the group of injuries that required hospitalization. By multiplying the number of incidents per injury type with the corresponding weight representing the QALY-loss and the monetary value per QALY, we arrive at the corresponding loss in quality of life estimate for the EU.

[323] We thank Dr. Christoph Rheinberger, Co-ordinator of Socio-economic Analysis of ECHA for our communication and for providing insights that helped us define the range of WTP values per QALY using existing VSL estimates.

[324] Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245.

[325] Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 503.

[326] To estimate VSLY we use the formula VSLY= r*VSL/(1-(1+r)^-L) where r is the discount rate and L is remaining life expectancy, see also Joseph E. Aldy & W. Kip Viscusi, 2008. "Adjusting the Value of a Statistical Life for Age and Cohort Effects," The Review of Economics and Statistics, MIT Press, vol. 90(3), pages 573-581.

[327] Daniel Herrera-Araujo, James K. Hammitt & Christoph M. Rheinberger (2020), "Theoretical bounds on the value of improved health", *Journal of Health Economics 72,* p. 1-15.

Table 98: Loss in quality of life after product-related injuries per injury type (based on medium estimate per QALY)

Type of injury	Treated and admitted to hospital or transferred to another hospital (incidence, EU27)	Loss of quality of life (monetized in €)
Fracture	1 024 668	16 650 861 140
Concussion	188 844	4 721 088 389
Open wound	107 130	4 017 362 551
Luxation, dislocation	41 510	1 037 757 406
Traumatic amputation	16 791	839 570 787
Injury to muscle and tendon	52 813	660 168 339
Burns, scalds	37 590	469 876 517
Contusion, bruise	210 579	0
Distortion and sprain	18 011	0
Abrasion	5 684	0
All other injury types	186 927	0
Unspecified/missing	26 200	0
Total (all injuries)	**1 916 748**	**28 396 685 129**

Source: Civic Consulting. Based on a medium estimate of EUR 125 000 per QALY (see text).

As shown in Table 98 above the monetized loss in quality of life after product-related injuries in the EU is estimated at EUR 28.4 billion per year. This estimate only concerns serious injuries, for which hospitalization was required.

The cost of product related premature death in the EU

Calculating the cost of product related premature death requires information regarding the occurrence of fatal non-intentional injuries in the EU. While mortality data is available from other sources such as Eurostat, the most detailed data is available through the WHO Mortality Database, which has therefore been used for the following analysis.

We first present the data in the WHO Mortality Database and its limitations, before describing the number of fatalities caused by mechanisms that are relevant for product safety in the EU, as extracted from the database. On this basis, we calculate the resulting cost of premature death per year.

WHO Mortality Database

In order to arrive at the number of fatal injuries in Europe, we use the WHO Mortality Database (WHO-MDB) which contains data for all countries participating in WHO[328]. By selecting only EU countries it is possible to arrive at the number of deaths for EU by age, sex and cause of death. The ICD-10 is the current standard for classification of diseases and incorporates the external causes of injury in a separate chapter, some of which are associated with certain products. For instance, injuries which are classified with the following codes are related to the respective consumer products:

- W07 Fall involving chair;
- W09 Fall involving playground equipment; and,

[328] WHO Mortality Database, accessible at: https://www.who.int/healthinfo/mortality_data/en/.

- W28 Contact with powered lawnmower.

Other external causes of injury are not certainly associated, but potentially associated with consumer products such as:

- W45 Foreign body or object entering through skin;
- X02 Exposure to controlled fire in building or structure; and,
- X13 Contact with steam and hot vapours.

Therefore, fatalities attributed to these and other similar causes cannot be clearly attributed to products but rather be considered as being potentially related to products. According to a recent analysis of the availability of EU data on product-related injuries, the extent of detail of this classification is such that it does not enable systematic identification of potential product involvement in fatal injuries[329]. In more detail, it elaborates:

> "Mortality statistics is one of the most complete and accurate epidemiological data collection practices in Europe. In all EU countries, the medical certification of death was made mandatory according to the Commission Regulation (EU) No 328/2011 on COD statistics. […] Most countries in the world and the EU use the WHO international standard form for describing the COD, which allows for the registration of the underlying event or injury that initiated the chain of events causing the fatal outcome (part I of the WHO COD form). The extent of detail on the non-medical circumstances of the injury event (external cause of morbidity and mortality), in the COD, is usually poor and does not allow for simple identification of a potentially involved product or a product category from this type of data source. Trends and inconsistencies in filling the mortality certificates have already been reported and efforts to increase the accuracy of the information recording are ongoing. […] the information on the cause of the mortality (by the use of ICD-10) that can currently be recovered from the death certificates is not specific enough to support consumer product safety work. In rare cases, some indication on limited range of product categories (e.g., sports equipment) may be retrieved (if the form is properly filled), but no specific details on the product can be recovered."

In spite of these limitations, the WHO Mortality database is the most detailed dataset that is currently available. It has the advantage that the detailed raw data is accessible on the WHO website[330]. Additionally, the detailed (four-digit) ICD-10 codes provide also information on the place of occurrence. This allows excluding fatalities occurring at work and other non-relevant fatalities.

Query used to extract data from the WHO-MDB

To enable a selection of fatal injury incidents that are relevant for this analysis we filter existing data by selecting injury incidents based on the ICD-10 codes that are listed in Table 99 below. More specifically, we selected ICD-10 codes from the chapter XX (External causes of morbidity and mortality) and then excluded the following cases:

- Transport accidents
- Intentional self-harm
- Assault
- Event of undetermined intent
- Legal interventions and operations of war
- Complications of medical and surgical care

[329] Radovnikovic, A. *et al*. (2020), 'Assessment of the opportunities for increasing the availability of EU data on consumer product related injuries', *Injury Prevention* 0, p. 8.

[330] https://www.who.int/healthinfo/statistics/mortality_rawdata/en/. The relevant file (Mortality, ICD-10 (part2/2)) can be downloaded and processed with statistical software. It contains the detailed mortality data for the tenth revision of the ICD (International Classification of Diseases). Last updated: 15 December 2019. This dataset was used for the analysis described in the following section.

- Sequelae of external causes of morbidity and mortality[331]
- Supplementary factors related to causes of morbidity and mortality classified elsewhere[332]

From the remaining codes we selected the ICD-10 codes that can be associated to product-related fatal injuries, based on the description of the code. Most of these codes have already been used by EuroSafe to identify product related fatal home injuries[333]. We added to these some additional codes which are clearly associated to product related injuries (such as falls involving ladder, chair, skates etc.). The final list of selected codes is presented in Table 99.

Table 99: ICD-10 codes <u>selected</u> for the analysis

Group	ICD-10 codes selected for the analysis
Falls involving products (e.g. bed, ladder, wheelchair, skates)	W02 Fall involving ice-skates, skis, roller-skates or skateboards
	W05 Fall involving wheelchair
	W06 Fall involving bed
	W07 Fall involving chair
	W08 Fall involving other furniture
	W09 Fall involving playground equipment
	W11 Fall on and from ladder
Objects, machinery, tools	W20 Struck by thrown, projected or falling object
	W21 Striking against or struck by sports equipment
	W22 Striking against or struck by other objects
	W23 Caught, crushed, jammed or pinched in or between objects
	W24 Contact with lifting and transmission devices, not elsewhere classified
	W25 Contact with sharp glass
	W26 Contact with other sharp object(s)
	W27 Contact with nonpowered hand tool
	W28 Contact with powered lawnmower
	W29 Contact with other powered hand tools and household machinery
	W44 Foreign body entering into or through eye or natural orifice
	W45 Foreign body or object entering through skin
Suffocation, strangulation	W75 Accidental suffocation and strangulation in bed
	W76 Other accidental hanging and strangulation
Choking, ingestion of objects	W80 Inhalation and ingestion of other objects causing obstruction of respiratory tract
	W81 Confined to or trapped in a low-oxygen environment
	W83 Other specified threats to breathing
	W84 Unspecified threat to breathing
Electric current, radiation	W85 Exposure to electric transmission lines
	W86 Exposure to other specified electric current
	W87 Exposure to unspecified electric current
	W89 Exposure to man-made visible and ultraviolet light
Fire, smoke	X01 Exposure to uncontrolled fire, not in building or structure
	X02 Exposure to controlled fire in building or structure
	X03 Exposure to controlled fire, not in building or structure
	X04 Exposure to ignition of highly flammable material
	X05 Exposure to ignition or melting of nightwear
	X06 Exposure to ignition or melting of other clothing and apparel
	X08 Exposure to other specified smoke, fire and flames
	X09 Exposure to unspecified smoke, fire and flames
Hot water, fluids	X10 Contact with hot drinks, food, fats and cooking oils
	X11 Contact with hot tap-water

[331] These are late effects of transport accidents, assault, intentional harm, acts of war etc.

[332] This category includes among others Y95 Nosocomial Condition, Y96 Work related condition, Y97 Environmental pollution related condition, Y98 Lifestyle related condition.

[333] EuroSafe, Injuries in the European Union, Report on injury statistics 2010-2012, Amsterdam, 2014.

	X12 Contact with other hot fluids
	X13 Contact with steam and hot vapours
	X14 Contact with hot air and gases
	X15 Contact with hot household appliances
	X16 Contact with hot heating appliances, radiators and pipes
	X17 Contact with hot engines, machinery and tools
	X18 Contact with other hot metals
	X19 Contact with other and unspecified heat and hot substances

Source: ICD-10, Version 2016, see https://icd.who.int/browse10/2016/en#/XX

From the remaining subset of cases we excluded fatal injuries that have occurred in places as for instance trade and service areas, industrial and construction areas, and farms, which are likely to be work related. In summary, the selection:

a. Takes explicitly into account all ICD-10 codes related to non-intentional fatal accidents that specify the involvement of a product (such as falls related to ladders or skates, contact with powered lawnmower, ignition or melting of nightwear).
b. Also include other accidental injuries caused by mechanisms that are relevant for product safety, namely:
    - Falls involving products;
    - Objects, machinery, tools;
    - Suffocation, strangulation;
    - Choking, ingestion of objects;
    - Electric current, radiation;
    - Fire, smoke;
    - Hot water, fluids.
c. Transport related fatal injuries are excluded; and finally
d. Fatal injuries occurring in work-related locations are also excluded.

The selected group of fatalities can be considered the best possible approximation regarding the number of fatal injuries related to products. Annex IIe contains in detail the selection criteria and the filters that we applied to WHO-MDB data to arrive at this group. To reflect the limitations of the data used, we refer in the following analysis to fatalities caused by mechanisms relevant for product safety, such as tools, strangulation, electric current, or fire.

Incidence of relevant fatalities in the EU

Raw data retrieved from the WHO-MDB indicates that the latest available data from 2013-2017 vary in terms of representation of the EU27 population. More specifically, we find that relevant data have not been submitted by all Member States for the selected year range and in particular that data is lacking for year 2017, including data from several large European countries such as France and Italy. Due to the significant data gaps, we therefore exclude year 2017 from the estimation and use data from years 2013 to 2016. For each of these years, we calculate a population extrapolation factor using EU27 population data, in order to be able to account for the missing countries in the estimation of the number of fatal injuries. Table 100 shows the resulting population extrapolation factors calculated on the basis of actual EU27 population and the population of the reporting countries.

Table 100: Population extrapolation factor based on EU-27 population data

	2013	2014	2015	2016
EU-27 population	441 257 711	442 883 888	443 666 812	444 802 830
Non-reporting countries	EL	-	SK	BG, DK, IE, LV, SK
Reporting EU population	430 254 096	442 883 888	438 245 463	419 820 300
Population extrapolation factor	**103%**	**100%**	**101%**	**106%**

Source: Civic Consulting, based on EU countries population data retrieved in July 2020 and information regarding which European countries did not report WHO mortality data during the years 2013-2016.

To arrive at the overall number of fatal injury incidents in the EU we take into account the fatal injuries occurring as a result of an accident that are included in the chapter of external causes of morbidity and mortality of the WHO-MDB. By adjusting for the EU27 population we arrive at a total of 550 814 accidental fatal injuries for the years 2013-2016, or 137 703 fatal injuries on average per year as indicated in Table 101 below. This figure includes all fatalities in the EU due to non-intentional accidents, such as transportation accidents, work accidents and all other non-intentional injuries with an external cause of injury, including consumer products.

Table 101: Fatal injuries related to external causes of morbidity and mortality (accidents), years 2013-2016

	2013	2014	2015	2016	Total
Fatal accidents according to WHO-MDB	130 404	132 745	138 347	136 168	537 664
Population extrapolation factor (to account for missing countries)	103%	100%	101%	106%	
Total adjusted	**133 739**	**132 745**	**140 058**	**144 271**	**550 814**
Average per year (2013-2016)					**137 703**

Source: Civic Consulting, based on raw data extracted from WHO-MDB.

From this group of cases we exclude all transport related fatal injuries, which are 26 959 on average per year, based on adjusted population values. The number of fatal injuries that occur as a result of other, not transport-related accidents is shown in Table 102.

Table 102: Fatal injuries occurring as a result of an accident (excluding transport-related accidents, years 2013-2016)

	2013	2014	2015	2016	Total
Fatal accidents excluding transport-related	104 088	105 519	111 547	111 165	432 319
Population extrapolation factor (to account for missing countries)	103%	100%	101%	106%	
Total adjusted	**106 750**	**105 519**	**112 927**	**117 780**	**442 976**
Average per year (2013-2016)					**110 744**

Source: Civic Consulting, extracted by WHO-MDB.

From the remaining subset of cases pertaining to non-intentional fatal injuries we further rule out the fatal injury causes presented in Table 103 below, which are not relevant to products and, in addition, exclude as explained above in paragraph 1.3.2, fatal injuries

occurring in work-related locations. At the same time, we make sure to include relevant cases, for which the description of the injury cause indicates product involvement e.g. fall involving chair, accidental suffocation and strangulation in bed etc. (see detailed description of the query used in the previous section and in Annex IIe).

Table 103: ICD-10 codes excluded from the analysis

Group and codes included in that group	Group codes that are excluded for not being product-related fatality causes
FALLS (W00-19)	W00 Fall on same level involving ice and snow
	W01 Fall on same level from slipping, tripping and stumbling
	W03 Other fall on same level due to collision with, or pushing by, another person
	W04 Fall while being carried or supported by other persons
	W10 Fall on and from stairs and steps
	W12 Fall on and from scaffolding
	W13 Fall from, out of or through building or structure
	W14 Fall from tree
	W15 Fall from cliff
	W16 Diving or jumping into water causing injury other than drowning or submersion
	W17 Other fall from one level to another
	W18 Other fall on same level
	W19 Unspecified fall
EXPOSURE TO INANIMATE MECHANICAL FORCES (W20-49)	W30 Contact with agricultural machinery
	W31 Contact with other and unspecified machinery
	W32 Handgun discharge
	W33 Rifle, shotgun and larger firearm discharge
	W34 Discharge from other and unspecified firearms
	W35 Explosion and rupture of boiler
	W36 Explosion and rupture of gas cylinder
	W37 Explosion and rupture of pressurized tyre, pipe or hose
	W38 Explosion and rupture of other specified pressurized devices
	W39 Discharge of firework
	W40 Explosion of other materials
	W41 Exposure to high-pressure jet
	W42 Exposure to noise
	W43 Exposure to vibration
	W49 Exposure to other and unspecified inanimate mechanical forces
EXPOSURE TO ANIMATE MECHANICAL FORCES (W50-64)	W50 Hit, struck, kicked, twisted, bitten or scratched by another person
	W51 Striking against or bumped into by another person
	W52 Crushed, pushed or stepped on by crowd or human stampede
	W53 Bitten by rat
	W54 Bitten or struck by dog
	W55 Bitten or struck by other mammals
	W56 Contact with marine animal
	W57 Bitten or stung by nonvenomous insect and other nonvenomous arthropods
	W58 Bitten or struck by crocodile or alligator
	W59 Bitten or crushed by other reptiles
	W60 Contact with plant thorns and spines and sharp leaves
	W64 Exposure to other and unspecified animate mechanical forces
ACCIDENTAL DROWNING AND SUBMERSION (W65-74)	W65 Drowning and submersion while in bath-tub
	W66 Drowning and submersion following fall into bath-tub
	W67 Drowning and submersion while in swimming-pool
	W68 Drowning and submersion following fall into swimming-pool
	W69 Drowning and submersion while in natural water
	W70 Drowning and submersion following fall into natural water
	W73 Other specified drowning and submersion
	W74 Unspecified drowning and submersion
	W77 Threat to breathing due to cave-in, falling earth and other substances
	W78 Inhalation of gastric contents

OTHER ACCIDENTAL THREATS TO BREATHING (W75-84)	W79 Inhalation and ingestion of food causing obstruction of respiratory tract
EXPOSURE TO ELECTRIC CURRENT, RADIATION (W85-99)	W88 Exposure to ionizing radiation
CONTACT WITH VENOMOUS ANIMALS AND PLANTS (X20-29)	X20 Contact with venomous snakes and lizards
	X21 Contact with venomous spiders
	X22 Contact with scorpions
	X23 Contact with hornets, wasps and bees
	X24 Contact with centipedes and venomous millipedes (tropical)
	X25 Contact with other venomous arthropods
	X26 Contact with venomous marine animals and plants
	X27 Contact with other specified venomous animals
	X28 Contact with other specified venomous plants
	X29 Contact with unspecified venomous animal or plant
EXPOSURE TO FORCES OF NATURE (X30-39)	X30 Exposure to excessive natural heat
	X31 Exposure to excessive natural cold
	X32 Exposure to sunlight
	X33 Victim of lightning
	X34 Victim of earthquake
	X35 Victim of volcanic eruption
	X36 Victim of avalanche, landslide and other earth movements
	X37 Victim of cataclysmic storm
	X38 Victim of flood
	X39 Exposure to other and unspecified forces of nature
ACCIDENTAL POISONING BY AND EXPOSURE TO NOXIOUS SUBSTANCES (X40-49)	X40 Accidental poisoning by and exposure to nonopioid analgesics, antipyretics and antirheumatics
	X41 Accidental poisoning by and exposure to antiepileptic, sedative-hypnotic, antiparkinsonism and psychotropic drugs, not elsewhere classified
	X42 Accidental poisoning by and exposure to narcotics and psychodysleptics [hallucinogens], not elsewhere classified
	X43 Accidental poisoning by and exposure to other drugs acting on the autonomic nervous system
	X44 Accidental poisoning by and exposure to other and unspecified drugs, medicaments and biological substances
	X45 Accidental poisoning by and exposure to alcohol
	X46 Accidental poisoning by and exposure to organic solvents and halogenated hydrocarbons and their vapours
	X47 Accidental poisoning by and exposure to other gases and vapours
	X48 Accidental poisoning by and exposure to pesticides
	X49 Accidental poisoning by and exposure to other and unspecified chemicals and noxious substances
OVEREXERTION, TRAVEL AND PRIVATION (X50-57)	X50 Overexertion and strenuous or repetitive movements
	X51 Travel and motion
	X52 Prolonged stay in weightless environment
	X53 Lack of food
	X54 Lack of water
	X57 Unspecified privation
ACCIDENTAL EXPOSURE TO OTHER AND UNSPECIFIED FACTORS (X58-59)	X58 Exposure to other specified factors
	X59 Exposure to unspecified factor

Source: ICD-10, Version 2016, see https://icd.who.int/browse10/2016/en#/XX

The selected fatal injury cases are grouped by cause of death (fall, choking, ingestion of objects etc.). We extract the number of fatal injuries per group in all specified places

of occurrence and calculate what proportion of these injuries happened at the selected places of occurrence - home, residential institution, school, sports area, street and highway, other specified places - that are considered relevant for the analysis. They show that 92% of fatal injury incidents occurred at the specified locations (8% occurred in work-related locations)[334]. We apply this factor to extrapolate the relevant share of fatal injuries for those entries in the WHO-MDB for which the place of occurrence is not specified (about two thirds of cases).

Table 104 presents the results of the estimation.

Table 104: Fatalities caused by mechanisms relevant for product safety, such as tools, strangulation, electric current, or fire (EU27, only injuries occurring outside of work-related locations)

Mechanisms relevant for product safety	Number of fatalities					
	2013	2014	2015	2016	Total	Annual average
Falls involving products	2016	2045	2311	2393	8766	**2191**
Objects, machinery, tools	1152	1116	1094	1038	4400	**1100**
Suffocation, strangulation	375	358	357	382	1472	**368**
Choking, ingestion of objects	2299	2369	2810	3355	10834	**2708**
Electric current, radiation	575	517	429	403	1924	**481**
Fire, smoke	1668	1514	1631	1593	6406	**1601**
Hot water, fluids	185	167	194	180	725	**181**
Total	**8271**	**8085**	**8827**	**9343**	**34526**	**8632**

Source: Civic Consulting, based on selection of WHO-MDB data on European Union-27 Member States, years 2013-2016. Data extrapolated to account for missing countries and unspecified place of occurrence.

As the table shows, an estimated 8 632 fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurred on average in the EU27 outside of work-related locations during the period 2013 to 2016 per year.

Cost of premature death

Based on the incidence figures presented above we calculate the cost of premature death related to the selected fatalities. We do so by using the Value of Statistical Life (VSL) method, which provides estimations of the cost of premature death that encompass both material and immaterial losses, i.e. the VSL method can enable estimation of premature death costs, including both lost earnings and loss of enjoyment of life[335]. Our approach is detailed in the following box:

Cost of premature death is estimated for all non-intentional fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) outside of work-related locations, on basis of the following equation:

$$LossFatal_{EU} = NrFatal_{EU} \times VSL_{EU}$$

[334] In the sensitivity analysis, we also explore a scenario in which only fatal accidents occurring at home/residential institutions are considered, see below.

[335] Ted R. Miller, "Willingness to Pay Comes of Age: Will the System Survive," *Northwestern University Law Review* 83, no. 4 (1989), p. 876-907.

Where:

$LossFatal_{EU}$ is the monetised total loss due to the relevant fatalities in the EU;

$NrFatal_{EU}$ is the number of relevant fatalities in the EU;

VSL_{EU} is the monetary value of a statistical life in the EU.

The monetary value used to quantify the value of a statistical human life is derived from individuals' willingness to pay (WTP) to eliminate a small risk of dying[336]. Numerous studies exist in which the VSL has been empirically estimated using the hedonic wage method, the stated preference method or other methods[337]. Table 105 presents some of the existing estimates.

Table 105: Estimates for the Value of a Statistical Life (VSL)

Source	VSL Estimate
OECD	$1.8 million – $5.4 million (in USD 2005)
U.S. Environmental Protection Agency U.S. Department of Transportation U.S. Department of Health and Human Services	$9 - $10 million (in USD 2015/2016)
European Chemicals Agency	€3.5 million (lower estimate) €5 million (higher estimate) (in EUR 2012)

Source: OECD (2012), Mortality risk valuation in environment, health and transport policies, OECD Publishing, available at: https://doi.org/10.1787/9789264130807-en; Kip W. Viscusi (2019), Identifying the legitimate role of the Value of a Statistical Life in Legal Contexts, *Journal of Legal Economics* 25(1-2), pp. 5-28; Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245; ECHA (2016), Reference willingness-to-pay values for monetizing chemicals health impacts, pp. 1-8, available at: https://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts.

As illustrated in the table above, the amounts of VSL estimates may vary between institutions because of the different times the underlying analyses were undertaken, the differences in the methodology used, and the different contexts for which the estimates were calculated. We use the estimates provided by the European Chemicals Agency (ECHA) to calculate the cost of premature death, which are also referred to as reference values in the Better Regulation Toolbox of the European Commission[338]. More specifically we use the average value of the higher and lower estimate for the value of a statistical life provided by ECHA (EUR 4.25 million) as a standard assumption for the cost of a premature death, while retaining the low and high estimates for later sensitivity analysis. Expressed in 2017 values (again inflated by using the labour cost index), we arrive at a VSL estimate of EUR 4.6 million. We use this estimate to arrive at the annual cost of premature death due to fatalities caused by mechanisms relevant for product safety.

We are aware of the discussion and the theoretical underpinnings regarding the relationship between age and the value of statistical life, according to which the VSL is affected by age. More specifically, in 2001 the European Commission recommended that

[336] It can also be derived by the willingness to accept (WTA) a small probability of death.

[337] The stated preference method tries to elicit the value of non-market goods by directly asking people how much they value these goods while the hedonic wage method uses labour market data that reveal the trade-offs workers make between job risks and additional pay. The hedonic wage method belongs to the group of revealed preference methods which infer WTP / WTA values from observed behaviour. See Alessandra Arcuri, 2012, "Risk Regulation" in: Roger J. Van den Bergh & Alessio M. Pacces (ed.), Regulation and Economics, chapter 6, Edward Elgar Publishing.

[338] Better Regulation Toolbox complementing the better regulation guideline presented in SWD (2017) 350, p. 245.

member countries use a VSL that declines with age[339], however, according to subsequent literature a person's willingness to pay for reduced risks does not steadily decline with age but rather follows an inverted U-shape[340]. However, an approach using different VSL values per age would be very complex to implement in our dataset because it would require numerous assumptions to be made regarding life expectancy of victims, which would reduce significantly the transparency of the approach. Similar methodological issues would be encountered if the value of statistical life year (VSLY), which is an estimate on the value placed on one year of life, would be used instead of the value of statistical life. In line with the previous argument, varying VSLY would need to be used depending on the age in which the accident occurred. As indicated before, we have assumed a constant VSL and derived on this basis a consistent estimate for VSLY, so that these methodological problems can be avoided. Combined with the inconclusiveness of the discussion regarding the exact effect of age on the VSL, and the different approaches currently followed by different institutions, the above issues have led us to apply a single monetary value for fatalities.

The value of statistical life expresses the present value of lost life years. This is assumed to be the life of an adult with a remaining life expectancy of 35 years. By multiplying the number of premature deaths with the VSL estimate we arrive at the annual cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) outside of work-related locations (see Table 106).

Table 106: Cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) (EU27, annual average 2013 to 2016, only fatalities occurring outside of work-related locations)

Mechanisms relevant for product safety	Incidence of fatalities (annual average 2013-2016)	Cost of premature death per year (in €)
Choking, ingestion of objects	2 708	12 486 294 787
Falls involving products	2 191	10 102 694 689
Fire, smoke	1 601	7 382 769 592
Objects, machinery, tools	1 100	5 071 519 845
Electric current, radiation	481	2 217 242 440
Suffocation, strangulation	368	1 696 321 359
Hot water, fluids	181	836 006 065
Total	**8 632**	**39 792 848 778**

As indicated in the table above, the cost of premature death due to fatalities caused by mechanisms relevant for product safety is estimated at EUR 39.8 billion per year for the EU.

[339] European Commission (2001), 'Recommended interim values for the value of preventing a fatality in DG Environment', p. 1-4, available at: https://ec.europa.eu/environment/enveco/others/pdf/recommended_interim_values.pdf.

[340] Joseph E. Aldy, W. Kip. Viscusi (2007), "Age Differences in the Value of Statistical Life: Revealed Preference Evidence", *Review of Environmental Economics and Policy* 1(2), p. 241-260; W. Kip Viscussi (2010), "The heterogeneity of the value of statistical life: introduction and overview", *Journal of Risk and Uncertainty* 40, p. 1-13.

Overview of results

Total detriment suffered by EU consumers and society

Table 107 summarises the results of the analysis, and provides the main components of the estimated detriment suffered by EU consumers and society. For non-fatal injuries, these are health care utilization costs, productivity losses and loss of quality of life for hospitalised cases. For fatal injuries, this is the cost of premature death.

Table 107: Estimated detriment suffered by EU consumers and society per year (EU27, in million Euro)

	Type of costs/loss	Cost/loss (in million €)
Injuries	Health care utilization	6 673.7
	Productivity losses	1 802.7
	Loss of quality of life (hospitalized cases)	28 396. 7
Fatalities	Premature death	39 792. 8
Total		**76 665. 9**

Source: Civic Consulting, see tables above. All amounts in EUR 2017.

In total, the detriment suffered by EU consumers and society is estimated to be EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations. The analysis therefore excludes losses caused by work and transportation accidents.

Preventable detriment suffered

As indicated before, while the available data allows estimating the number of non-fatal injuries that are related to a product, it cannot provide information with regards to whether the injury was actually caused by the product design or the lack of product safety. The situation is even more difficult with respect to fatalities, due to the mentioned limitations of the ICD-10 coding system, so that we have based the estimate on the best possible approximation of product-related fatalities.

Previous research has explored how many of the injuries and fatalities that are related to consumer products were caused by the product, or could have been prevented through better design, instruction or a safety device. In the following we present several of these estimates:

- It is estimated that in around 15% of incidents related to consumer products the injury could have been prevented by improved user instructions and/or better design of the product, and that in half of these cases the injury was due to product malfunction, as stated by EuroSafe[341];

[341] https://www.eurosafe.eu.com/key-actions/consumer-safety

- Research conducted by the Accident Research Centre (ARC) of the University of Monash in Australia concluded that "at least 15 percent of all unintentional injuries are directly related to a design failure or product malfunction"[342].

- Another publication of the ARC by the same author on consumer product-related injury in Australia stated that "around 6% of hospital separations ... were considered to be due to product failure or malfunction. A further 9.7% ... were attributed to situations in which a design solution or safety device may have prevented ... the injury"[343].

It was beyond the scope of this analysis to conduct own research in this respect, which requires detailed investigations of injury mechanisms and assessment of circumstances, as are conducted e.g. by the US CPSC based on the US NEISS injury database. However, we have discussed and validated these estimates in interviews conducted for this study with product safety experts in Europe and Australia. Based on the above quoted sources and the results of the interviews with product safety experts we consider 15% a reasonable and conservative estimate for the proportion of the total detriment that was caused by consumer products, or could have been prevented through better design, instruction or a safety device.

Based on the total amount calculated above, the preventable detriment suffered by EU consumers and society due to product-related accidents can therefore be estimated at EUR 11.5 billion per year[344]. This includes health care utilization costs, productivity losses, loss of quality of life for hospitalised cases, and the cost of premature death. The estimate can be considered to be conservative, as is does not include product-related injuries in which the consumer did not visit a hospital emergency department, but was treated in primary health care facilities (e.g. a general practitioner). Also, productivity losses due to non-paid work (e.g. household work), and quality of life loss due to injuries that did not lead to hospitalisation are not considered. The analysis also excludes losses caused by work and transportation accidents.

Sensitivity analysis

The previous sections indicate that the most significant components of consumer detriment resulting from product-related injuries are the loss of quality of life and the cost of premature death. These components account for approximately 90% of the total detriment suffered by EU consumers and society annually due to non-fatal product-related injuries and fatalities caused by mechanisms relevant for product safety (with the rest accruing due to health care utilization costs and productivity losses). As expected, the cost of premature death exceeds by far all other costs and comprises about 52% of the total annual consumer detriment. Because of their proportion in the overall consumer detriment, it is important to test the robustness of the estimated costs against different assumptions regarding the cost of premature death and the loss of quality of life.

The first scenario to be tested against the main scenario (elaborated in the previous sections) involves using the lower estimate of the VSL to recalculate the costs incurred as a result of premature death. This lower VSL estimate also affects the calculation of the monetary value for a QALY resulting in a lower estimate that affects the calculation of the loss of quality of life. The second scenario involves the opposite recalculation, namely using the high estimate of the VSL and the corresponding QALY value to

[342] Watson, W. et al (1999). Consumer product related injuries in older persons, Accident Research Centre (ARC) of the University of Monash. The quote refers to all unintentional injuries, not just to those occurring to older persons.

[343] Watson, W. et al (2006), Consumer product-related injury in Australia: Direct hospital and medical costs to government. Accident Research Centre (ARC) of the University of Monash.

[344] 15% of the total detriment of EUR 76.6 billion per year.

recalculate the costs incurred as a result of premature death and of lost quality of life. Table 108 summarizes the estimates applied in each scenario.

Table 108: VSL/QALY estimates

	Main scenario	Low VSL estimate	High VSL estimate
VSL	€ 4.6 million	€ 3.8 million	€ 5.4 million
WTP per QALY	€ 125 000	€ 100 000	€ 150 000

Source: Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245 and Civic Consulting calculations.

The third and fourth scenarios take into account the fact that the type of the injury as such e.g. injury to muscle, burn etc. does not convey the severity of the injury which may significantly influence the magnitude of the loss. Therefore, to account for the possibility of a mild and severe occurrence of the same type of injury we estimate the loss of quality of life using both low and high QALY losses per each type of injury as is shown in Table 109. The rest of the assumptions (monetary value of a VSL, a QALY) remain the same as in the main scenario.

Table 109: QALY losses per type of injury

	QALY losses		
Type of injury	**Main scenario**	**Low**	**High**
Traumatic amputation	0.4	0.27	0.49
Concussion	0.2	0.15	0.37
Open wound	0.3	0.28	0.48
Luxation, dislocation	0.2	0.06	0.37
Fracture	0.13	0.03	0.2
Injury to muscle and tendon	0.1	0.024	0.34
Burns, scalds	0.1	0.05	0.19
Contusion, bruise	0	0	0
Distortion and sprain	0	0	0
Abrasion	0	0	0
All other injury types	0	0	0

Source: Cost-Effectiveness Registry, see https://cevr.tuftsmedicalcenter.org/databases/cea-registry, retrieved in July 2020. Note that for the cases of contusion, distortion, abrasion a QALY loss of 0 is assumed given that these injuries are temporary and least serious in terms of experience inconvenience.

The fifth and final scenario involves taking into account for the calculation of the cost of premature death only the fatalities caused by mechanisms relevant for product safety that occur at home keeping everything else constant. Table 110 on the following page shows the results for the estimated detriment suffered by EU consumers when recalculated under the five sensitivity scenarios of a lower value of VSL and QALY, higher value of VSL and QALY, lower QALY losses, higher QALY losses and fatal injuries occurring at home. Underlined in the table are the estimates that differ compared to the main scenario.

Table 110: Annual costs of injuries and fatalities related to consumer products - Sensitivity analysis (all estimates for EU27 in million EUR 2017)

Consumer detriment		Main scenario	Low VSL	High VSL	Low QALY losses	High QALY losses	Home fatalities
Type of costs/loss		VSL: € 4.6 million WTP per QALY: € 125 000	VSL: € 3.8 million WTP per QALY: € 100 000	VSL: € 5.4 million WTP per QALY: € 150 000	QALY losses: Low estimates used per type of injury	QALY losses: High estimates used per type of injury	Only fatalities occurring at home
A. Costs and losses of non-fatal injuries related to consumer products	Health care utilization costs	€ 6 673. 7	€ 6 673. 7	€ 6 673. 7	€ 6 673. 7	€ 6 673. 7	€ 6 673. 7
	Productivity losses	€ 1 802. 7	€ 1 802. 7	€ 1 802. 7	€ 1 802. 7	€ 1 802. 7	€ 1 802. 7
	Loss of quality of life (hospitalized cases)	€ 28 396. 7	€ 22 717. 3	€ 34 076. 0	€ 12 404. 3	€ 46 864. 1	€ 28 396. 7
B. Costs of premature death		€ 39 792. 8	€ 32 770. 6	€ 46 815. 1	€ 39 792. 8	€ 39 792. 8	€ 27 917. 7
C. Estimated total detriment suffered by EU consumers and society (Sum A + B)		**€ 76 665. 9**	**€ 63 964. 3**	**€ 89 367. 5**	**€ 60 673. 5**	**€ 95 133. 4**	**€ 64 790. 8**
D. Preventable detriment suffered by EU consumers and society due to product-related accidents (15% of total annual cost of injury calculated under C)		***€ 11 499. 8***	***€ 9 594. 6***	***€ 13 405. 1***	***€ 9 101. 0***	***€ 14 270. 0***	***€ 9 718. 6***

Source: Civic Consulting based on IDB-FDS non-fatal injury data, fatal injury data extracted by WHO-MDB, VSL estimates provided in EU Commission's Better Regulation Toolbox and own calculations.
Note: Underlined in the table are the estimates that differ compared to the main scenario.

As indicated in Table 110 above, the sensitivity scenario with the largest impact in terms of total detriment suffered by EU consumers and the society in relation to products is the fourth scenario using high QALY losses for each type of injury, which increases by approximately EUR 20 billion the estimated total consumer detriment and, in effect, also the detriment that could be prevented by better product design and/or product instructions. In contrast, the use of higher estimates for the value of statistical life and the quality adjusted life year have a relatively smaller impact on consumer detriment.

In terms of the range of results produced by the sensitivity analysis, varying the assumptions has resulted:

- For the loss of quality of life in a range of values between EUR 12.4 billion and EUR 46.8 billion which translates to an estimate of total consumer detriment ranging from EUR 60.6 billion up to EUR 95.1 billion.

- For the costs of premature death in a range of values between EUR 32.7 billion and EUR 46.8 billion calculated on the basis of low and high VSL respectively. The home fatalities scenario arrives at a cost of premature death of EUR 27.9 billion indicating, in comparison with the main scenario, that approximately 70% of the costs of premature death relate to fatal injuries caused by mechanisms relevant for product safety that occur at home.

The results of the sensitivity analysis, while non-trivial, do not change the core conclusions of the main scenario. The loss of quality of life and the costs of premature death remain the most important components of the total detriment suffered by EU consumers and society even under the scenario using the most conservative estimates for lost life expectancy and for quality adjusted life year. The costs of premature death comprise a high proportion of the annual total consumer detriment under all scenarios and are especially high for fatal injuries caused by mechanisms relevant for product safety occurring at home. The sensitivity analysis also shows that under a variety of different scenarios, the preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at between EUR 9.1 billion to EUR 14.3 billion.

Annex II: Supporting materials for analysis of detriment due to product-related injuries

a) Overview of existing approaches for estimating the cost of product-related injuries

Our research regarding literature and studies estimating consumer detriment in terms of the cost of injuries, has revealed that very few studies seem to exist with regards to estimating the cost of injuries and premature deaths related to products. In contrast, there exist multiple estimates with regards to the cost of occupational injuries and the cost of transport-related injuries[345].

The following sub-sections present two approaches that have been used in the United States and Australia to produce estimates for the cost of product-related injuries and deaths. To our knowledge, similar approaches to calculate the cost of product related injuries have so far not been applied by EU Member States. For comparison purposes, we also present the methodology used in Canada to provide a cost of injury estimate, which however, does not specifically aim at estimating the share of these costs that are related to products. Note that in each case we use the terminology used in the relevant source document.

The US Injury Cost Model

The first approach has been developed by the United States Consumer Product Safety Commission (CPSC), an independent regulatory commission seeking to protect the public from unreasonable risks of injury and death related with the use of consumer products and to promote the safety of consumer products[346]. In view of these goals, the CPSC developed an injury cost model (ICM) in the late 1970s to estimate the cost of injuries to society associated with consumer products, last updated in 2018[347]. The injury cost estimates facilitate consumer policy decisions and are communicated to the legislature and the public.

The ICM focuses on non-fatal injuries and uses the National Electronic Injury Surveillance System, hereafter NEISS, as the principal source of data about injuries associated with consumer products. NEISS is an injury surveillance system that requires users (hospital employees) to report on various aspects of injuries treated in emergency hospital departments including injured body part, injury type/diagnosis, place where the accident happened (home, street, school etc.) as well as the type of product involved (using a detailed coding manual for products). For NEISS product-related injury means:

- All poisonings and chemical burns to children under 5 years of age; and

[345] See e.g. studies on estimating the cost of occupational injuries and fatalities: National Institute for Occupational Safety and Health (2011), 'The Economic Burden of Occupational Fatal Injuries to Civil Workers in the United States based on the census of fatal occupational injuries, 1992-2002, available at: https://www.cdc.gov/niosh/docs/2011-130/pdfs/afinal.pdf?id=10.26616/NIOSHPUB2011130, International Labour Office (2012), 'Estimating the Economic Costs of Occupational Injuries and Illnesses in Developing Countries: Essential Information for Decision-Makers', available at: https://www.ilo.org/safework/info/publications/WCMS_207690/lang--en/index.htm. For studies estimating the cost of transport-related injuries see e.g. Ministry of Transport New Zealand annual reports on the estimation of costs of road crashes and injuries at: https://www.transport.govt.nz/mot-resources/road-safety-resources/roadcrashstatistics/social-cost-of-road-crashes-and-injuries/. See also EU-funded study Safety Cube (2018), 'Costs related to serious road injuries', available at: https://www.safetycube-project.eu/.

[346] For more details, see www.cpsc.gov.

[347] Pacific institute for Research and Evaluation (2018), 'The Consumer Product Safety Commission's Revised Injury Cost Model'.

- All injuries where a consumer product, sport, or recreational activity is associated with the reason for the visit or related to a condition treated;
- Illnesses only if a consumer product, sport, or recreational activity is associated with the onset of the illness.

As a result of this definition, NEISS does not differentiate injuries that are associated with consumer products from those caused by consumer products/product design[348]. To find out about the injury cause, supplemental investigation by means of an ad hoc inquiry is needed.

The combination of available data from NEISS and of information retrieved from 15 other databases, allows CPSC to arrive at estimations regarding injury costs. It is noted that the other databases do not follow the same system of classification with NEISS, but most of them record injuries based on the International Classification of Diseases (ICD) 9th version. ICD-9 is a classification system for injuries that includes more detailed coding regarding diagnoses, however it does not include information on whether a product was related with the injury. Instead of that, ICD-9 uses a supplementary list of codes, the so-called external cause of injury codes or E-Codes which explain the mechanism and manner of the injury as well as indicate the place of occurrence of the injury. Hence, under ICD-9 an injury is classified based on the diagnosis of the injury and the E-code. By subtracting from the E-codes the ones that are certainly unrelated to products e.g. intentional injuries, transport injuries, environmental/natural injuries, work-related injuries etc. the CPSC arrives at a subset of injuries that are likely associated with consumer products. Whenever CPSC uses databases with ICD-9 recorded injuries, the relevant (product-related) injuries are first identified and then mapped into NEISS injury diagnoses.

The injuries that are taken into account for the cost estimation are[349]:

- Product related injuries for which hospital admission has taken place;
- Product related injuries that were treated in a hospital emergency department; and,
- Product related injuries that were treated in a non-hospital setting e.g. a doctor's office or in a hospital outpatient department.

Using primarily available data from NEISS as well as information from the rest of datasets, the following costs are estimated:

a) *Medical costs:* These include costs of emergency transport, long-term care, treatment as well as costs of health insurance claims per injury diagnosis. They are calculated using estimates of hospital charges, ambulance transport costs, rehabilitation expenses as well as estimates of costs for processing health claims;

b) *Work losses:* Comprising both short-term work loss due to recovery from an injury and long-term work loss as a result of lasting disability. This category also includes employer productivity losses as well costs/work loss incurred by the family while caring for the injured. The calculation of these costs is differentiated depending on the time spent off work. To arrive at short-term work loss, household work loss, school work loss etc., the number of lost days is multiplied with the value of work per day, while long-term work loss is calculated as a percentage of the present value of expected lifetime work;

[348] As mentioned explicitly on their website "These data enable CPSC analysts to make timely national estimates of the number of injuries associated with (but not necessarily caused by) specific consumer products".

[349] Pacific institute for Research and Evaluation (2018), 'The Consumer Product Safety Commission's Revised Injury Cost Model', p. 9 ff.

c) *Pain and suffering costs:* These include pain, suffering and loss of quality of life as a result of the injury. They are calculated based on jury awards in product liability cases and other cases involving products, as well as assessments of Quality Adjusted Life Years (QALYs) indicating how people value the loss in their quality of life relating to the injury.

Inflation adjustments are applied to the information retrieved from different databases using specialized price indexes (employment cost index for work losses and index for personal consumption expenditures for medical costs) to express cost estimates in US dollars of the same year. Finally, whenever costs extend more than a year beyond the injury, the ICM applies a discount rate of 3% to compute their present value (as well as an alternative discount factor of 7% for sensitivity analysis).

The ICM has been revised and updated multiple times since the 1970s. According to the most recent estimates expressed in 2010 US dollars, the total lifetime medical cost of all survivors of consumer-product injuries between 2010-2014 is estimated at approximately USD 100.7 billion per year, while total work loss amounts to about USD 190.2 billion per year[350]. The pain and suffering for the same product related injury survivors is estimated at USD 852.3 billion per year based on jury awards[351].

To estimate the cost of fatalities related to consumer products, CPSC collects information from death certificates and uses estimates of the Value of Statistical Life (VSL) to arrive at the overall cost of product related fatalities. The VSL estimates are derived from research on consumers' willingness to pay to avoid small fatality risks. The amount currently used by the CPSC as the value per statistical life is USD 8.7 million in 2004 dollars[352].

The Australian approach

A different approach has been used by the Australian Competition and Consumer Commission (ACCC) to estimate the total cost of unsafe products to the Australian economy. The reports and literature publicly available do not contain a detailed elaboration of the sources of injury data or the details of the method used, it is however indicated that the approach builds on official statistics about the number of injuries and deaths as well as on the estimated proportion of incidents caused by unsafe products[353].

The cost estimate is calculated by taking into account:

a) The number of healthy life years lost due to the short-term and long-term disability resulting from the product-caused injury;

b) The number of healthy life years lost due to the premature death occurring as a result of the product-caused injury; and

c) The Value of a Statistical Life Year (VSLY) which represents the monetary value society would be willing to forego to reduce premature death by saving a statistical life year.

Multiplying the total number of healthy life years lost due to the product-caused injury or death by the value of a statistical life year yields, according to the approach, the total

[350] Ibid., p. 46 table 9 for lifetime total medical cost per consumer-product injury 2010–2014 and p. 67 table 14 for lifetime total work-loss cost per consumer-product injury 2010–2014.

[351] Ibid., Table 20. Pain and Suffering Cost per Survivor of Consumer-Product Injury by Injury Diagnosis or Body Part Injured, 2010–2014, p. 87.

[352] CPSC (2018), 'Valuing reductions in fatal risks to children', p. 1.

[353] The Australian Government the Treasury (2019), 'Improving the Effectiveness of the Consumer Product Safety System', Consultation Regulation Impact Statement, p. 18.

cost of injury and death that is caused by unsafe consumer products[354]. Based on this approach, ACCC has estimated the economic cost of injury and death *caused* by unsafe consumer products at approximately 4.5 billion Australian dollars per year[355]. ACCC clarifies that this cost may be an underestimation given that only a small fraction of product-caused incidents are reported to the ACCC.

The Canadian approach

In Canada, a 2015 report produced with support from the Public Health Agency of Canada quantifies the cost of injury to society, updating a similar report published in 2009. It examines all injuries at the national level, as well as providing provincial breakdowns. According to the report, preventable injuries cost Canadians more than CAD 26.8 billion a year. The direct costs of injury in 2010 were estimated as CAD 15.9 billion and indirect costs were CAD 10.9 billion. The estimate considers direct costs (health care costs arising from injuries) and indirect costs (costs related to reduced productivity from hospitalization, disability, and premature death). The study applied an incidence costing, human capital approach. That is, the population of Canadian residents injured in 2010 was costed over the lifetime of the injured individuals, with the costs (both direct and indirect) being discounted to a present value in 2010 at 3% per annum. The methodology used differs substantially from the US and Australian approach in that intangible costs associated with injuries, such as pain and suffering etc. are not monetised. While separate estimates are provided according to the main categories of incidents, such as transport incidents, falls, drowning, fire/burns, unintentional poisoning and other categories, it is not specified or estimated which of these incidents were related to a consumer product[356].

b) Query for product-related injuries

To arrive at the number of injury incidents related we perform the following query in the full dataset of the European Injury Database (IDB-FDS) for the years 2013 to 2017 (5 years). The injury figures for this five-year period will then be extrapolated to EU level using IDB-MDS data to calculate the average number of injuries in the EU per year.

The extrapolation and the economic analysis will be based on the 5-year average (average cases per year).

Filter 1

To exclude cases that have been caused intentionally, as a result of violence, intentional self-harm, assault etc. we filter injuries by selecting UNINTENTIONAL in data element INTENT. We also select UNSPECIFIED INTENT as most cases with this filter will be accidental while violence, self-harm, assault etc. will be excluded.

INTENT= 1 UNINTENTIONAL

9 UNSPECIFIED INTENT

Filter 2

[354] Ibid., p. 64.

[355] This amount excludes hospital costs to government as well as costs of injuries/deaths caused by quad bikes.

[356] See: Parachute. (2015). The Cost of Injury in Canada. Parachute: Toronto

To arrive at injury incidents that are not related with transport accidents, we filter injury incidents by selecting NO and UNKNOWN in data element TRANSPORT INJURY EVENT. This selection will exclude transport accidents while most unknown transport injury events will be non-transport related.

TRANSPORT INJURY EVENT= 2 NO

9 UNKNOWN

Filter 3

The next step involved excluding injury incidents that are work related. To achieve that we filter our injuries related with paid work by selecting all activity codes except PAID WORK in the data element ACTIVITY.

ACTIVITY= 02 UNPAID WORK

03 EDUCATION

04 SPORTS AND EXERCISE DURING LEISURE TIME

05 LEISURE OR PLAY

06 VITAL ACTIVITY

07 BEING TAKEN CARE OF

08 TRAVELLING NOT ELSEWHERE CLASSIFIED

96 NOT POSSIBLE TO RECORD/REPORT FOR LEGAL REASONS

98 OTHER SPECIFIED ACTIVITY

99 UNSPECIFIED ACTIVITY

Filter 4

From the data element OBJECT/SUBSTANCE/PRODUCT INVOLVED IN INJURY we choose the majority of objects/substances/products, excluding only FOOD/DRINK and PHARMACEUTICAL SUBSTANCES to find the total number of home, leisure, sport and school accidents. The following first level codes are selected.

OBJECT/SUBSTANCE/PRODUCT= 01 LAND VEHICLE OR MEANS OF LAND TRANSPORT
02 MOBILE MACHINERY OR SPECIAL PURPOSE VEHICLE
03 WATERCRAFT OR MEANS OF WATER TRANSPORT
04 AIRCRAFT OR MEANS OF AIR TRANSPORT
05 FURNITURE/FURNISHING

06 INFANT OR CHILD PRODUCT
07 APPLIANCE MAINLY USED IN HOUSEHOLD
08 UTENSIL OR CONTAINER
09 ITEM MAINLY FOR PERSONAL USE
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY

12 WEAPON
13 ANIMAL, PLANT, OR PERSON
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING
15 GROUND SURFACE OR SURFACE CONFORMATION
16 MATERIAL NEC
17 FIRE, FLAME, OR SMOKE
18 HOT OBJECT/SUBSTANCE NEC
21 OTHER NON-PHARMACEUTICAL CHEMICAL SUBSTANCE
40 MEDICAL/SURGICAL DEVICE
41 LABORATORY EQUIPMENT
96 NOT POSSIBLE TO RECORD/REPORT DUE TO LEGAL REASONS
98 OTHER SPECIFIED OBJECT/SUBSTANCE
99 UNSPECIFIED OBJECT/SUBSTANCE

From the above selection, to arrive at injuries relating and/or caused by non-food products only, we choose those products that are also used by the Consumer Market Score Board[357].

OBJECT/SUBSTANCE/PRODUCT= (non-food products)	05 FURNITURE/FURNISHING 06 INFANT OR CHILD PRODUCT 07 APPLIANCE MAINLY USED IN HOUSEHOLD 08 UTENSIL OR CONTAINER 09 ITEM MAINLY FOR PERSONAL USE 10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY 11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY 14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING 15 GROUND SURFACE OR SURFACE CONFORMATION 17 FIRE, FLAME, OR SMOKE 18 HOT OBJECT/SUBSTANCE NEC

The rest are grouped as follows:

'other specified'	01 LAND VEHICLE OR MEANS OF LAND TRANSPORT 02 MOBILE MACHINERY OR SPECIAL PURPOSE VEHICLE 03 WATERCRAFT OR MEANS OF WATER TRANSPORT 04 AIRCRAFT OR MEANS OF AIR TRANSPORT 12 WEAPON 13 ANIMAL, PLANT, OR PERSON 16 MATERIAL NEC 21 OTHER NON-PHARMACEUTICAL CHEMICAL SUBSTANCE 40 MEDICAL/SURGICAL DEVICE 41 LABORATORY EQUIPMENT 96 NOT POSSIBLE TO RECORD/REPORT DUE TO LEGAL REASONS 98 OTHER SPECIFIED OBJECT/SUBSTANCE

[357] European Commission (2014), 'Consumer Markets Scoreboard. Making markets work for consumers', 10th edition, p. 60-61.

'unspecified/missing'	99 UNSPECIFIED OBJECT/SUBSTANCE

Please note that in this data element it is possible to differentiate between

- 'direct object/substance/product' which is producing the actual physical harm
- 'underlying object/substance/product' which is involved at the start of the injury
- 'intermediate object/substance/product' which are involved in the injury event.

For the purpose of identifying injury incidents that were caused/initiated by a non-food product, we select the category UNDERLYING OBJECT/SUBSTANCE/ PRODUCT, as the trigger of the injury.

Filter 5 (breakdown)

To enable a selection of product caused/related injuries that had a considerable impact we select from the data element TREATMENT AND FOLLOW-UP the following categories.

TREATMENT AND FOLLOW-UP=	02 SENT HOME AFTER TREATMENT 03 TREATED AND REFERRED TO GENERAL PRACTITIONER FOR FURTHER TREATMENT 04 TREATED AND REFERRED FOR FURTHER TREATMENT AS AN OUTPATIENT 05 TREATED AND ADMITTED TO THIS HOSPITAL 06 TRANSFERRED TO ANOTHER HOSPITAL 07 DECEASED BEFORE ARRIVAL OR AT EMERGENCY DEPARTMENT 08 DECEASED DURING HOSPITALIZATION 98 OTHER 99 UNKNOWN

Based on the data, and once it is known what the percentage of treatment=98 or 99 is, it will be decided at later stage how to deal with unknown/unspecified treatment. It is in any case needed to report them separately for the extrapolation of costs from specified treatment.

Filter 6 (breakdown)

To arrive at injury incidents based on place of occurrence we filter injuries by selecting HOME, SCHOOL, EDUCATIONAL AREAS and SPORTS AND ATHLETICS AREA as the PLACE OF OCCURRENCE, as well as the rest of the codes which we will group as 'other'.

PLACE OF OCCURENCE=	01 HOME 02 RESIDENTIAL INSTITUTION 04 SCHOOL, EDUCATIONAL AREA 05 SPORTS AND ATHLETICS AREA
To be presented as 'other'	03 MEDICAL SERVICE AREA 06 TRANSPORT AREA: PUBLIC HIGHWAY, STREET OR ROAD 07 TRANSPORT AREA: OTHER 08 INDUSTRIAL OR CONSTRUCTION AREA 09 FARM OR OTHER PLACE OF PRIMARY PRODUCTION

10 RECREATIONAL AREA, CULTURAL AREA, OR PUBLIC BUILDING
11 COMMERCIAL AREA (NON-RECREATIONAL)
12 COUNTRYSIDE
96 NOT POSSIBLE TO REPORT/RECORD FOR LEGAL REASONS
98 OTHER SPECIFIED PLACE OF OCCURRENCE
99 UNSPECIFIED PLACE OF OCCURRENCE

To summarize, the following data elements and data categories are selected to arrive at the non-food product-related injuries.

- INTENT= 1 UNINTENTIONAL
  9 UNSPECIFIED INTENT
- TRANSPORT INJURY EVENT= 2 NO
  9 UNKNOWN
- ACTIVITY= 02 UNPAID WORK
  03 EDUCATION
  04 SPORTS AND EXERCISE DURING LEISURE TIME
  05 LEISURE OR PLAY
  06 VITAL ACTIVITY
  07 BEING TAKEN CARE OF
  08 TRAVELLING NOT ELSEWHERE CLASSIFIED
  96 NOT POSSIBLE TO RECORD/REPORT FOR LEGAL REASONS
  98 OTHER SPECIFIED ACTIVITY
  99 UNSPECIFIED ACTIVITY
- OBJECT/SUBSTANCE/PRODUCT= (non-food products)
  05 FURNITURE/FURNISHING
  06 INFANT OR CHILD PRODUCT
  07 APPLIANCE MAINLY USED IN HOUSEHOLD
  08 UTENSIL OR CONTAINER
  09 ITEM MAINLY FOR PERSONAL USE
  10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY
  11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY
  14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING
  17 FIRE, FLAME, OR SMOKE
  18 HOT OBJECT/SUBSTANCE NEC

  ('other specified')
  01 LAND VEHICLE OR MEANS OF LAND TRANSPORT
  02 MOBILE MACHINERY OR SPECIAL PURPOSE VEHICLE
  03 WATERCRAFT OR MEANS OF WATER TRANSPORT
  04 AIRCRAFT OR MEANS OF AIR TRANSPORT
  12 WEAPON
  13 ANIMAL, PLANT, OR PERSON
  16 MATERIAL NEC
  21 OTHER NON-PHARMACEUTICAL CHEMICAL SUBSTANCE

40 MEDICAL/SURGICAL DEVICE
41 LABORATORY EQUIPMENT
96 NOT POSSIBLE TO RECORD/REPORT DUE TO LEGAL REASONS
98 OTHER SPECIFIED OBJECT/SUBSTANCE

'unspecified/missing' 99 UNSPECIFIED OBJECT/SUBSTANCE

- TREATMENT AND FOLLOW-UP= 02 SENT HOME AFTER TREATMENT
03 TREATED AND REFERRED TO GENERAL PRACTITIONER FOR FURTHER TREATMENT
04 TREATED AND REFERRED FOR FURTHER TREATMENT AS AN OUTPATIENT
05 TREATED AND ADMITTED TO THIS HOSPITAL
06 TRANSFERRED TO ANOTHER HOSPITAL
98 OTHER
99 UNKNOWN

- PLACE OF OCCURENCE= 01 HOME
04 SCHOOL, EDUCATIONAL AREA
05 SPORTS AND ATHLETICS AREA

To be presented as 'other' 02 RESIDENTIAL INSTITUTION
03 MEDICAL SERVICE AREA
06 TRANSPORT AREA: PUBLIC HIGHWAY, STREET OR ROAD
07 TRANSPORT AREA: OTHER
08 INDUSTRIAL OR CONSTRUCTION AREA
09 FARM OR OTHER PLACE OF PRIMARY PRODUCTION
10 RECREATIONAL AREA, CULTURAL AREA, OR PUBLIC BUILDING
11 COMMERCIAL AREA (NON-RECREATIONAL)
12 COUNTRYSIDE
96 NOT POSSIBLE TO REPORT/RECORD FOR LEGAL REASONS
98 OTHER SPECIFIED PLACE OF OCCURRENCE
99 UNSPECIFIED PLACE OF OCCURRENCE

c) Methodology for calculating the EU-estimate of product related home and leisure injuries using IDB data

A countable statistical unit "non-fatal injury" can be obtained from medical services or related administrative acts. Visits to primary health care facilities (e.g. a general practitioner) are not sufficiently documented in most European countries, but visits to secondary health care facilities, e.g. hospitals, are recorded almost everywhere. The European IDB system is based on a sample of reference hospitals and their emergency departments throughout Europe and covers all injury patients - ambulatory treated as well as admitted patients. These data are complementary to deaths statistics, hospital discharge statistics, special registers as of road traffic accidents and work-place accidents and household-surveys as the European Health Information System EHIS.

There are two IDB datasets: The IDB-FDS (Full Data Set) contains many items on external circumstances of the injury (such as involvement of products) and is collected from about 100 reference hospital. The second dataset, IDB-MDS (Minimum Data Set), is a simplification of the FDS and requires less efforts for hospitals to capture the relevant data. MDS data are available from more hospitals (more than 200) and provide better samples for estimating national injury rates. IDB injury rates of patients seeking medical advice in emergency departments of hospitals are available for 16 EU-countries. The IDB-database contains data for the years 2009-2018, but the upload for 2018 has not been completed yet. In most countries, data stem from a sample of reference hospitals. These are hospitals of different sizes, in rural and urban areas, children's hospitals and university clinics, which are expected to be representative for the given country. As not all countries reported data for every year, the sample of hospitals differed between the years. It was therefore decided to use a five-years average (period 2013-2017) and to refrain from interpreting differences of IDB injury rates between years.

The extrapolation of IDB data applied in this study follows a two-step approach:

Step 1: Calculation of injury-rates and extrapolation to the EU

IDB injury rates are expressed as the percentage of the national resident population, which suffered an hospital-treated injury in a given year. The EU injury rate used for the extrapolation to the EU-27 is calculated as the mean of national rates of EU-member states reporting data to the IDB. For the projection of the EU injury rates, the overall mean was calculated on basis of the mean values of the national IDB injury rates 2013-2017 (see following table).

Table 111: IDB injury rates 2013-2017, in percent of total population (IDB-MDS)

Country	2013	2014	2015	2016	2017	Mean 2013-2017
Austria	9.76	9.70	8.71	8.44	8.31	8.98
Cyprus			4.78	3.07	2.01	3.28
Denmark	9.68	9.90	9.69	9.38		9.66
Estonia	6.26	6.74	7.69	11.52	11.33	8.71
Spain	6.13					6.13
Finland	3.98	3.79		4.47	4.49	4.18
Ireland	6.43					6.43
Lithuania	8.30	10.70	11.07	11.27	11.12	10.49
Luxembourg	11.43	11.95	12.13	11.28	11.23	11.61

Latvia	8.41	8.32	8.43	8.78	9.36	8.66
Malta	6.64	2.90	3.35	6.00		4.72
Netherlands	4.38	4.57	5.97	5.84	4.76	5.10
Portugal	3.53	7.52	6.76	5.50	6.81	6.01
Romania	6.40					6.40
Sweden	5.52	5.59	5.63			5.58
Slovenia	4.99	4.90	5.09	5.01	5.46	5.09
Overall mean	*6.79*	*7.21*	*7.44*	*7.55*	*7.49*	***7.30***

As the table above illustrates, the overall injury rate varied between 6.79% (for 2013, based on data from 15 countries) and 7.55% (2016, 12 countries) with an average of 7.30% for 2013 to 2017. Applying the estimated injury rate of 7.30% to the average population of the EU-27 during the same period (443 629 134 as published by Eurostat - population by 1 January), the estimated share of the EU-27 population that sought medical advice in emergency departments of hospitals annually was 32 366 924 in the period 2013 to 2017 (rounded: 32 367 000 injury patients per year).

Step 2: Estimation of product-related injuries

For estimating product-related unintentional injuries ("accidents"), an additional analysis of IDB-FDS data was conducted, as only the IDB-FDS contains Information on products involved in the injuries. For the period 2013 to 2017 FDS-data are available from 17 EU Member States – in total 1 486 170 valid cases. On average these are 1 486 170/5 = 297 234 FDS-cases per year. Assuming that both MDS and FDS samples are randomly drawn from the same EU population, then the 297 234 FDS-cases correspond to the estimated 32 367 000 injury patients that were seeking medical advice in emergency departments of hospitals per year. The sample rate is therefore 0.92% and the annual extrapolation factor 108.9[358].

Table 112: Total of injury cases reported in the IDB-FDS 2013-2017 (number of cases)

Country	2013	2014	2015	2016	2017	Total
Austria	10579	9583	11141	15509	15848	62660
Cyprus	381	0	0	0	0	381
Czech Republic	9645	718	0	0	0	10363
Denmark	32425	31387	0	0	0	63812
Germany	3760	3815	9297	8668	0	25540
Hungary	3132	549	0	0	0	3681
Italy	18629	0	20261	0	0	38890
Latvia	11746	13764	14312	14858	18253	72933
Luxembourg	11320	14857	13896	17031	17834	74938
Malta	28066	12473	14582	26427	0	81548
Netherlands	73472	79583	76857	78747	81239	389898
Poland	258	418	0	0	0	676
Portugal	7370	4136	15175	25887	51109	103677
Romania	2889	0	0	0	0	2889
Slovenia	78834	75790	78986	72960	81131	387701

[358] When we take all 1 486 170 cases of the 5-year-period and scale it to the annual 32 367 000 IDB-cases in the EU-27, the corresponding extrapolation factor is 21.78 (equivalent to 108.9/5).

Spain	23440	0	0	0	0	23440
Sweden	53807	42164	47172	0	0	143143
Total	**369753**	**289237**	**301679**	**260087**	**265414**	**1486170**

For the current study only injury cases, which are unintentional (accidental), and not work-place or transport (traffic) related are considered, i.e. the so-called "home and leisure accidents". 1 049 668 FDS-cases (70.6% of all 1 486 170 cases) were related to such "home and leisure accidents". As elaborated in the main analysis, as well as in the query for extraction of relevant IDB cases (see Annex I), a total of twelve product groups were identified (following the approach that the consumer markets scoreboard used for extracting IDB-FDS data). These product groups are:

05 FURNITURE/FURNISHING
06 INFANT OR CHILD PRODUCT
07 APPLIANCE MAINLY USED IN HOUSEHOLD
08 UTENSIL OR CONTAINER
09 ITEM MAINLY FOR PERSONAL USE
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING
15 GROUND SURFACE OR SURFACE CONFORMATION
17 FIRE, FLAME, OR SMOKE
18 HOT OBJECT/SUBSTANCE NEC

In 505 531 cases of all 1 049 668 home and leisure accidents one of these products has been specified as being involved in the injury event. In 323 264 cases other objects or substances are involved, while for 220 873 cases the relevant information is missing. The full data is presented in the table below, which for illustration purposes also includes data on injuries per age group.

Table 113: Product-related injuries recorded in IDB-FDS by age and extrapolation to EU (annual average 2013-2017)

Product group	Age			Total[b)]
	0-14	15-64	65+	
05 FURNITURE/FURNISHING	24 384	18 257	16 927	59 568
06 INFANT OR CHILD PRODUCT	21 817	2 279	203	24 299
07 APPLIANCE MAINLY USED IN HOUSEHOLD	2 767	5 029	1 725	9 521
08 UTENSIL OR CONTAINER	3 002	17 108	1 780	21 890
09 ITEM MAINLY FOR PERSONAL USE	3 258	7 133	7 620	18 011
10 EQUIPMENT MAINLY USED FOR SPORTS/RECREATIONAL ACTIVITY	38 826	34 349	1 224	74 400
11 TOOL, MACHINE, APPARATUS MAINLY USED FOR WORK-RELATED ACTIVITY	2 066	22 420	6 423	30 910
14 BUILDING, BUILDING COMPONENT, OR RELATED FITTING	53 511	100 581	62 461	216 560
15 GROUND SURFACE OR SURFACE CONFORMATION	10 620	22 621	10 928	44 179
17 FIRE, FLAME, OR SMOKE	256	1 290	230	1 776
18 HOT OBJECT/SUBSTANCE NEC	2 079	2 065	273	4 417
A. TOTAL PRODUCT-RELATED INJURIES RECORDED IN IDB-FDS	**162 586**	**233 132**	**109 794**	**505 531**
Other specified	80 602	187 113	55 524	323 264
Unspecified/missing	64 696	108 917	47 256	220 873

B. TOTAL HOME AND LEISURE INJURIES RECORDED IN IDB-FDS	**307 884**	**529 162**	**212 574**	**1 049 668**
EU27 - TOTAL PRODUCT-RELATED INJURIES	*3 540 919*	*5 077 323*	*2 391 176*	*11 009 833*
EU27 - TOTAL ALL HOME AND LEISURE INJURIES RECORDED	*6 705 328*	*11 524 487*	*4 629 596*	*22 860 456*

By applying the extrapolation factor calculated above the estimated number of ED-treated injuries in the EU-27 per year can be estimated: In an estimated 11 009 833 home and leisure accidents products are involved in the injury event. Further breakdowns, e.g. by age-group or product-groups follow the same approach, e.g. 21 817 FDS-cases of child injuries (0-14 years of age) involving infant or child products equals estimated 475 147 cases in the EU-27. For details, see main analysis.

The accuracy of these estimates cannot be validated by other data and may be biased by the incomplete scope of involved countries and years or other sampling issues. However, IDB data are based on a harmonised methodology, which is applied in a wide-spread sample of reference hospitals throughout Europe, and it can be expected that this approach gives a realistic picture of the magnitude of product-related injuries in the EU.

d) ICD-10 codes for 'other external causes of accidental injury'[359]

HOME LEISURE SPORT AND SCHOOL ACCIDENTS	
W00 Fall on same level involving ice and snow	W73 Other specified drowning and submersion
W01 Fall on same level from slipping, tripping and stumbling	W74 Unspecified drowning and submersion
W02 Fall involving ice-skates, skis, roller-skates or skateboards	W75 Accidental suffocation and strangulation in bed
W03 Other fall on same level due to collision with, or pushing by, anothe	W76 Other accidental hanging and strangulation
W04 Fall while being carried or supported by other persons	W77 Threat to breathing due to cave-in, falling earth and other su
W05 Fall involving wheelchair	W78 Inhalation of gastric contents
W06 Fall involving bed	W80 Inhalation and ingestion of other objects causing obstruction
W07 Fall involving chair	W81 Confined to or trapped in a low-oxygen environment
W08 Fall involving other furniture	W83 Other specified threats to breathing
W09 Fall involving playground equipment	W84 Unspecified threat to breathing
W10 Fall on and from stairs and steps	W85 Exposure to electric transmission lines
W11 Fall on and from ladder	W86 Exposure to other specified electric current
W12 Fall on and from scaffolding	W87 Exposure to unspecified electric current
W13 Fall from, out of or through building or structure	W88 Exposure to ionizing radiation
W14 Fall from tree	W89 Exposure to man-made visible and ultraviolet light
W15 Fall from cliff	W90 Exposure to other nonionizing radiation
W16 Diving or jumping into water causing injury other than drowning or	W91 Exposure to unspecified type of radiation
W17 Other fall from one level to another	W92 Exposure to excessive heat of man-made origin
W18 Other fall on same level	W93 Exposure to excessive cold of man-made origin
W19 Unspecified fall	W94 Exposure to high and low air pressure and changes in air pres
W20 Struck by thrown, projected or falling object	W99 Exposure to other and unspecified man-made environmental
W21 Striking against or struck by sports equipment	X01 Exposure to uncontrolled fire, not in building or structure
W22 Striking against or struck by other objects	X02 Exposure to controlled fire in building or structure
W23 Caught, crushed, jammed or pinched in or between objects	X03 Exposure to controlled fire, not in building or structure
W24 Contact with lifting and transmission devices, not elsewhere classi	X04 Exposure to ignition of highly flammable material
W25 Contact with sharp glass	X05 Exposure to ignition or melting of nightwear
W26 Contact with other sharp object(s)	X06 Exposure to ignition or melting of other clothing and apparel
W26.0 Contact with knife, sword or dagger	X08 Exposure to other specified smoke, fire and flames
W27 Contact with nonpowered hand tool	X09 Exposure to unspecified smoke, fire and flames
W28 Contact with powered lawnmower	X10 Contact with hot drinks, food, fats and cooking oils
W29 Contact with other powered hand tools and household machinery	X11 Contact with hot tap-water
W30 Contact with agricultural machinery	X12 Contact with other hot fluids
W31 Contact with other and unspecified machinery	X13 Contact with steam and hot vapours
W35 Explosion and rupture of boiler	X14 Contact with hot air and gases
W36 Explosion and rupture of gas cylinder	X15 Contact with hot household appliances
W37 Explosion and rupture of pressurized tyre, pipe or hose	X16 Contact with hot heating appliances, radiators and pipes
W38 Explosion and rupture of other specified pressurized devices	X17 Contact with hot engines, machinery and tools
W40 Explosion of other materials	X18 Contact with other hot metals
W41 Exposure to high-pressure jet	X19 Contact with other and unspecified heat and hot substances
W42 Exposure to noise	X40 Accidental poisoning by and exposure to nonopioid analgesics,
W43 Exposure to vibration	X41 Accidental poisoning by and exposure to antiepileptic, sedativ
W44 Foreign body entering into or through eye or natural orifice	X42 Accidental poisoning by and exposure to narcotics and psycho
W45 Foreign body or object entering through skin	X43 Accidental poisoning by and exposure to other drugs acting on
W46 Contact with hypodermic needle	X44 Accidental poisoning by and exposure to other and unspecifie
W49 Exposure to other and unspecified inanimate mechanical forces	X45 Accidental poisoning by and exposure to alcohol
W50 Hit, struck, kicked, twisted, bitten or scratched by another person	X46 Accidental poisoning by and exposure to organic solvents and
W51 Striking against or bumped into by another person	X47 Accidental poisoning by and exposure to other gases and vapo
W64 Exposure to other and unspecified animate mechanical forces	X48 Accidental poisoning by and exposure to pesticides
W65 Drowning and submersion while in bath-tub	X49 Accidental poisoning by and exposure to other and unspecifie
W66 Drowning and submersion following fall into bath-tub	X50 Overexertion and strenuous or repetitive movements
W67 Drowning and submersion while in swimming-pool	X58 Exposure to other specified factors
W68 Drowning and submersion following fall into swimming-pool	X59 Exposure to unspecified factor
W69 Drowning and submersion while in natural water	Y85 Sequelae of transport accidents
W70 Drowning and submersion following fall into natural water	Y86 Sequelae of other accidents
	Y89 Sequelae of other external causes

e) Query for fatalities related to products

To arrive at product related fatalities we apply the following filtering on WHO-Detailed Mortality Data using specific ICD-10 (version 2016) codes[360], see Annex II.

Filter 1

To enable a selection of injury incidents that could have been caused by product-related external causes we filter existing data by selecting injury incidents based on the ICD-10 codes that are listed in the table below. More specifically, we select codes from the category XX EXTERNAL CAUSES OF MORBIDITY AND MORTALITY (V01-Y98).

To arrive at the following table of selected codes that could be potentially related with product-related fatal injury incidents we exclude the following cases:

- Transport accidents (V01-V99)
- Intentional self-harm (X60-X84)
- Assault (X85-Y09)
- Event of undetermined intent (Y10-Y34)
- Legal interventions and operations of war (Y35-Y36)
- Complications of medical and surgical care (Y40-Y84)
- Sequelae of external causes of morbidity and mortality (Y85-Y89)[361]
- Supplementary factors related to causes of morbidity and mortality classified elsewhere (Y90-Y98)[362]

From the remaining codes W00-X59 OTHER EXTERNAL CAUSES OF ACCIDENTAL INJURY we select the ones that can be associated to product related fatal injuries. Most of these codes have already been used by EuroSafe to identify product related fatal home injuries.[363] We add to these some more codes which can be associated to product related injuries (mostly falls). Note that at the left column we list the group and codes included in that group and at the right column we list only a subset of the group codes, which are the codes that have been selected as product-related fatality causes. In the middle column, we indicate the group heading which will be selected for the result tables, largely similar to the relevant EuroSafe analyses (as percentage of absolute numbers), i.e.:

- Falls involving products (e.g. ladders, chairs, skates)
- Objects, machinery, tools
- Suffocation, strangulation
- Choking, ingestion of objects
- Electric current, radiation
- Fire, smoke
- Hot water, fluids

The following table presents the definition of the groups in detail.

[360] The International Statistical Classification of Diseases and Related Health Problems 10th Revision, 2016 version is available at: https://icd.who.int/browse10/2016/en#/ .

[361] These are late effects of transport accidents, assault, intentional harm, acts of war etc.

[362] This category includes among others Y95 Nosocomial Condition, Y96 Work related condition, Y97 Environmental pollution related condition, Y98 Lifestyle related condition.

[363] EuroSafe, Injuries in the European Union, Report on injury statistics 2010-2012, Amsterdam, 2014.

Group and codes included in that group	Grouping for presentation of results	Group codes, which are the codes that have been selected as product-related fatality causes
FALLS (W00-19)	Falls involving products (e.g. bed, ladder, wheelchair, skates)	W02 Fall involving ice-skates, skis, roller-skates or skateboards
		W05 Fall involving wheelchair
		W06 Fall involving bed
		W07 Fall involving chair
		W08 Fall involving other furniture
		W09 Fall involving playground equipment
		W11 Fall on and from ladder
EXPOSURE TO INANIMATE MECHANICAL FORCES (W20-49)	Objects, machinery, tools	W20 Struck by thrown, projected or falling object
		W21 Striking against or struck by sports equipment
		W22 Striking against or struck by other objects
		W23 Caught, crushed, jammed or pinched in or between objects
		W24 Contact with lifting and transmission devices, not elsewhere classified
		W25 Contact with sharp glass
		W26 Contact with other sharp object(s)
		W27 Contact with nonpowered hand tool
		W28 Contact with powered lawnmower
		W29 Contact with other powered hand tools and household machinery
		W44 Foreign body entering into or through eye or natural orifice
		W45 Foreign body or object entering through skin
OTHER ACCIDENTAL THREATS TO BREATHING (W75-84)	Suffocation, strangulation	W75 Accidental suffocation and strangulation in bed
		W76 Other accidental hanging and strangulation
	Choking, ingestion of objects	W80 Inhalation and ingestion of other objects causing obstruction of respiratory tract
		W81 Confined to or trapped in a low-oxygen environment
		W83 Other specified threats to breathing
		W84 Unspecified threat to breathing
EXPOSURE TO ELECTRIC CURRENT, RADIATION (W85-99)	Electric current, radiation	W85 Exposure to electric transmission lines
		W86 Exposure to other specified electric current
		W87 Exposure to unspecified electric current
		W89 Exposure to man-made visible and ultraviolet light
EXPOSURE TO SMOKE, FIRE AND FLAMES (X00-09)	Fire, smoke	X01 Exposure to uncontrolled fire, not in building or structure
		X02 Exposure to controlled fire in building or structure
		X03 Exposure to controlled fire, not in building or structure
		X04 Exposure to ignition of highly flammable material
		X05 Exposure to ignition or melting of nightwear
		X06 Exposure to ignition or melting of other clothing and apparel
		X08 Exposure to other specified smoke, fire and flames
		X09 Exposure to unspecified smoke, fire and flames
CONTACT WITH HEAT AND HOT SUBSTANCES (X10-19)	Hot water, fluids	X10 Contact with hot drinks, food, fats and cooking oils
		X11 Contact with hot tap-water
		X12 Contact with other hot fluids
		X13 Contact with steam and hot vapours
		X14 Contact with hot air and gases
		X15 Contact with hot household appliances
		X16 Contact with hot heating appliances, radiators and pipes
		X17 Contact with hot engines, machinery and tools
		X18 Contact with other hot metals
		X19 Contact with other and unspecified heat and hot substances

Filter 2

We use the fourth digit e.g. W11X to filter the data additionally by selecting specific place of occurrence codes[364]. For these two options exists:

A. Focus on home injuries (as has been done by a previous analysis by EuroSafe), i.e. focusing on FORTH DIGIT = 0 (Home)
B. Exclude places of occurrence that are clearly work related, namely 5 (Trade and service area), 6 (Industrial and construction area), 7 (Farm) and 9 (Unspecified place), and focus on the remaining cases. Included would therefore be:

0 Home	Apartment Boarding-house Caravan [trailer] park, residential Farmhouse Home premises House (residential) Noninstitutional place of residence Private: • driveway to home • garage • garden to home • yard to home Swimming-pool in private house or garden
1 Residential institution	Children's home Dormitory Home for the sick Hospice Military camp Nursing home Old people's home Orphanage Pensioner's home Prison Reform school
2 School, other institution and public administrative area	Building (including adjacent grounds) used by the general public or by a particular group of the public such as: • assembly hall • campus • church • cinema • clubhouse • college • court-house • dancehall • day nursery • gallery • hospital • institute for higher education • kindergarten • library

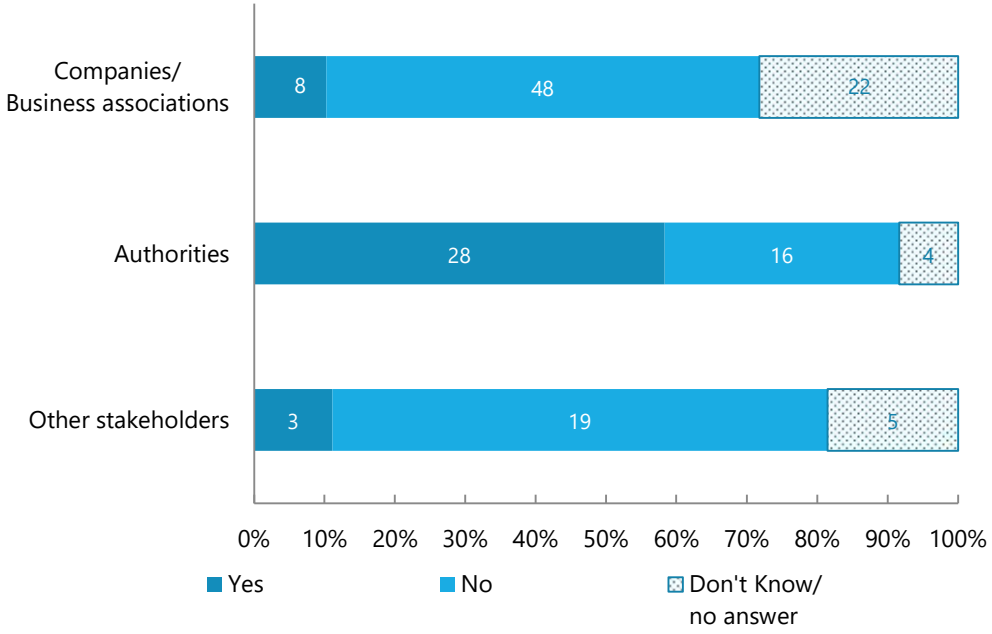
[364] See WHO ICD-10 version 2016, Place of occurrence codes available at: https://icd.who.int/browse10/2016/en#/XX.

	• movie-house • museum • music-hall • opera-house • post office • public hall • school (private)(public)(state) • theatre • university • youth centre
3 Sports and athletics area	Baseball field Basketball-court Cricket ground Football field Golf-course Gymnasium Hockey field Riding-school Skating-rink Squash-court Stadium Swimming-pool, public Tennis-court
4 Street and highway	Freeway Motorway Pavement Road Sidewalk
8 Other specified places	Beach Campsite Canal Caravan site NOS Derelict house Desert Dock NOS Forest Harbour Hill Lake Marsh Military training ground Mountain Park (amusement) (public) Parking-lot and parking-place Pond or pool Prairie Public place NOS Railway line River Sea Seashore Stream Swamp Water reservoir Zoo

Annex III: Analysis of costs for accident reporting

In our surveys, we asked businesses and other stakeholders whether they had ever reported a product-related death or serious injury associated with a consumer product that they manufactured, imported, or sold (e.g. based on a consumer complaint) to a national authority. We also asked authorities whether they had ever received such a report. The results are presented in the following figure:

Figure 32: Have you ever reported a product-related death or serious injury associated with a consumer product you manufactured, imported, or sold (e.g. based on a consumer complaint) to a national authority?



Source: Civic Consulting survey. Note that authorities were asked: Have you ever been informed by companies, consumers/consumer organisations or other organisations regarding cases of product-related death or serious injury associated with a consumer product?

The figure shows that only a minority of respondents ever reported a product-related death or serious injury associated with a consumer product to a national authority. However, more than a half of responding authorities did receive such reports. We also asked respondents to provide data to estimate how many hours of staff time was needed to process and register this information in a database, if applicable (on average per case). Only a small number of respondents provided data. Based on the data provided, an estimate between 5 and 8 hours per case to gather all information concerning the case and file a report appears to be realistic, and the subsequent estimate of related costs is based on a figure of 6.5 work hours per case for both authorities and businesses (i.e. 13 work hours per case in total).

Reporting of consumer product related accidents is already mandatory in Australia, Canada and the US. In Australia, during the last financial year (1 July 2019 to 30 June 2020) a total of 6 911 reports of unsafe products received that are typically consumer driven, and 3 025 mandatory injury reports were received from businesses[365]. In Canada, a total of 2 343 consumer product reports were received between January 1, 2019, and December 31, 2019, of which 23 mentioned a death and 794 mentioned a

[365] Communication of the authors with ACCC.

non-fatal injury[366]. Roughly 65% of these cases were reported from businesses (equivalent to 1 522 per year). No data was available from the US.

To derive at an estimate of the expected number of business reports, if a similar requirement were made in a revised GPSD, we have used the following approach:

- Taking into account the population size of the reference countries Canada (scenario 1) and Australia (scenario 2), we have extrapolated the number of cases that can be expected to be reported in the EU, based on the current reporting figures in both countries;
- As Canada and Australia operate fully developed and long-established systems of mandatory injury reporting, we have assumed that the case load of a similar system in the EU would gradually increase during a ten-year period, in which consumers, companies and authorities would be accustomed to report relevant injuries. This would translate in increasing number of injury reports received, starting with 10% of the case numbers in the reference countries in year 1, 20% of the case numbers in year 2, until similar reporting numbers as in the reference countries could be expected in year 10;
- We monetise the related costs of the system, using the same approach as for the calculation of compliance costs (see baseline, section 7.1), and the above-mentioned figure of 6.5 hours per case on average for companies to file the report concerning the death or serious injury. We use the same number of hours of staff time for authorities to process and register this information[367].

The calculation results for both scenarios are presented in the following paragraphs:

a) Scenario 1: Assuming that reporting rates would be similar to those in Canada (with a population of 37.8 million at the end of 2019[368]), the expected equivalent number of accident reports filed by businesses in the EU (population 447.7 million) could be expected to be in the range of 18 000 reports per year once the system is fully established (year 10). In the first year, we would expect a total of 1 800 cases, with a continuing increase until year 10. Using the approach outlined above, we arrive at a cost estimate of EUR 0.81 million per year[369] in the first year of operation, increasing to a total of EUR 8.1 million per year once the system is fully established in year 10. This estimate concerns the combined costs of businesses and authorities, with a roughly evenly split (i.e. half of the costs accrue to companies, the other half to authorities).

b) Scenario 2: Assuming that reporting rates would be similar to those in Australia (with a population of 25.5 million at the end of 2019[370]), the expected equivalent number of accident reports filed by businesses in the EU could be expected to be in the range of 53 000 reports per year once the system is fully established (year 10). In the first year, we would expect a total of 5 300 cases, with a continuing increase until year 10. Using the approach outlined above, we arrive at a cost estimate of EUR 2.39 million per year in the first year of operation, increasing to a total of EUR 23.9 million per year once the system is fully established in year

366 Consumer Product Safety Program Annual Surveillance Report 2019.

367 In both cases, changes to the activities as consequence of the injury reports (e.g. design changes to unsafe products for businesses, or increased surveillance of a product sector that has caused multiple accidents in the case of authorities) are not considered.

368 Statistics Canada, https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000901

369 Applying Euro-denominated costs for staff based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour (business costs). The average wage of 28.00 EUR used for the assessment of authority staff costs corresponds to the EU27 average wage of "administrative and support service activities" (18.70 EUR) and "professional, scientific and technical activities" (37.30 EUR) for 2017 (latest figure available in Eurostat database). To account for overhead costs, a 25% mark-up was added to staff-related costs.

370 https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/dec-2019

10. This estimate concerns the combined costs of businesses and authorities, with a roughly evenly split (i.e. half of the costs accrue to companies, the other half to authorities).

In addition to the mentioned costs, a centralized database with reporting forms would need to be implemented, likely in the context of the Safety Gate/RAPEX system. As the system's web interface is regularly improved, the related costs to extend it are likely to be minor[371].

The calculation does not consider potential efficiency gains in the processing of cases. It is possible that the number of working hours per case will decrease, as the related procedures are likely to be better established and streamlined over time. Also, market surveillance activities will be better targeted as they can directly focus on those products that cause most detriment in terms of accidents, which can be expected to lead to savings and gains in effectiveness. Finally, it is questionable whether the calculated work hours by authorities can be considered to be additional costs, as likely existing staff would be reallocated to conduct this task. The calculated figures can therefore be considered to be the upper limit of the costs that would accrue due to mandatory injury reporting.

It can be concluded that a mandatory reporting system for product related injuries and fatalities in the EU could be expected to cost between EUR 0.8 million and EUR 2.4 million in the first year of its operation, with a gradual increase until the estimated maximum costs of EUR 8 million to EUR 24 million are reached, depending on the number of reports filed.

In the three non-EU/EEA countries that were subject to case studies (see Part 1 for detailed case study reports), the accident reporting system is considered to be a cornerstone of the product safety system. It is a key data source to determine the annual product safety priorities and surveillance activities. The accident reports are also an important data source for standardisation activities and targeted product safety enquiries. Establishing a similar system in the EU can therefore be expected to be a cost-effective supplement to the existing EU framework established by the GPSD, as the resulting information will provide essential information to complement injury data from hospitals and mortality data. The data will also allow the EC and Member States' authorities to focus market surveillance and standardisation on those issues that matter most in terms of EU consumers' safety and health.

[371] Also not included are costs that relate to the filing of reports by consumers and other non-business stakeholders, as these would be voluntary and could be expected to occur anyhow.

Annex IV: Benefits of measures concerning online sales channels

In section 4.2 of the report, we have elaborated in detail on the challenges posed by e-commerce for product safety. A key problem for market surveillance identified by MSAs and other stakeholders concerns B2C transactions with operators in non-EU/EEA countries, in which products from those countries are delivered on an individual basis. The evidence presented in the problem analysis includes:

- Increasing share of Safety Gate/RAPEX notifications mentioning online sales channels: Approximately 5% of all notifications in 2018 concerned products purchased from an online trader. This figure doubled to almost 10% in 2019. Main categories of notified products that were (also) sold online were toys (33%) and electrical products (24%). No data was available for previous years.
- Some authorities have specifically controlled online marketplaces, e.g. in France. The DGCCRF reports that specific control plans on the safety of products sold on Internet marketplaces in 2018 and 2019 have on average found 25% of dangerous products. The authority concluded that it found a significantly higher share of unsafe products on online marketplaces compared to products sampled across all distribution channels. On average, the share of dangerous non-food products found in DGCCRF samples was 13% (average data for 2019).
- In 2015, the OECD conducted a sweep, in which 25 countries including 15 EU Member States[372] undertook a coordinated inspection of 1 709 products sold online[373]. One of the focus points of the exercise was whether banned or recalled products were available online. 693 products were inspected for the purpose of detecting banned and recalled products. In each jurisdiction, a wide variety of banned and recalled products were identified, including small high-powered magnets, sky lanterns and novelty lighters. More than two-thirds (68%) of these products were available for sale in the participating jurisdictions.

No consistent data is available on the incidence of unsafe products on the EU market. In the surveys for this study, we therefore asked market surveillance authorities, companies/business associations and other stakeholders to provide their best estimate of the share of unsafe products on the market in their respective area of activity, both for consumer products sold in brick-and-mortar shops and for consumer product sold online by traders targeting consumers in their country. The average assessment for each stakeholder group is provided in Table 114 below.

[372] Austria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungry, Latvia, Malta, Poland, Portugal, Slovenia, Spain, and Sweden.

[373] All results quoted from OECD (2016-11-03), "Online Product Safety: Trends and Challenges", OECD Digital Economy Papers, No. 261, OECD Publishing, Paris. http://dx.doi.org/10.1787/5jlnb5q93jlt-en

Table 114: In your view, what is the best estimate of the share of unsafe products on the market in your area of activity (i.e. the estimated number of unsafe products per 100 products sold on the market)? – average assessment by stakeholders

Sales channel	Companies/ Business associations	Authorities	Other stakeholders	Average
Brick-and-mortar shops	3%	4%	5%	**4%**
Online	10%	7%	10%	**9%**

Source: Civic Consulting surveys of authorities, businesses, business organisations and other stakeholders. Average assessments by stakeholder group, not considering responses of 'Don't know/no answer'. For detailed results by stakeholder group, see Annex. N=153. Note: The average figures are calculated based on 100 (brick-and-mortar)/105 (online) stakeholders that had an opinion (53/48 indicated Don't know or provided no answer).

The results presented in the table above clearly show that respondents tended to see on average a higher incidence of unsafe products in the online sales channel. However, authorities, businesses and other stakeholders often provided very differentiated answers in the surveys conducted for this study and in complementary interviews during our case studies, which show a complex picture (see Part 1 of this report, EQ3). Also, not all business stakeholders agreed that there was a difference between sales channels in terms of the incidence of unsafe products at all. A large online retailer suggested that "overall, products on the market tend to be safe and one must diligently try to find ones that are not safe". This respondent assessed for both online and offline sales channels an incidence of 0.01% or less of products. Another large online operator suggested that an "in-depth study comparing online and off-line product safety would be very useful. It might be the case that it easier to find unsafe products online but it does not imply that it is the case in reality". In general, however, a majority of respondents considered the differences between sales channels to be very significant[374].

In the following analysis, we will use this stakeholder assessment as best available estimate to first analyse the potential detriment accruing currently to consumers due to unsafe products on the EU market, and then to consider the impact that increasing e-commerce and the implementation of different policy options could be expected to have on this baseline situation.

A key challenge in this respect is the size of the detriment to consumers posed by unsafe products. Detriment could occur in various scenarios:

1. A product is unsafe and may at the same time be of very low quality, so that it breaks before it can harm a consumer. In this case, the detriment to the consumer is the value of the product that was unsafe[375];
2. A consumer could become aware that a product is unsafe (e.g. because of a newspaper report), and throw it away. Again, the detriment is the value of the product that was unsafe;

[374] Assessments were provided on a six-point Likert scale, and averaged on basis of the mid-point of the percentage ranges provided. The most frequent assessment chosen for each sales channel was as follows: For 'brick-and-mortar' shops the most frequent assessment was 'Unsafe products are relatively common (2% to 5% of products)', which was chosen by 31 of the 100 respondents that had an opinion in this respect. In contrast, for 'online' shops the most frequent assessment was 'Very easy to find unsafe products (15% or more of products)', which was chosen by 49 of the 103 respondents that had an opinion. Note that an estimated incidence of "0.01% or less" was included with the value of 0.1%, and "15% or more" with the value of 15%, when calculating the average.

[375] One could argue that the period of time of use until the product broke would need to be subtracted from this detriment, assuming a typical lifetime of the respective product. This aspect is ignored in this analysis, for simplification purposes.

3. A consumer could become aware that a product is unsafe (e.g. because it is recalled), and return it to the seller/producer. The consumer would often receive a refund of the purchase price or a similar new product. In this case, the detriment would be mostly the loss of time for the transaction. This is not a minor aspect: In a study on consumer detriment conducted for the European Commission, the monetised time loss in some consumer goods markets (e.g. clothing, footwear and bags) was estimated to be higher than the post-redress financial detriment (i.e. the detriment accruing to consumers after any redress obtained was subtracted)[376];
4. An unsafe product could lead to damage of other goods. A dramatic example are hoverboards, which are causing large number of incidents due to fires or overheating[377]. The material damage related to such incidents may be very high, if e.g. a house burns down;
5. An unsafe product could lead to injuries and fatalities, which cause substantial detriment in the EU every year (see below).

Due to data limitations, it is not possible to quantify the occurrence of product-related injuries and fatalities, or damage to other goods caused by unsafe products according to sales channel. We will therefore in this analysis use as proxy for the detriment caused by an unsafe product its value (as expressed by its purchase price). This fully covers the detriment accrued in situations 1 and 2 listed above. It would constitute an overestimate regarding products recalled and returned by consumers (situation 3). Finally, it would constitute a large underestimate for situations 4 and 5 (i.e. damage to other goods or persons). A final situation not listed above, concerns the case that an unsafe product may not cause any detriment over its lifetime, e.g. because a consumer is very careful in its handling or just lucky. However, as product safety legislation is intended to protect all consumers, even those that are less careful, competent or lucky, this case is not considered here. In conclusion, the approach used in this analysis seems to rather underestimate than overestimate detriment, in light of the different situations analysed.

Also, another consideration supports using the value of an unsafe product as a proxy of the detriment incurred by its buyer. Willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g. a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased. This confirms that using the value of an unsafe product as proxy for the related consumer detriment is justified.

In our baseline analysis (section 7, Table 16), we have estimated the total EU27 household consumption of non-harmonised consumer products (excluding food and medical products) at EUR 428 664 million per year. Combining this data with the previously presented estimate of the incidence of unsafe consumer products, we derive at the estimate presented in Table 115 below.

[376] See Civic Consulting (2017), Consumer market study on measuring consumer detriment in the EU.

[377] Incidents documents by the US CPSC are provided on the following website: www.cpsc.gov/Safety-Education/Safety-Education-Centers/hoverboards

Table 115: Estimated value of unsafe non-harmonised products (baseline estimate, EU27, EUR million)

Sales channel	Share in retail (2019)[a)]	Retail value of non-harmonised products[b)] (EUR million)	Share of unsafe products estimated by stakeholders[c)]	Estimated value of unsafe non-harmonised products[d)] (EUR million)
Brick-and-mortar shops[e)]	89.8%	384 940	4%	15 398
Online	10.2%	43 724	9%	3 935
Total	100%	428 664	n.a.	**19 333**

Source: Civic Consulting. Notes: a) Western Europe, www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected b) Based on the estimated total EU27 household consumption of non-harmonised consumer products (excluding food and medical products). c) Based on surveys of authorities, businesses, business organisations and other stakeholders. d) Calculated by multiplying the incidence of unsafe non-harmonised products with retail value. Due to data limitations, we assume that incidence of unsafe products is similar across all categories of non-harmonised consumer products. e) Includes all other retail sales channels that are not e-commerce.

As the table indicates, the value of unsafe non-harmonised products per year (which is in our approach equivalent to the related consumer detriment) is estimated at EUR 3.9 billion for the online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion. This figure is by its nature an approximate estimate, as the data on which it is based has considerable limitations, and the result is affected by the underlying assumptions.

The first assumption is to apply the stakeholder estimate of incidence of unsafe products to the market as a whole. This appears to be justified, as market surveillance authorities and companies/business associations from a wide range of consumer product sectors have provided an assessment. Also, while there were some dissenting opinions among respondents (see above), overall, there was a great degree of consistency between most respondents in each stakeholder category, and between stakeholder categories.

The second assumption is that detriment is equally distributed across (non-harmonised) product categories and price ranges. This implies that non-harmonised products of all product categories and price ranges have the same likelihood to be unsafe. This assumption is likely a major simplification, as unsafe products may be more frequent in lower price ranges (e.g., low priced lighting chains). Also, specific product categories targeted at children or the elderly may be more likely to be considered unsafe than products targeted at other consumers, due to the vulnerability of the respective target groups. However, there is also some indication that unsafe products can be found in all price categories, and for all target groups. Unfortunately, no empirical data is available regarding these issues, that would allow a firm conclusion in this respect, which could be applied to adapt the methodology of the estimate accordingly. Therefore, the lack of data described above are important limitations of this analysis, which need to be considered when interpreting the results.

Before proceeding with the analysis, we therefore validate our estimate of consumer detriment. For this purpose, we compare it to the estimates of detriment due to product related injuries in the EU (elaborated for this study) and those existing in other jurisdictions. While these estimates concern a different aspect, namely the harm related to products (as opposed to the value of unsafe products), a comparison can show whether the approach used here leads to a realistic dimension of consumer detriment. A problem for this comparison is that estimates of the detriment due to product-related injuries do not differentiate between harmonised and non-harmonised products. For the comparison, we therefore first have to scale up the estimate provided above to account

for the total size of the consumer product market (including harmonised products)[378]. Doing so leads to an estimate of EUR 93.9 per capita in the EU27[379]. This is the estimated sum of consumer detriment related to harmonised and non-harmonised products, based on product value, and expressed on a per capita basis, to simplify the comparison with estimates from other jurisdictions.

This estimate compares to an estimated detriment of EUR 171.1 per capita in the EU due to product-related injuries and premature death (see Annex I)[380]. In Australia, an estimate by the ACCC concluded that the economic cost of injury and death caused by unsafe consumer products are equivalent to EUR 110.3 per capita of the population[381], and in the US, the CPSC considers product-related detriment to amount to the equivalent of EUR 2715.4 per capita[382]. The figures for the US are much higher, as the methodology applied differs, property damage is also considered and pain and suffering for product related injury survivors is based on jury awards, which may be much higher in the US than in other jurisdictions. It can be concluded that the analysis of product-related injuries and deaths both in the EU, and in other jurisdictions confirms the conservative character of the methodological approach used in this estimate, in which the value of unsafe products is used as a proxy for the detriment caused to consumers.

As the share of online retail is projected to grow rapidly over the next years, detriment as estimated above is expected to increase. This effect can be estimated on basis of scenarios for the expected growth of consumption and online retail. The following table shows the parameters used for the baseline scenario. Both the assumptions regarding the growth rates in consumption and the growth rates regarding the online share of retail are conservative, and reflect current estimates reflecting the impact of the COVID-19 crisis.

[378] Total market size is EUR 931 878 million for non-food goods, excl. medical products and vehicles (for harmonised and non-harmonised consumer products), see Table 16 in section 7.1. The resulting detriment can be calculated analogous to the estimate provided in Table 115.

[379] Based on a population of 447.7 million for the EU27.

[380] Detriment suffered by EU consumers and society related to products is estimated to be EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations. The analysis excludes losses caused by work and transportation accidents.

[381] ACCC has estimated the economic cost of injury and death *caused* by unsafe consumer products at approximately 4.5 billion Australian dollars per year (this amount excludes hospital costs to government as well as costs of injuries/deaths caused by quad bikes). ACCC clarifies that this cost may be an underestimation given that only a small fraction of product-caused incidents are reported to the ACCC. We have converted this figure based on a population of 25.5 million and an exchange rate of 0.6253 EUR per Australian dollar (31.12.2019).

[382] The CPSC estimates that deaths, injuries, and property damage from consumer product incidents cost the US more than $1 trillion annually. See https://www.cpsc.gov/About-CPSC. The figure was converted based on a population of 328.2 million and an exchange rate of 0.8912 EUR per US dollar (31.12.2019).

Table 116: Baseline scenario for retail value of non-harmonised products and share of online retail (EU27)

	2019 (base-line)	2020	2021	2022	2023	2024	2025	2026	2029	2034
Growth rate of retail value (from previous year) [a)]	n.a.	-7.4%	4.1%	3%	1% per year					
Retail value (EUR million)[b)]	428 664	396 943	413 218	425 614	429 870	434 169	438 511	442 896	456 316	479 593
Online share in retail (%)[c)]	10.2%	13.2%	12.8%	13.2%	13.8%	14.5%	15.2%	15.9%	18.0%	21.5%

Source: Civic Consulting. Notes: a) Estimated on basis of projected GDP growth rates for the EU27, see Autumn 2020 Economic Forecast, https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_20_2040. Growth rate of 1% assumed as minimum on average for period 2023 to 2034. b) Calculated on basis of growth rate indicated. c) 2019-2023, Western Europe, www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected. Linear extrapolation to subsequent years (average growth rate of share of online retail of 0.7% per year).

With the data presented in the previous table, it is possible to translate the measures taken under each policy option into scenarios that compare the detriment in the baseline scenario with the detriment under the modified assumptions in each scenario. Under all scenarios, we assume that growth rates of retail value of non-harmonised products in the EU and of the online share in retail are identical to the baseline scenario outlined in Table 116 above. This implies that we consider it very unlikely that any of the measures proposed could have an impact on retail values or the share of online retail.

We also assume that the situation in the offline sales channels remains largely as it is in the baseline situation, with the incidence of 4% of unsafe products being unchanged in the near future. However, in the mid-to long-term we assume across all scenarios an effect of technological progress, standardisation, which is expected to reduce the incidence of unsafe products over time. In our estimate, we do not consider the effect of potentially increasing recall effectiveness, due to measures in this respect, as we would assume that these measures will equally apply to both online and offline sales channels, and therefore can be neglected for this estimate (the benefits of recalls are separately considered in Annex V).

The following table presents the scenario assumptions for the offline sales channels (brick-and-mortar stores etc). We assume that the effects of new legislation under Options 2 to 4 are notable in 2025.

Table 117: Scenario assumptions for incidence of unsafe products in <u>offline</u> sales channels over time, depending on policy measures taken

Scenario	2019 (base-line)	2020	2021	2022	2023	2024	2025	2026	2029	2034
Option 0. 'Status quo': Baseline scenario not involving any new actions[a)]	4.0%						4.0%	4.0%	3.5%	3.5%
Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD [a)]							4.0%	4.0%	3.5%	3.5%
Option 2. Targeted revision of the GPSD (Directive or Regulation) [a)]							4.0%	4.0%	3.5%	3.5%
Option 3. Full revision of the GPSD and recasting as Regulation[b)]							**3.9%**	**3.8%**	**3.0%**	**3.0%**
Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020 [b)]							As in Option 3			

Source: Civic Consulting. Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. Notes: **bold** = value is different compared to baseline scenario. a) Assumed is a reduction in share of unsafe products after 2028 due to the mid- to long-term effects of technological progress, standardisation etc. b) Assumed is a reduction in share of unsafe products after 2024 due to stronger deterrence effect (due to penalties and sanctions), as well as the mid- to long-term effects of technological progress, standardisation etc.

As shown in the table above, the scenario assumptions for Options 1 and 2 for the offline sales channels do not differ from the baseline scenario, as no relevant measures are foreseen that could be expected to affect the incidence of unsafe products offline. In contrast, under Options 3 and 4 we expect slight additional effects also regarding offline sales channels, due to the deterrence effects of penalties and sanctions, which can be expected to increase the incentives of business operators for improved management of product safety (see last row of Table 117 above, in bold).

As key measures under the options affect online sales, we would assume stronger effects regarding the incidence of unsafe products sold online. Again, we foresee a slight reduction already under the scenarios for baseline and Option 1 due to technological progress and the effects of standardisation efforts (from 9% to 8.5% over time). A gradual additional reduction of the incidence of unsafe products in this sales channel to 7.5% forms the basis of the scenario for the implementation of Option 2 (due to enshrining provisions of the Product Safety Pledge in law, covering some additional platforms), and to 5.0% under Options 3 and 4 (as due diligence obligations for platforms, as well as sanctions and penalties are expected to lead to more significant effects). The details are provided in Table 118 below).

Note that under all scenarios we assume that more unsafe products will continue to be sold online, due to the much large number of different products offered online, the large number of niche products which are unlikely to be subject to market surveillance, and specific enforcement issues that will remain relevant for the online sales channels (e.g. increased difficulties to enforce measures against operators in other Member States);

Table 118: Scenario assumptions for incidence of unsafe products in online sales channels over time, depending on policy measures taken

Scenario	2019 (base-line)	2020	2021	2022	2023	2024	2025	2026	2029	2034
Option 0. 'Status quo': Baseline scenario not involving any new actions[a)]	9.0%						9.0%	9.0%	8.5%	8.5%
Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD [a)]							9.0%	9.0%	8.5%	8.5%
Option 2. Targeted revision of the GPSD (Directive or Regulation) [b)]							**8.5%**	**8.0%**	**7.5%**	**7.5%**
Option 3. Full revision of the GPSD and recasting as Regulation[c)]							**8.0%**	**7.0%**	**6.0%**	**5.0%**
Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020 [c)]							As in Option 3			

Source: Civic Consulting. Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. Notes: **bold** = value is different compared to baseline scenario. a) Assumed is a reduction in share of unsafe products after 2028 due to the mid- to long-term effects of technological progress, standardisation etc. b) Assumed is a reduction in share of unsafe products after 2024 due to making most provisions of the Product Safety Pledge legally binding for all online marketplaces targeting EU consumers, as well as the mid- to long-term effects of technological progress, standardisation etc. c) Assumed is an additional reduction in share of unsafe products after 2024, as due diligence obligations for marketplaces are introduced and a stronger deterrence effect is expected (due to penalties and sanctions). As in previous options, the mid- to long-term effects of technological progress, standardisation etc. is also considered (similar across all scenarios).

Based on these assumptions, we can now estimate the reduction in consumer detriment due to unsafe products under the different scenarios. Table 119 below provides the sum of consumer detriment due to unsafe products in online and offline sales channels for each scenario, which is affected by the size of total retail, the share of online in total retail, and the respective incidence rates of unsafe products.

Table 119: Expected consumer detriment due to unsafe products under the different scenarios (EU27, in EUR million, total of online and offline sales channels)

Scenario	2019	2020	2021	2022	2023	2024	2025	2026	2029	2034
Option 0. 'Status quo': Baseline scenario not involving any new actions	19 333	18 498	19 173	19 834	20 161	20 514	20 873	21 237	20 078	21 941
Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD							20 873	21 237	20 078	21 941
Option 2. Targeted revision of the GPSD (Directive or Regulation)							**20 540**	**20 533**	**19 257**	**20 910**
Option 3. Full revision of the GPSD and recasting as Regulation							**19 835**	**19 083**	**16 154**	**16 450**
Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020							As in Option 3			

Source: Civic Consulting. Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025. Notes: **bold** = value is different compared to baseline scenario.

As indicated in Table 119 above, consumer detriment in the EU27 due to unsafe non-harmonised products is expected to decline in 2020 and 2021, in line with the contraction of the economy due to the COVID-19 crisis, and the related reduced consumption. Consumption is assumed to reach pre-crisis levels in 2022/23. Consumer detriment is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce[383]. We do not expect that Option 1 would change this situation, due to the very limited nature of the measures taken. In contrast, Options 2, 3 and 4 are expected to reduce consumer detriment, when compared to the baseline. Table 120 below presents the differences to the baseline scenario, or in other words: the benefits for society in terms of reduced consumer detriment under each scenario.

[383] Note that we refer here solely to detriment related to unsafe products. It is well documented that e-commerce also brings important welfare benefits due to increased choice and sometimes lower prices, which are not considered here.

Table 120: Expected reduction in consumer detriment due to unsafe products under the different scenarios (EU27, in EUR million)

Scenario	2019	2020	2021	2022	2023	2024	2025	2026	2029	2034
Option 1. Improved implementation and enforcement of the existing legal framework, without revision of the GPSD	0	0	0	0	0	0	0	0	0	0
Option 2. Targeted revision of the GPSD (Directive or Regulation)							**333**	**704**	**821**	**1 031**
Option 3. Full revision of the GPSD and recasting as Regulation							**1 038**	**2 153**	**3 924**	**5 491**
Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020							As in Option 3			

Source: Civic Consulting. Based on assumption that new regulation replacing GPSD comes into effect on 1.1.2025.

The table shows that benefits for society compared to the baseline scenario are highest under Options 3 and 4. Under Options 3 and 4 the benefits in terms of reduced consumer detriment are expected to amount to approximately EUR 1.0 billion in the first year of implementation, increasing to approximately EUR 5.5 billion over the next decade. In contrast, Option 2 is expected to lead to a reduction in consumer detriment compared to the baseline of EUR 333 million in the first year, increasing to approximately EUR 1.0 billion over time.

These results reflect the assumptions made, namely that the measures taken under Options 3 and 4 are likely to be most effective to address the challenges for product safety posed by online sales channels, especially through due diligence obligations for platforms, the extension of certain obligations e.g., for fulfilment service providers, and sanctions and penalties (which are expected to reduce the incidence of unsafe products in both online and offline sales channels due to their deterrence effects). The scenarios provided above assume that measures under Options 3 and 4 will effectively contribute to aligning the level of product safety in all sales channels, and thereby most effectively reduce the incidence of unsafe products on the market. The extent to which these effects materialise, will however, also depend on other factors, including the overall legal framework for e-commerce, most notably the new Digital Services Act.

Annex V: Benefits of measures in the field of recalls

A fundamental obligation that derives from the GPSD is the obligation of producers and distributors to notify the authorities and take the necessary actions for consumer protection, once one of the products that they have placed on the market is identified as dangerous[384]. Corrective measures to be taken by producers may include withdrawing products from the supply chain, adequately and effectively warning consumers and, as a measure of last resort, recalling products that have already been supplied to consumers[385]. As elaborated in section 4.5 of this report, evidence collected through surveys of MSAs and general stakeholders as well as from other studies indicates that the effectiveness of product recalls from consumers is relatively low[386]. Reasons include:

- The GPSD does not contain any specific rules for recall procedures and timelines, communication or the remedies to be offered to consumers. This is a significant shortcoming suggesting that existing GPSD requirements are in themselves currently not sufficient to ensure effective recalls;
- The GPSD is not fully adapted to ensure adequate traceability[387], which puts a strain in the implementation of corrective measures, in particular recalls.

The problem analysis concluded that the limited effectiveness of recalls may negatively affect consumer safety and the degree to which there is a level playing field for businesses in the internal market, affecting therefore the extent to which the objectives of the GPSD are achieved in practice. The limited effectiveness of recalls also leads to consumer detriment, the size of which is estimated in this Annex.

For estimating consumer detriment due to ineffective recalls, we follow the approach explained in Annex IV, namely to use the value of an unsafe product as a proxy for the detriment it causes to consumers that have bought it. A detailed justification of this approach is provided in the same Annex. Key elements include:

- *Unsafe products may cause consumer injuries and death*. This is illustrated by well publicised examples of recalled products, such as Takata airbags (which are estimated to have caused at least 35 deaths and 300 injuries worldwide[388]) and Fisher-Price's rock 'n play baby sleepers (associated with 59 baby deaths in the US[389]). However, the lack of systematic data in this respect makes an estimate of consumer detriment based on injuries and deaths specifically related to recalls challenging;
- *Unsafe products lose their value*. Willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased.

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384 GPSD Art 5 (3).

385 See GPSD Art 5 (1), (b) of the third subparagraph, and last paragraph.

386 See Part 1 of this report, EQ6.

387 Problematic aspects regarding traceability include the lack of specific/mandatory traceability requirements.

388 https://www.consumerreports.org/car-recalls-defects/takata-airbag-recall-everything-you-need-to-know/

389 https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2fwww.washingtonpost.com%2fbusiness%2f2019%2f10%2f17%2fstudy-concludes-design-rock-n-play-other-infant-sleepers-led-deaths%2f

Using the value of an unsafe product as proxy for the related consumer detriment appears therefore to be justified. This approach leads to a conservative estimate, as additional detriment that may be caused by recalled products in terms of injuries or damage to other goods, or the environment is not considered.

When using the value of a recalled product to analyse consumer detriment, two situations can be differentiated:

3. *An unsafe product is recalled and returned to a producer.* Assuming that it is repaired or replaced by a good of the same quality, consumer detriment is compensated in terms of the value of the good. The resulting consumer detriment can be approximated as being zero[390];
4. *An unsafe product is recalled and not returned to a producer.* In this case the consumer detriment is the value of the product, as discussed.

Both situations will be considered in the following scenario analysis, differentiating a baseline scenario with low recall effectiveness (current situation) to a scenario where recall effectiveness is improved. The analysis focuses on non-harmonised products, for which the GPSD fully applies.

Currently, no comprehensive register of recalls exists in the EU. We therefore have to estimate the total number of recalls regarding non-harmonised products, and the number of affected items. The first data set we use for this purpose are notifications in Safety Gate/RAPEX, which include the information whether a notified product was recalled or not. In the period 2013 to 2019, a total of close to 6 000 recalls were notified in Safety Gate/RAPEX, of which 1 320 related to ten product categories that are clearly not harmonised. Four of these product categories account for close to 90% of recalls of non-harmonised products: Clothing, textiles and fashion items; childcare articles and children's equipment; lighting chains; and hobby/sports equipment (see Table 121).

Table 121: Number of recalls in non-harmonised product categories notified in Safety Gate/RAPEX (2013-2019)

Product category	Total number of recalls 2013-2019	Average per year	In percent of total
Clothing, textiles and fashion items	698	100	53%
Childcare articles and children's equipment	203	29	15%
Lighting chains	131	19	10%
Hobby/sports equipment	130	19	10%
Jewellery	45	6	3%
Decorative articles	41	6	3%
Laser pointers	30	4	2%
Furniture	25	4	2%
Lighters	16	2	1%
Gadgets	1	0	0%
Total	***1320***	***189***	***100%***

Source: Civic Consulting, based on data from Safety Gate/RAPEX. All alerts, risk level: products with serious risks and products with other risk levels

[390] In reality, even in this situation consumers incur a detriment due to the time spent for the transaction, e.g., for returning the product by mail or in person to a shop. However, this additional detriment is not considered here, to provide a conservative, simplified estimate.

However, the figures presented in the table above may not provide the full picture, as not all recalls in a country are necessarily notified at EU level. Member States are required to notify corrective measures in cases where the effects of the product risk can go beyond the territory of the Member State, implying that not all recalls in a country are necessarily notified at EU level. We therefore collected data on recalls directly from the relevant Member States' market surveillance authorities[391]. The number of recalls related to non-harmonised products was available for 17 Member States (see Table 122).

Table 122: Number of recalls related to non-harmonised products according to market surveillance authorities (last available year)

Product category	Population (million)	Recalls of non-harmonised products	Number of recalls per million population
Austria	8.8	:	:
Belgium	11.4	54	4.7
Bulgaria	7.1	:	:
Croatia	4.1	40	9.8
Cyprus	0.9	:	:
Czech Republic	10.6	6	0.6
Denmark	5.8	18	3.1
Estonia	1.3	:	:
Finland	5.5	34	6.2
France	66.9	100	1.5
Germany	82.8	49	0.6
Greece	10.7	130	12.1
Hungary	9.8	:	:
Ireland	4.8	56[a)]	11.7
Italy	60.5	:	:
Latvia	1.9	4	2.1
Lithuania	2.8	0	0
Luxembourg	0.6	:	:
Malta	0.5	20[a)]	40.5
Netherlands	17.2	:	:
Poland	38.0	108[a)]	2.8
Portugal	10.3	36	3.5
Romania	19.5	24	1.2
Slovenia	2.1	7	3.3
Slovakia	5.4	:	:
Spain	46.7	:	:
Sweden	10.1	16	1.6
Median			***3.1***

Source: Civic Consulting. Notes: Data provided for last available year, mostly 2018. See GPSD implementation study. a) Number of recalls of non-harmonised products estimated as 46% of total recalls, in line with share in EU market.

[391] See GPSD implementation study.

The total number of recalls reported from the listed 17 countries is 702. For those countries for which no information was available, we can extrapolate the number of recalls based on the median provided in Table 122 above (which is 3.1 recalls per million population and year). We derive at an estimated figure of 1 193 recalls per year, of which 189 are notified through Safety Gate/RAPEX. A problem is that both figures cannot simply be added, as some of the national recalls may have been caused by the RAPEX notification (outside the notifying countries). In these cases a reacting Member States would typically indicate that it has taken measures in a follow-up notification. However, the number of follow-up notifications is low for the selected product categories, on average 0.72 per notification. This means that in addition to the 189 recalls notified on Safety Gate/RAPEX, on average an additional 136 follow-up notifications by MSAs were transmitted through the system in which a Member State reacted on the recall (indicating the measures taken in this Member State, if any). Assuming that all reacting Member States also conducted a recall, we can subtract the sum of original notifications and follow-up notifications (in total 325) from the 1 193 recalls extrapolated for the EU27, and derive at an estimate of 869 national recalls. In conclusions, we can estimate that in the EU27 approximately 189 recalls with EU relevance (and therefore notified through Safety Gate/RAPEX) are recorded per year, and in addition 869 national recalls of non-harmonised products.

To establish the number of affected items per recall, we draw on a dataset presented in detail in Part 1 of this study (section 6.1). Notifications may include information concerning the number of items that are being affected by the measures taken. This information is part of the RAPEX notification that is only accessible for market surveillance authorities. For the purposes of this study, the European Commission provided an extract of this data, covering a twelve-month period from May 2019 to April 2020, and including information for a total of 536 notifications in which more than 1 000 items were affected. The dataset included the geographical area of circulation to which the number of items referred, differentiating between national circulation, EU/EEA wide circulation, global circulation or unknown. In the following, we use the figures for national circulation and EU/EEA wide circulation as proxies for the number of items affected by recalls (i.e. we do not consider those notifications where the number of items was provided, but it related to global circulation, or the circulation area was unknown). By applying this approach, we find that notifications of unsafe products in which the circulation is EU/EEA wide, concern on average 109 453 items. Notifications where data is provided on national circulation concern on average 16 021 items. Multiplying these figures with the respective types of recalls, we arrive at an estimate of 20.6 million items subject to recalls with EU relevance, and 13.9 million items subject to national recalls of non-harmonised products. Note that this is a rough approximation for the purpose of this estimation[392].

Assuming that the number of affected items is similar across product categories, and that the recalls notified in Safety Gate/RAPEX are similarly distributed across product categories as national recalls, we can calculate the number of recalled items in each product category per year (see Table 123).

[392] These estimates have been elaborated for the purpose of assessing consumer benefit of recalls. Actual numbers may differ, as 10 Member States did not report figures, and an extrapolation method was applied to approximate the missing values.

Table 123: Number of recalls and affected items, EU27

Product category	In percent of total	Estimated number of EU wide recalls	Estimated number of national recalls	Number of items subject to EU wide recalls (million)	Number of items subject to national recalls (million)	Total number of items recalled (in million)
Clothing, textiles and fashion items	53%	100	459	10.9	7.4	18.3
Childcare articles and children's equipment	15%	29	134	3.2	2.1	5.3
Lighting chains	10%	19	86	2.0	1.4	3.4
Hobby/sports equipment	10%	19	86	2.0	1.4	3.4
Jewellery	3%	6	30	0.7	0.5	1.2
Decorative articles	3%	6	27	0.6	0.4	1.1
Laser pointers	2%	4	20	0.5	0.3	0.8
Furniture	2%	4	16	0.4	0.3	0.7
Lighters	1%	2	11	0.3	0.2	0.4
Gadgets	0%	0.15	1	0.02	0.01	0.03
Total	***100%***	***189***	***869***	***20.6***	***13.9***	***34.6***

Source: Civic Consulting, based on data from Safety Gate/RAPEX and GPSD implementation study.

Once the number of affected items per product category is established, two additional pieces of information to estimate detriment under the relevant scenarios are needed. These are the average value per item in each product category, and the return rates of recalled products (as indicator for recall effectiveness) under the different scenarios.

The average values per item in each product category used for this analysis are presented in the following table. They have been established on basis of previous consumer research (for the category clothing, textiles and fashion items), and a review of online offers, considering a range of low to mid-priced articles in each category (in line with the aim to elaborate a conservative estimate).

Table 124: Scenario assumptions for average value per recalled item (all scenarios)

Product category	Average value per recalled item assumed for the scenarios (EUR)
Clothing, textiles and fashion items	60[a)]
Childcare articles and children's equipment	30
Lighting chains	15
Hobby/sports equipment	80
Jewellery	10
Decorative articles	5
Laser pointers	5
Furniture	150
Lighters	0.3
Gadgets	20

Source: Civic Consulting. Notes: Average values are determined considering a range of low to mid-priced articles in each category. a) Average value determined on basis of consumer research regarding purchases of clothing, footwear and bags, see Civic Consulting (2017), Study on measuring consumer detriment in the European Union, Final report Part 1 – Main report

Consistent data on recall effectiveness is scarce. A recent OECD report concludes that in spite of recent efforts to enhance the impact of product recalls, "some data suggest that a large proportion of products that have been the subject of one or several recalls over the past decade remain in the homes of consumers, exposing them to threats of injury or even death"[393]. In our interviews we asked MSAs to estimate recall effectiveness in terms of the percentage of recalled consumer products that were actually returned. Few authorities provided (widely varying) estimates. Several MSAs suggested that even though they collect related data, in reality it was difficult to determine the effectiveness of product recalls. MSAs suggested that recall effectiveness depended on a variety of factors, including price and type of product (with more consumers returning expensive products, especially cars), the quality of an economic operators' traceability system, its willingness to cooperate, the sales channel used (with typically more tracing information being available for online purchases), etc. Recalls were reported to be very ineffective regarding low priced products[394]. This is also reflected in the following return rates, which have been used by an MSA in the past as benchmarks to determine the effectiveness of recalls[395]:

- For products cheaper than EUR 25, a return rate of 10% is considered good, because a lot of the products will also be thrown away;
- For products between EUR 25 and EUR 400, a return rate of around 50% is considered effective;
- For more expensive products there is the expectation of a higher rate of products returned (more than 50%).

In the following, we use these benchmark values as basis for our scenario assumptions. In line with the currently low level of recall effectiveness for low- and medium-priced products, we assume for the baseline scenario that on average only half of the listed benchmark levels are achieved in practice (across the EU). In contrast, under the improved recall effectiveness scenario (Options 3 and 4), we assume that the above benchmarks reflect the average return rates achieved. In line with our research results, we also assume that products with a value of less than EUR 10 are not returned at all, neither now nor in the future, as the transaction costs in terms of time loss are typically higher for consumers than the possible benefit (a replacement product). This implies average return rates for recalled products as follows:

- For products below a value of EUR 10 we assume a return rate of 0% under all scenarios;
- For products of a value between EUR 10 and EUR 25 Euros, we assume a return rate of 5% in the baseline situation, and 10% in the improved effectiveness scenario;
- For products of a value between EUR 25 and EUR 400, we assume a return rate of 25% in the baseline situation, and 50% in the improved effectiveness scenario;
- The last price category (products of more than EUR 400) is not used for this scenario analysis, in line with the conservative approach used (all products are assumed to fall under this threshold, see Table 124 above).

Finally, we also consider an intermediate scenario (option 2), which brings some improvements in return rates, but not as significant as under the improved effectiveness

393 OECD, Enhancing Product Recall Effectiveness Globally, 17 December 2018

394 See also GPSD implementation study.

395 This information was indicated on the MSA's website, but has been removed in the meantime, as the price of a product is only one of the parameters when assessing whether a recall has been effective. Other elements are the business' knowledge about its customers, the risk with the product and the sales channels. Still, the figures are seen to give a good estimate of what return rates can be expected for a given product, and have therefore been used in this assessment. They should, however, not be considered as reliable thresholds for what constitutes an effective recall.

scenario. The resulting scenario assumptions for each product category are provided in Table 125 below.

Table 125: Scenario assumptions regarding return rates for recalled products

Product category	Return rates assumed for the scenarios		
	Baseline scenario	Intermediate scenario (Option 2)	Improved recall effectiveness scenario (Options 3 and 4)
Clothing, textiles and fashion items	25%	37.5%	50%
Childcare articles and children's equipment	25%	37.5%	50%
Lighting chains	5%	7.5%	10%
Hobby/sports equipment	25%	37.5%	50%
Jewellery	5%	7.5%	10%
Decorative articles	0%	0.0%	0%
Laser pointers	0%	0.0%	0%
Furniture	25%	37.5%	50%
Lighters	0%	0.0%	0%
Gadgets	5%	7.5%	10%

Source: Civic Consulting.

With these assumptions it is possible to estimate consumer detriment under all three scenarios. Table 126 below provides the estimate for the baseline scenario. In the table, we list all required information items for each product category:

- Total number of items recalled (in million)
- Average value per item assumed for the scenario analysis (in EUR)
- Total value of recalled products (in EUR million)
- Return rates under the scenario (in %)
- Value of products collected from consumers (in EUR million);
- Value of products that remain with consumers (equivalent to consumer detriment, in EUR million).

Table 126: Consumer detriment due to recalls (baseline scenario), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products collected from consumers (EUR million)	Value of recalled products that remain with consumers (equivalent to consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1 096	25%	274	822
Childcare articles and children's equipment	5.3	30	159	25%	40	120
Lighting chains	3.4	15	51	5%	3	49
Hobby/sports equipment	3.4	80	272	25%	68	204
Jewellery	1.2	10	12	5%	0.6	11
Decorative articles	1.1	5	5	0%	0	5
Laser pointers	0.8	5	4	0%	0	4
Furniture	0.7	150	98	25%	25	74
Lighters	0.4	0.3	0.1	0%	0	0.1
Gadgets	0.03	20	0.5	5%	0	0.5
Total	*34.6*		*1 699*		*410*	***1 290***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124 above. b) See Table 125 above.

As indicated in Table 126, total consumer detriment under the baseline scenario with low recall effectiveness is about EUR 1.3 billion per year.

Under the assumption that return rates of recalled products are somewhat improved due to limited legislative measures (intermediate scenario, Option 2), this detriment is expected to be reduced to approximately EUR 1.1 billion per year (see Table 127).

Table 127: Consumer detriment due to recalls (intermediate scenario, Option 2), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products collected from consumers (EUR million)	Value of recalled products that remain with consumers (equivalent to consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1096	37.5%	411	685
Childcare articles and children's equipment	5.3	30	159	37.5%	60	100
Lighting chains	3.4	15	51	7.5%	4	48
Hobby/sports equipment	3.4	80	272	37.5%	102	170
Jewellery	1.2	10	12	7.5%	0.9	11
Decorative articles	1.1	5	5	0.0%	0	5
Laser pointers	0.8	5	4	0.0%	0	4
Furniture	0.7	150	98	37.5%	37	61
Lighters	0.4	0.3	0.1	0.0%	0	0.1
Gadgets	0.03	20	0.5	7.5%	0.04	0.5
Total	*34.6*		*1699*		*615*	***1085***
Consumer benefit *(= reduction of detriment compared to baseline)*						***205***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124 above. b) See Table 125 above.

It can be concluded that under a scenario of somewhat improved recall effectiveness (Option 2), consumer detriment in the EU can be expected to be reduced by EUR 205 million per year.

Under the assumption that return rates of recalled products are improved due to legislative measures to reach the benchmark values outlined above (under Option 3 and 4), the detriment is expected to be reduced to approximately EUR 0.9 billion per year (see Table 128).

Table 128: Consumer detriment due to recalls (improved effectiveness scenario, Options 3 and 4), EU27

Product category	Total number of items recalled (million)	Average value per item[a)] (EUR)	Total value recalled products (EUR million)	Return rates[b)]	Value of recalled products collected from consumers (EUR million)	Value of recalled products that remain with consumers (equivalent to consumer detriment, EUR million)
Clothing, textiles and fashion items	18.3	60	1096	50%	548	548
Childcare articles and children's equipment	5.3	30	159	50%	80	80
Lighting chains	3.4	15	51	10%	5	46
Hobby/sports equipment	3.4	80	272	50%	136	136
Jewellery	1.2	10	12	10%	1.2	11
Decorative articles	1.1	5	5	0%	0	5
Laser pointers	0.8	5	4	0%	0	4
Furniture	0.7	150	98	50%	49	49
Lighters	0.4	0.3	0.1	0%	0	0.1
Gadgets	0.03	20	0.5	10%	0	0.5
Total	*34.6*		*1699*		*820*	***880***
Consumer benefit *(= reduction of detriment compared to baseline)*						***410***

Source: Civic Consulting. Notes on scenario assumptions: a) See Table 124 above. b) See Table 125 above.

It can be concluded that under a scenario of improved recall effectiveness, consumer detriment in the EU can be expected to be reduced by EUR 410 million per year.

As mentioned above, these estimates are based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product caused damage to persons, other goods or the environment. Also, the return rates underlying the intermediate scenario and the improved effectiveness scenario are still relatively low and might be further increased through appropriate measures by producers and authorities, considering e.g., the increased availability of customer data in online transactions. If return rates were to be improved beyond our assumptions, consumer detriment would accordingly be further reduced, compared to the estimates provided above.

Annex VI: Data for the analysis of GPSD compliance costs

Table 129: Annual product safety-related costs in % of annual turnover from consumer products, by revenue size class, empirical estimates from survey respondents

Approximate size (in Euro) of annual EU turnover in 2019	Annual compliance costs in % of annual turnover from consumer products
200 000	3.33%
200 000	132.00%
2 000 000	0.24%
5 000 000	1.45%
10 000 000	2.06%
10 000 000	1.78%
20 000 000	0.36%
20 000 000	0.65%
20 000 000	7.92%
50 000 000	0.56%
50 000 000	13.24%
50 000 000	0.63%
100 000 000	0.59%
100 000 000	0.58%
100 000 000	9.78%
100 000 000	0.11%
100 000 000	7.59%
500 000 000	0.51%
500 000 000	0.00%
500 000 000	0.34%
1 000 000 000	0.13%
1 000 000 000	0.06%
1 000 000 000	2.65%
1 000 000 000	0.02%
1 000 000 000	0.13%
5 000 000 000	0.10%
5 000 000 000	0.01%
5 000 000 000	0.04%
5 000 000 000	0.10%
20 000 000 000	0.01%
20 000 000 000	0.00%
20 000 000 000	0.19%
20 000 000 000	0.53%
50 000 000 000	0.17%
50 000 000 000	0.00%
50 000 000 000	0.00%

Table 130: Annual product safety-related costs in % of annual turnover from consumer products, by number of employees, empirical estimates from survey respondents

Number of people employed in 2019	Annual compliance costs in % of annual turnover from consumer products
1 – 9 employees	132%
10 – 19 employees	1.68%
10 – 19 employees	0.24%
10 – 19 employees	1.96%
20 – 49 employees	3.33%
50 – 249 employees	0.41%
50 – 249 employees	0.59%
50 – 249 employees	0.14%
50 – 249 employees	0.76%
50 – 249 employees	2.24%
50 – 249 employees	7.92%
250 – 499 employees	0.61%
250 – 499 employees	10.08%
250 – 499 employees	7.59%
250 – 499 employees	0.65%
1000 employees or more	0.13%
1000 employees or more	0.06%
1000 employees or more	2.65%
1000 employees or more	0.01%
1000 employees or more	14.14%
1000 employees or more	0.65%
1000 employees or more	0.20%
1000 employees or more	0.02%
1000 employees or more	0.10%
1000 employees or more	0.60%
1000 employees or more	0.00%
1000 employees or more	0.22%
1000 employees or more	0.02%
1000 employees or more	0.00%
1000 employees or more	0.04%
1000 employees or more	0.13%
1000 employees or more	0.10%
1000 employees or more	0.00%
1000 employees or more	0.54%
1000 employees or more	0.00%
1000 employees or more	0.38%

Table 131: Annual product safety-related costs in % of annual turnover from consumer products, by role of company (according to stated commercial activities), empirical estimates from survey respondents

Role company in the supply of consumer products to EU consumers	Approximate size (in Euro) of annual EU turnover in 2019	Annual compliance costs in % of annual turnover from consumer products
Importer;Retailer/other type of distributor directly selling to consumers (including online retail)	1 000 000 000	0.02%
Importer;Wholesale	100 000 000	0.14%
Importer;Wholesale;Retailer/other type of distributor directly selling to consumers (including online retail)	1 000 000 000	0.13%
Manufacturer/producer	20 000 000	0.41%
Manufacturer/producer	5 000 000	1.68%
Manufacturer/producer	1 000 000 000	2.65%
Manufacturer/producer	100 000 000	0.65%
Manufacturer/producer	100 000 000	10.08%
Importer;Retailer/other type of distributor directly selling to consumers (including online retail)	1 000 000 000	0.02%
Importer;Wholesale	100 000 000	0.14%
Importer;Wholesale;Retailer/other type of distributor directly selling to consumers (including online retail)	1 000 000 000	0.13%
Retailer/other type of distributor directly selling to consumers (including online retail)	20 000 000 000	0.01%
Retailer/other type of distributor directly selling to consumers (including online retail)	200 000	3.33%
Retailer/other type of distributor directly selling to consumers (including online retail)	200 000	132.00%
Retailer/other type of distributor directly selling to consumers (including online retail)	1 000 000 000	0.13%
Retailer/other type of distributor directly selling to consumers (including online retail)	20 000 000	0.65%
Retailer/other type of distributor directly selling to consumers (including online retail);Online marketplace or other online intermediary	50 000 000 000	0.20%
Retailer/other type of distributor directly selling to consumers (including online retail);Online marketplace or other online intermediary	500 000 000	0.00%
Wholesale;Retailer/other type of distributor directly selling to consumers (including online retail)	2 000 000	0.24%
Manufacturer/producer	20 000 000	0.41%
Manufacturer/producer	5 000 000	1.68%

Role company in the supply of consumer products to EU consumers	Approximate size (in Euro) of annual EU turnover in 2019	Annual compliance costs in % of annual turnover from consumer products
Manufacturer/producer	1 000 000 000	2.65%
Manufacturer/producer	100 000 000	0.65%
Manufacturer/producer	100 000 000	10.08%
Manufacturer/producer	5 000 000 000	0.10%
Manufacturer/producer	500 000 000	0.60%
Manufacturer/producer	20 000 000 000	0.00%
Manufacturer/producer	50 000 000 000	0.00%
Manufacturer/producer	100 000 000	7.59%
Manufacturer/producer	10 000 000	2.24%
Manufacturer/producer;Importer	50 000 000	14.14%
Manufacturer/producer;Importer	5 000 000 000	0.02%
Manufacturer/producer;Importer	5 000 000 000	0.04%
Manufacturer/producer;Importer	50 000 000	0.76%
Manufacturer/producer;Importer	10 000 000	1.96%
Manufacturer/producer;Importer	500 000 000	0.38%

Table 132: Sample statistics of annual product safety-related costs in % of annual turnover from consumer products, by company group on basis of companies' stated commercial activities

	Distribution (import, wholesale, retail including online retail, excluding online marketplaces)	Manufacturer/producer (including importers)	Online marketplaces of which some are also manufacturers and distributors
Number of responses	9	22	5
Min	0.0%	0.0%	0.0%
Max	132.0%	14.1%	0.6%
Average	15.2%	2.4%	0.3%
Q1	0.1%	0.1%	0.0%
Q2 (median)	0.1%	0.6%	0.2%
Q3	0.6%	2.2%	0.5%
Q1 to Q3 (middle 50% of values)	0.13% - 0.65%	0.10% - 1.2.17%	0.00% - 0.54%

Table 133: Annual turnover of EU companies in relevant product sectors, by company size class, 2017, in million EUR

Annual turnover		Total of harmonised and non-harmonised products		
NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Manufacture of textiles	C13	18 297	28 200	20 625
Manufacture of wearing apparel	C14	18 769	17 522	24 460
Manufacture of leather and related products	C15	18 308	15 382	18 781

Annual turnover		Total of harmonised and non-harmonised products		
NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Manufacture of products of wood, cork, straw and plaiting materials	C162	33 597	24 683	26 328
Manufacture of articles of paper and paperboard	C172	15 392	30 710	51 906
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	C203	5 471	12 545	21 943
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	C204	6 901	16 255	38 507
Manufacture of rubber and plastic products	C22	54 859	99 177	150 000
Manufacture of glass and glass products	C231	4 093	9 242	31 591
Manufacture of other porcelain and ceramic products	C234	953	1 709	
Manufacture of cutlery, tools and general hardware	C257	7 065	16 638	23 744
Manufacture of other fabricated metal products	C259	26 961	32 147	31 915
Manufacture of computer, electronic and optical products	C26	26 567	46 282	
Manufacture of electrical equipment	C27	30 504	54 000	230 000
Manufacture of other general-purpose machinery	C282	36 151	55 297	115 648
Manufacture of metal forming machinery and machine tools	C284	6 550		
Manufacture of transport equipment n.e.c.	C309	2 197		
Manufacture of furniture	C31	35 557	29 026	33 934
Manufacture of jewellery, bijouterie and related articles	C321	5 273		
Manufacture of musical instruments	C322	422		189
Manufacture of sports goods	C323	1 828		
Manufacture of games and toys	C324	1 142		
Manufacturing n.e.c.	C329	6 089	4 916	4 953
Total of manufacturing		**362 944**	**493 730**	**824 523**
TOTAL		**1 681 197**		

Source: Eurostat, own calculations.

Table 134: Annual turnover of EU companies in relevant retail and wholesale services sectors, 2017, in million EUR

Annual turnover		Total of harmonised and non-harmonised products		
NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Wholesale on a fee or contract basis	G461	98 713		111 515
Wholesale of household goods	G464	399 053	308 690	351 141

Annual turnover		Total of harmonised and non-harmonised products		
NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Wholesale of information and communication equipment	G465	105 947	116 371	139 937
Retail sale in non-specialised stores	G471	194 858	117 796	709 963
Retail sale of information and communication equipment in specialised stores	G474	31 443		
Retail sale of other household equipment in specialised stores	G475	122 492	26 136	119 645
Retail sale of cultural and recreation goods in specialised stores	G476	46 117	8 509	32 913
Retail sale of other goods in specialised stores	G477	362 485	55 808	174 460
Retail sale via stalls and markets	G478	16 725	364	
Retail trade not in stores, stalls or markets	G478	74 904	27 145	60 891
Total of wholesale		**603 713**	**425 061**	**602 593**
Total of retail		**849 023**	**235 759**	**1 097 871**
Total wholesale and retail		**1 452 737**	**660 819**	**1 700 464**
Total		**3 814 020**		

Source: Eurostat, own calculations.

Table 135: Extra-EU exports by NACE Rev. 2 activity and enterprise size class, 2017, in million EUR

Extra-EU exports	Fewer than 10 employees	From 10 to 49 employees	From 50 to 249 employees	250 employees or more
Total - all NACE activities	86 619	119 862	269 623	959 797
All NACE activities (except industry; wholesale and retail trade; repair of motor vehicles and motorcycles)	12 779	14 319	38 046	40 767
Agriculture, forestry and fishing	922	1 274	928	1 260
Industry (except construction)	16 414	55 264	172 668	858 420
Mining and quarrying	112	100	744	1 855
Manufacturing	15 126	53 080	165 610	838 929
Manufacture of food products	806	3 257	10 648	34 583
Manufacture of beverages	345	1 070	1 837	4 945
Manufacture of tobacco products	53	22	67	699
Manufacture of textiles	431	1 576	3 312	4 112

Manufacture of wearing apparel	547	1 703	2 662	4 598
Manufacture of leather and related products	385	1 992	3 081	4 373
Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials	319	1 489	3 242	4 226
Manufacture of paper and paper products	139	462	2 844	9 924
Printing and reproduction of recorded media	142	289	588	512
Manufacture of coke and refined petroleum products	13	121	339	25 718
Manufacture of chemicals and chemical products	1 278	4 332	15 955	78 375
Manufacture of basic pharmaceutical products and pharmaceutical preparations	367	378	8 074	61 328
Manufacture of rubber and plastic products	385	2 144	8 024	15 140
Manufacture of other non-metallic mineral products	392	1 522	4 060	9 909
Manufacture of basic metals	878	1 142	6 183	34 101
Manufacture of fabricated metal products, except machinery and equipment	1 102	4 998	13 193	17 989
Manufacture of computer, electronic and optical products	985	3 400	10 528	44 377
Manufacture of electrical equipment	338	2 178	8 156	46 110
Manufacture of machinery and equipment n.e.c.	2 107	12 188	38 380	115 878
Manufacture of motor vehicles, trailers and semi-trailers	495	802	3 765	187 164
Manufacture of other transport equipment	773	901	3 408	82 327
Manufacture of furniture	362	1 500	2 563	4 100
Other manufacturing	802	2 607	7 622	16 599

Repair and installation of machinery and equipment	582	1 202	2 056	2 683
Electricity, gas, steam and air conditioning supply	228	40	160	1 783
Water supply; sewerage, waste management and remediation activities	189	459	1 421	758
Construction	653	1 033	932	1 791
Wholesale and retail trade; repair of motor vehicles and motorcycles	56 846	48 921	58 355	65 511
Wholesale and retail trade and repair of motor vehicles and motorcycles	7 339	3 165	3 345	3 902
Wholesale trade, except of motor vehicles and motorcycles	45 338	42 036	52 002	46 727
Retail trade, except of motor vehicles and motorcycles	4 177	3 612	2 599	11 471
Transportation and storage	2 425	3 188	8 150	6 888
Information and communication	455	865	1 596	2 973
Financial and insurance activities	1 675	81	13 247	140
Real estate activities	749	3 147	21	
Professional, scientific and technical activities	3 237	3 060	7 965	14 024
Administrative and support service activities	994	790	1 282	745
Other NACE activities	1 204	361	290	2 481
Unknown NACE activity	103			

Source: Eurostat.

Table 136: Export volumes (2017, in million EUR) and share of extra-EU exports in relevant sectors, by enterprise size class

		From 0 to 49 employees	50 – 249 employees	250 or more employees
Manufacture of textiles	Turnover	18 297	28 200	20 625
	Extra-EU exports	6 634	9 055	13 082
	in %	36.3%	32.1%	63.4%
Manufacture of wood and of products of wood and cork, except furniture; manufacture of	Turnover	49 440	36 366	35 355

articles of straw and plaiting materials				
	Extra-EU exports	1 808	3 242	4 226
	in %	3.7%	8.9%	12.0%
Manufacture of paper and paper products	Turnover	18 508	46 017	116 387
	Extra-EU exports	601	2 844	9 924
	in %	3.2%	6.2%	8.5%
Manufacture of computer, electronic and optical products	Turnover	26 567	46 282	
	Extra-EU exports	4 385	10 528	44 377
	in %	16.5%	22.7%	
Manufacture of electrical equipment	Turnover	30 504	54 000	230 000
	Extra-EU exports	2 516	8 156	46 110
	in %	8.2%	15.1%	20.0%
Manufacture of furniture	Turnover	35 557	29 026	33 934
	Extra-EU exports	1 862	2 563	4 100
	in %	5.2%	8.8%	12.1%
Wholesale trade, except of motor vehicles and motorcycles	Turnover	603 713	425 061	602 593
	Extra-EU exports	87 374	52 002	46 727
	in %	14.5%	12.2%	7.8%
Retail trade, except of motor vehicles and motorcycles	Turnover	849 023	235 759	1 097 871
	Extra-EU exports	7 789	2 599	11 471
	in %	0.9%	1.1%	1.0%
Simple average of export shares	Manufactured products	12.2%	15.6%	19.3%
	Distribution services	7.7%	6.7%	4.4%
Weighted average of export shares	**Manufactured products**	**10.0%**	**15.2%**	**17.7%**
	Distribution services	**6.6%**	**8.3%**	**3.4%**

Table 137: Annual turnover of companies in relevant product sectors, by company size class, 2017, in million EUR, excluding extra-EU exports

NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Manufacture of textiles	C13	7 579	11 005	7 803
Manufacture of wearing apparel	C14	7 774	6 838	9 255
Manufacture of leather and related products	C15	7 583	6 002	7 106

NACE_R2/SIZE_EMP	Code	From 0 to 49 employees	50 – 249 employees	250 or more employees
Manufacture of products of wood, cork, straw and plaiting materials	C162	13 916	9 632	9 961
Manufacture of articles of paper and paperboard	C172	6 375	11 984	19 639
Manufacture of paints, varnishes and similar coatings, printing ink and mastics	C203	2 266	4 895	8 302
Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	C204	2 859	6 343	14 569
Manufacture of rubber and plastic products	C22	22 723	38 701	56 753
Manufacture of glass and glass products	C231	1 695	3 606	11 952
Manufacture of other porcelain and ceramic products	C234	395	667	
Manufacture of cutlery, tools and general hardware	C257	2 926	6 493	8 984
Manufacture of other fabricated metal products	C259	11 168	12 545	12 075
Manufacture of computer, electronic and optical products	C26	11 004	18 060	
Manufacture of electrical equipment	C27	12 635	21 072	87 021
Manufacture of other general-purpose machinery	C282	14 974	21 578	43 756
Manufacture of metal forming machinery and machine tools	C284	2 713		
Manufacture of transport equipment n.e.c.	C309	910		
Manufacture of furniture	C31	14 728	11 327	12 839
Manufacture of jewellery, bijouterie and related articles	C321	2 184		
Manufacture of musical instruments	C322	175		71
Manufacture of sports goods	C323	757		
Manufacture of games and toys	C324	473		
Manufacturing n.e.c.	C329	2 522	1 919	1 874
Total of relevant manufacturing products		**150 335**	**192 666**	**311 959**
TOTAL		**654 960**		

Table 138: Annual turnover of companies in relevant wholesale/retail sectors, by company size class, retail and wholesale services sectors, 2017, in million EUR, excluding extra-EU exports

NACE_R2/SIZE_EMP		From 0 to 49 employees	50 – 249 employees	250 or more employees
Wholesale on a fee or contract basis	G461	42 434		49 541

Wholesale of household goods	G464	171 540	130 265	155 997
Wholesale of information and communication equipment	G465	45 543	49 108	62 168
Retail sale in non-specialised stores	G471	83 763	49 709	315 406
Retail sale of information and communication equipment in specialised stores	G474	13 516		
Retail sale of other household equipment in specialised stores	G475	52 655	11 029	53 153
Retail sale of cultural and recreation goods in specialised stores	G476	19 824	3 591	14 622
Retail sale of other goods in specialised stores	G477	155 820	23 551	77 505
Retail sale via stalls and markets	G478	7 189	154	
Retail trade not in stores, stalls or markets	G478	32 199	11 455	27 051
Total of wholesale		**259 516**	**179 372**	**267 706**
Total of retail		**364 967**	**99 488**	**487 737**
Total wholesale and retail		**624 484**	**278 861**	**755 443**
Total		**1 658 787**		

Table 139: Annual turnover of companies selling consumer products, by company size class, retail and wholesale services sectors, 2017, in million EUR, excluding extra-EU exports

Sector	Turnover
Agents involved in the sale of furniture, household goods, hardware and ironmongery	5 485
Agents involved in the sale of textiles, clothing, fur, footwear and leather goods	7 213
Wholesale of textiles	22 782
Wholesale of clothing and footwear	137 481
Wholesale of electrical household appliances	130 849
Wholesale of china and glassware and cleaning materials	43 212
Wholesale of perfume and cosmetics	51 300
Wholesale of furniture, carpets and lighting equipment	39 811
Wholesale of watches and jewellery	16 390
Wholesale of other household goods	163 239
Wholesale of computers, computer peripheral equipment and software	n/a
Wholesale of electronic and telecommunications equipment and parts	n/a

Annex VII: Summary of analytical methods used

This Annex provides an overview of the following analytical methods and techniques as well as the related data sources used for the impact assessment:

- Estimation of the detriment due to product-related injuries and fatalities in the EU;
- Estimation of costs of compliance with the GPSD for EU businesses;
- Estimation of costs of compliance with the GPSD for Member states;
- Estimation of the costs of implementing specific policy options for the potential revision of the GPSD;
- Estimation of benefits of measures concerning online sales channels;
- Estimation of benefits of measures in the field of recalls; and
- Methods for other supporting estimations.

They are elaborated in the following sub-section.

Estimation of the detriment due to product-related injuries and fatalities in the EU

The cost of non-fatal product related injuries in the EU

For the calculation of the cost of non-fatal product related injuries in the EU[396], we use the European Injury Database (IDB) as a source of data on product-related injuries. The data are voluntarily contributed by the Member States participating in the IDB, which were 15 out of 28 Member States in 2016[397]. Two levels of datasets exist in the IDB: the full dataset indicated as IDB-FDS and the minimum dataset referred to as IDB-MDS. The IDB-FDS provides more detailed information with regards to the circumstances of the injury and the products involved, in comparison to the IDB-MDS, which includes limited information pertaining to the injury, but provides data that can be used to extrapolate data to the EU level. For the analysis, both datasets have been used.

The analysis focused on accidental, non-intentional injuries and excluded transport injury events and work-related injuries. As IDB data has also been used as an indicator for the European Commission's Consumer Market Scoreboard, we have selected the same product groups used by the Consumer Market Scoreboard to define consumer products as represented in the IDB[398].

To estimate the number of injuries related to different product groups we have used the number of injuries recorded in the IDB-FDS between 2013-2017. On basis of the data provided in the IDB we estimated the total number of injuries in the EU27 on average per year between 2013-2017, using Eurostat population data to extrapolate the FDS data. The method for extrapolation is elaborated in detail in Annex IIc.

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396 The analysis refers to the European Union of 27 Member States. The monetary values in the analysis are expressed in EUR 2017; in cases where 2017 values have not been available, monetary values were inflated to 2017 values using Eurostat's Labour Cost IndexEurostat, Labour cost index by NACE Rev. 2 activity - nominal value, annual data [lc_lci_r2_a]. NACE_R2: Industry, construction and services (except activities of households as employers and extra-territorial organisations and bodies). Extracted 16/06/2020.

397 Ibid., p. 26.

398 See European Commission (2014), 'Consumer Markets Scoreboard. Making markets work for consumers', 10th edition, p. 60-61.

Health care utilization

Health care utilization costs include the costs of hospitalization/hospital admission, the costs of treatment in a hospital emergency department, as well as the costs of being treated in a non-hospital setting e.g. at a doctor's office or as an outpatient. To calculate the cost of health care corresponding to the product-related injuries, it is necessary to retrieve data regarding the consequences of the injuries in terms of the required medical attention as well as the unit costs for each type of health care. The data contained in the IDB-FDS enabled us to identify between three different groups of product-related injuries in terms of the type of treatment required: Patients with product-related injuries that are sent home after treatment; Patients with product-related injuries that are either treated and referred to a general practitioner for further treatment or treated and referred for further treatment as an outpatient; Patients with product-related injuries that are treated and admitted to hospital or transferred to another hospital.

To arrive at the costs of health care utilization we used the approach as described in the following box:

Health care utilisation costs for a given injury type can be estimated by multiplying the average cost of treatment by the number of cases, as indicated below:

$$HeathCareUtil_{EU} = \sum [NrInjuries_{EU,Cat} \times AvgTreatmentCost_{EU,Cat}]$$

Where:

HealthCareUtil$_{EU}$ is the total cost of health care utilisation at the EU level;

NrInjuries$_{EU,Cat}$ is the number of product-related injuries by treatment category;

AvgTreatmentCost$_{EU,Cat}$ is the average cost of treatment for the given injury in a given MS, by treatment category.

For assessing average treatment costs, we used unit cost values for health service delivery from the WHO-CHOICE project, which are provided for different world regions in 2010 international dollars[399]. After converting the two types of costs into EUR 2010 using the OECD purchasing power parity (PPP) exchange rate[400], we inflated them to EUR 2017 using Eurostat's Labour Cost Index. Based on these conversions we calculated the average cost per inpatient bed hospital day and the average cost per outpatient visit. We used the calculated values to estimate respectively the cost of the three groups of treatment (as indicated above).

Productivity losses

The cost of productivity losses is considered for this assessment to correspond to the value of missed time from work. The cost of productivity losses was calculated first by estimating the number of work days lost as a consequence of the injury related to a product and then multiplying this number by the EU average gross daily earnings. Product related injuries for which the type of treatment is not indicated or recorded are not taken into account for the assessment of productivity losses. The detailed approach for determining productivity losses is provided in the following box:

399 WHO Economic Analysis and Evaluation Team (2010), 'WHO-CHOICE estimates of cost for inpatient and outpatient health service delivery', pp. 1-60, available at: https://www.who.int/choice/cost-effectiveness/inputs/country_inpatient_outpatient_2010.pdf.

400 OECD (2020), Purchasing power parities (PPP) (indicator), available at: doi: 10.1787/1290ee5a-en (accessed on 06 July 2020).

The cost of **productivity losses** for a given treatment category are calculated as the cost of missed work. In order to account for the fact that a disproportionate number of injuries occur among children, we take into consideration the proportion of victims that are of working age. The calculation can be expressed as:

$$ProdLoss_{EU} = \sum [NrInjuries_{EU,Cat} \times WAPop_{EU} \times LMP_{EU} \times Wage_{EU} \times DaysLost_{Cat}]$$

Where:

ProdLoss$_{EU}$ is the total cost of productivity losses in the EU;

NrInjuries$_{EU,\ Cat}$ is the number of product-related injuries in a given treatment category;

WAPop$_{EU}$ is the proportion of the injured persons that are of working age;

LMP$_{EU}$ is the labour market participation rate in the EU for working age population;

Wage$_{EU}$ is the average daily wage in the EU; and

DaysLost$_{Cat}$ is the average number of days of work lost for a given treatment category.

Loss of quality of life

To estimate the impact of the injury in terms of reduced life quality we use the Quality Adjusted Life Year (QALY), a measure that integrates evaluation of the quality and quantity of life[401]. For calculating the cost due to reduced quality of life, we have used the following approach[402].

Loss of quality of life will be considered for serious injuries, which are considered to be those for which hospitalisation was required, according to the following equation.

$$LossQualityLife_{EU} = \sum [NrInjuries_{EU,Hosp,Inj} \times LossQALY_{Inj} \times ValueQALY_{EU}]$$

Where:

LossQualityLife$_{EU}$ is the monetised total loss of quality of life of patients hospitalised due to product-related injuries in the EU;

NrInjuries$_{EU,Hosp,\ Inj}$ is the number of hospitalised cases for each main type of injury related to products in the EU;

LossQALY$_{Inj}$ is the Quality Adjusted Life Year loss for each main type of injury;

ValueQALY$_{EU}$ is the monetary value assigned to a Quality Adjusted Life Year.

For each of the injuries we have identified on basis of IDB data, we used a corresponding QALY-weight that expresses the impact of the injury in terms of the quality of life of individuals, using relevant specific estimates. Another approach that has been used to estimate the WTP for a QALY involves taking advantage of the existing literature on the Value of Statistical Life (VSL). This approach, the validity of which was also confirmed by an expert of the European Chemicals Agency (ECHA), is also consistent with the VSL approach that is used below to calculate the cost of premature death. We followed this approach to derive the monetary value for one QALY, using the VSL range of estimates between €3.5 million (lower estimate) and €5 million (higher estimate) included in the Commission's Better Regulation Toolbox[403]. After expressing them in EUR 2017 using

[401] Adler, Matthew D. "QALY's and Policy Evaluation: A New Perspective." *Yale Journal of Health Policy, Law, and Ethic*s 6, (2006), Hammitt, James K. "QALYs Versus WTP." *Risk Analysis* 22, no. 5 (2002): 985-1001.

[402] See Karapanou, Vaia. *Towards a Better Assessment of Pain and Suffering Damages for Personal Injuries. A proposal based on Quality Adjusted Life Years.* Cambridge, Antwerp, Portland: Intersentia, 2014.

[403] Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245.

the labour cost index we converted them to VSLY estimates by applying a discount factor of 4%[404] and a remaining life expectancy of 35 years, which is commonly considered as the remaining life expectancy of an adult at the time of injury[405]. Finally, considering that the resulting values based on the VSL are upper bound estimates that tend to overestimate the value per QALY by a factor of two on average, we divided the estimated amounts by two[406]. The resulting range of willingness to pay estimates per QALY used in this study are listed in the following table.

Source	WTP for a QALY estimate
Civic Consulting based on VSL estimates provided in EU Commission's Better Regulation Toolbox	€101 706 (low estimate) €123 500 (medium estimate) €145 294 (high estimate) (in EUR 2017)

The cost of product related premature death in the EU

In order to arrive at the number of fatal injuries in Europe, we have used the WHO Mortality Database (WHO-MDB) which contains data for all countries participating in WHO[407]. To enable a selection of fatal injury incidents that are relevant for this analysis we have filtered existing data by selecting injury incidents based on specific ICD-10 codes. Based on the incidence figures extracted from the WHO dataset we calculated the cost of premature death related to the selected fatalities. Our approach is detailed in the box:

Cost of premature death is estimated for all non-intentional fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) outside of work-related locations, on basis of the following equation:

$$LossFatal_{EU} = NrFatal_{EU} \times VSL_{EU}$$

Where:

$LossFatal_{EU}$ is the monetised total loss due to the relevant fatalities in the EU;

$NrFatal_{EU}$ is the number of relevant fatalities in the EU;

VSL_{EU} is the monetary value of a statistical life in the EU.

The monetary value used to quantify the value of a statistical human life is derived from individuals' willingness to pay (WTP) to eliminate a small risk of dying[408]. Numerous studies exist in which the VSL has been empirically estimated using the hedonic wage method, the stated preference method or other methods[409]. We have used the estimates provided by the European Chemicals Agency (ECHA) to calculate the cost of premature

[404] Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 503.

[405] To estimate VSLY we use the formula VSLY= r*VSL/(1-(1+r)^-L) where r is the discount rate and L is remaining life expectancy, see also Joseph E. Aldy & W. Kip Viscusi, 2008. "Adjusting the Value of a Statistical Life for Age and Cohort Effects," The Review of Economics and Statistics, MIT Press, vol. 90(3), pages 573-581.

[406] Daniel Herrera-Araujo, James K. Hammitt & Christoph M. Rheinberger (2020), "Theoretical bounds on the value of improved health", *Journal of Health Economics 72,* p. 1-15.

[407] WHO Mortality Database, accessible at: https://www.who.int/healthinfo/mortality_data/en/.

[408] It can also be derived by the willingness to accept (WTA) a small probability of death.

[409] The stated preference method tries to elicit the value of non-market goods by directly asking people how much they value these goods while the hedonic wage method uses labour market data that reveal the trade-offs workers make between job risks and additional pay. The hedonic wage method belongs to the group of revealed preference methods which infer WTP / WTA values from observed behaviour. See Alessandra Arcuri, 2012, "Risk Regulation" in: Roger J. Van den Bergh & Alessio M. Pacces (ed.), Regulation and Economics, chapter 6, Edward Elgar Publishing.

death, which are also referred to as reference values in the Better Regulation Toolbox of the European Commission[410]. More specifically we use the average value of the higher and lower estimate for the value of a statistical life provided by ECHA (EUR 4.25 million) as a standard assumption for the cost of a premature death, while retaining the low and high estimates for later sensitivity analysis. Expressed in 2017 values (again inflated by using the labour cost index), we arrived at a VSL estimate of EUR 4.6 million. We have used this estimate to arrive at the annual cost of premature death due to fatalities caused by mechanisms relevant for product safety.

Estimation of costs of compliance with the GPSD for EU businesses (baseline business costs)

We first focused on the estimation of the baseline market size, i.e. the total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer products in the EU[411], before analysing company level compliance cost data, and extrapolating it to EU level, based on the estimated baseline market size. The analysis is structured according to six steps:

Step 1: Estimation of EU companies' total annual turnover from the production and/or sales of non-harmonised consumer products in the EU

Based on NACE industry codes and sector descriptions, we identified those manufacturing sectors (NACE Rev. 2, B-E), wholesale services sectors and retail sectors (NACE Rev. 2, G) in which consumer products are produced and/or sold, i.e. we excluded sectors that clearly focus on the production and sales of industrial products. Sectors related to motor vehicles have been excluded, in line with the focus on non-harmonised consumer products. While retail sale can be assumed to be largely related to consumer products (although retailers may also sell to professional users, and may sell services), the wholesale and manufacturing in the listed areas clearly also contain industrial/professional products, an issue considered in Step 3 below. To arrive at the share of non-harmonised products produced and/or sold in these sectors, we applied the estimate provided in the 2017 EU impact assessment for the new Market Surveillance Regulation, which estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products[412].

Step 2: Deduction of extra-EU export

To calculate the net turnover for non-harmonised consumer products that are only sold in the EU, we deducted the share of extra-EU exports from the total turnover of EU companies. The calculation is based on an approximation of sector-specific export shares. The extra-EU trade by enterprise characteristics data provided by Eurostat do not exactly match the sector classification of turnover data by enterprise size class[413]. We therefore approximated the extra-EU export shares of manufacturing, wholesale and retail sectors on the basis of those sectors for which we found full concordance in the two datasets[414]. The estimated extra-EU export shares of manufacturing, wholesale and

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410 Better Regulation Toolbox complementing the better regulation guideline presented in SWD (2017) 350, p. 245.

411 All estimates in this section refer to the EU27 as of 2020.

412 SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

413 In the Annex, we provided detailed trade volumes of extra-EU exports by NACE Rev. 2 activity and enterprise size class.

414 These sectors are: "Manufacture of textiles, Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials", "Manufacture of paper and paper products", "Manufacture of computer, electronic and optical products", "Manufacture of electrical equipment", "Manufacture of furniture", "Wholesale trade, except of motor vehicles and motorcycles", and "Retail trade, except of motor vehicles and motorcycles". In the Annex, we provide shares of extra-EU exports in key consumer products sectors broken-down by enterprise size class.

retail sectors were subtracted from the annual turnover of EU companies with non-harmonised products in the selected sectors.

Step 3: Deduction of industrial and professional products

We corrected the EU turnover derived in Step 2 by the percentage shares of turnover that can be attributed to the production and/or sales of consumer products in manufacturing, wholesale and retail sectors. For this purpose, we drew on a different dataset, namely the final consumption expenditure of households by consumption purpose[415]. We again correct for the share of harmonised products, and arrived at an estimate for total household consumption of non-harmonised products. For the following analysis we assumed that this consumption of non-harmonised consumer products is equivalent to the total turnover from non-harmonised consumer products sold by EU retailers. The estimated retail turnover from non-harmonised products indicated before was adjusted accordingly, and the resulting amount was allocated between the three enterprise size classes. Due to data limitations, the same methodology could not be applied for manufacturing and wholesale sectors[416]. For manufacturing and wholesale sectors, we estimated the share of turnover that can be attributed to consumer products on the basis of the share of "consumer-oriented" wholesale services in total wholesale services. It is assumed that the same share reflects the portion of consumer products produced and/or sold by manufacturers. Based on this approach, we could calculate the total annual EU turnover of EU companies from non-harmonised consumer products.

Step 4: Derivation of empirical estimates for companies' product safety-related costs on the basis of survey responses

In our company cost survey and the complementary interviews conducted with selected companies, businesses were asked to indicate staff time used for managing product safety, testing for product safety, recalls and other consumer product safety related activities. We asked respondents to consider all costs for ensuring product safety of both harmonised and non-harmonised consumer products (excluding pharmaceuticals, medical devices or food), as the identification of costs for non-harmonised products only was not considered to be feasible. In addition to staff requirements, companies were asked to provide estimates for other costs to comply with safety requirements for consumer products (e.g. costs for external legal advice, costs for external safety testing, costs for certification of safety of products etc.)[417]. The cost estimates provided by the respondents also include business-as-usual costs, which would incur even in absence of product safety regulation (see Step 6). These estimates were used to estimate companies' annual regulatory compliance costs in Euro terms. The calculation of Euro-denominated costs for staff was based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour[418]. To account for overhead costs, a 25% mark-up was added to staff-related costs. Subsequently, the costs for each company were related to the EU turnover for consumer products, i.e. we expressed companies' annual cost resulting from activities to comply with safety requirements for (harmonised and non-harmonised) consumer products as a share of the related turnover.

Step 5: Extrapolation of EU companies' annual costs related to the GPSD incl. business-as-usual costs that occur also in absence of regulation

For each enterprise size class, we multiplied the empirical median values for companies' relative product safety-related costs, which were derived in Step 4, with the annual turnover of EU companies that can be attributed to the production and/or sales of non-

[415] Eurostat, Final consumption expenditure of households by consumption purpose (COICOP 3 digit) [nama_10_co3_p3].

[416] Eurostat data do not allow to extract "pure" consumer products for manufacturing and wholesale sectors, i.e. final products that are consumed by households.

[417] Business stakeholders were asked to estimates average costs per month in EUR.

[418] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

harmonised consumer products in the EU (Step 3). The results of this calculation still include business-as-usual costs.

Step 6: Deduction of business-as-usual costs and extrapolation of EU companies' annual compliance cost related to the GPSD

In our company survey and interviews, we asked businesses to indicate the share of the total product safety-related costs that they would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence), hereafter referred to as business-as-usual costs, BAU. These estimates reflected the self-assessment of the companies that are part of the sample, and are therefore subjective in nature. However, as concerns differences between manufacturers, on the one hand, and wholesalers and retailers, on the other, we considered the estimates to be in line with expectations and a credible basis for the final step of the assessment. We applied the empirical median values of these shares to the product safety-related cost estimates derived in Step 5. Excluding business-as-usual costs, we obtained compliance costs of EU companies that can be attributed to non-harmonised consumer products, i.e. the costs for businesses to comply with the GPSD.

Estimation of costs of compliance with the GPSD for Member States (baseline costs for Member States)

The estimation of MSAs' staff-related costs related to market surveillance activities for non-harmonised consumer products in the EU was based on the following three steps:

Step 1: Identification of MSAs annual FTEs for market surveillance activities related to non-harmonised consumer products

For our estimate we used the number of full time equivalent (FTE) staff for market surveillance of consumer products as provided in the country research. Where the available country estimates related to the market surveillance of non-harmonised consumer products, this figure was directly used in the calculation. Where estimates related to the total staff for market surveillance of both harmonised and non-harmonised consumer products, we allocated staff according to the 54%/46% ratio for harmonised/non-harmonised products circulating within the European Single Market to derive an estimate for related market surveillance activities[419]. It should be noted that a share of 46% in staff time for market surveillance of non-harmonised consumer products is 12 percentage points higher than the empirical median share indicated by MSAs for activities devoted to non-harmonised products in the stakeholder survey (34%), potentially causing an estimate at the higher end of MSAs' actual costs that can be attributed to market surveillance activities for non-harmonised consumer products. For seven countries, no information on staff numbers was available at all.

Step 2: Approximation of annual FTEs for market surveillance activities related to non-harmonised consumer products for countries for which data was not available

For the seven countries, for which no staff data was available (Croatia, Germany, Hungary, Italy Slovenia, Slovakia, and Spain) we estimated the number of FTEs on the basis of the data for the remaining 20 Member States. To account for institutional differences with regard to the level of centralisation, we considered two clusters of countries, in line with the characteristics of the respective market surveillance systems as described above: Cluster 1: responsibility for market surveillance is centralised (no sub-national administrations involved); Cluster 2: responsibility for market surveillance

[419] As mentioned before, the 2017 EU impact assessment for the new Market Surveillance Regulation estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products. See SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country.

To derive estimates for the number of FTEs per million population for Slovenia and Slovakia (more centralised market surveillance), we applied the sample median of 3.5 FTEs per million population. To derive FTE estimates for the number of FTEs per million population for Croatia, Germany, Hungary, Italy and Spain (more decentralised market surveillance), we applied the sample median of 4.6 FTEs per million population.

Step 3: Calculation of annual staff costs for market surveillance activities related to non-harmonised consumer products

In the final step, we calculated the EUR equivalent of the estimated number of staff required for market surveillance of non-harmonised consumer products by multiplying the number of FTEs per million population by:

- The size of population for each country (in million);
- The number of person-hours per year (1 720) [420]; and
- The average wage of 28.00 EUR, which corresponds to the EU27 average wage of "administrative and support service activities" (18.70 EUR) and "professional, scientific and technical activities" (37.30 EUR) for 2017 (latest figure available in Eurostat database).

Estimation of the costs of implementing specific policy options for the potential revision of the GPSD

Companies assessed in their responses to our cost survey the change that the implementation of each option would cause in their recurrent costs, e.g. costs related to additional staff and additional resources for due diligence measures such as IT systems and external services, in addition to one-off costs, such as familiarisation costs and costs from adapting to regulatory changes (e.g. for external advice). Both types of costs were analysed.

To estimate the impact of the implementation of each option on EU businesses' recurrent costs, we applied the percentage change in recurrent (annual) costs as assessed by respondents to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (baseline estimates). Applying the sample median as best estimate for the extent to which recurrent costs would increase under each option, we calculated the change in the estimated annual consumer product safety-related costs of EU businesses in Euro terms for manufacturers, wholesalers and retailers.

Our estimation of EU businesses' total one-off costs was based on individual respondents' estimates for the total additional staff needed and the total additional non-staff costs that arise from familiarisation and implementation efforts under each option. Based on the respondents estimates, we calculated staff costs in Euro terms and added other (non-staff) one-off costs. The calculation of Euro-denominated costs for staff was based on the EU's (weighted) average wage for the business economy, which in 2019 was EUR 27.50 per hour[421]. To account for overhead costs, a 25% mark-up was added to staff-related costs.

The total one-off costs for each company were divided by the EU turnover for consumer products, i.e. we expressed companies' total additional one-off costs resulting from

[420] Following EU Horizon 2020 guidelines, one person year corresponds to 1 720 person-hours per year. See, e.g. the H2020 Programme: User's Guide for the Personnel Costs Wizard.

[421] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

activities to comply with safety requirements for consumer products under Option3 as a share of the related turnover. Applying the sample median to the estimated annual turnover for manufacture, wholesale and retail of consumer products in the EU resulted in estimates for additional one-off cost for manufacturers, wholesalers and retailers.

The estimate of recurrent and one-off costs of MSAs was conducted using a similar approach, with estimates on how the implementation of each option would change their recurrent costs derived from the answers to our survey of authorities. Again, we multiplied the empirical median with baseline costs, to estimate recurrent costs, and separately assessed one-off costs.

Estimation of benefits of measures concerning online sales channels

No consistent data is available on the incidence of unsafe products on the EU market. In the analysis, we used stakeholder assessments as best available estimate to first analyse the potential detriment accruing currently to consumers due to unsafe products on the EU market, and then consider the impact that increasing e-commerce and the implementation of different policy options could be expected to have on this baseline situation. A key challenge in this respect is the size of the detriment to consumers posed by unsafe products. An unsafe product could lead to injuries and fatalities, which cause substantial detriment in the EU every year. Due to data limitations, it is not possible to quantify the occurrence of product-related injuries and fatalities, or damage to other goods caused by unsafe products according to sales channel. We therefore in this analysis use as proxy for the detriment caused by an unsafe product its value (as expressed by its purchase price). This approach seems to rather underestimate than overestimate detriment, in light of the different situations analysed. In our baseline analysis, we have estimated the total EU27 household consumption of non-harmonised consumer products (excluding food and medical products) at EUR 428 664 million per year. Combining this data with the estimate of the incidence of unsafe consumer products, we derive the value of unsafe products per year (which is in our approach equivalent to the related consumer detriment) at EUR 3.9 billion for the online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion. This figure is by its nature an approximate estimate, as the data on which it is based has considerable limitations, and the result is affected by the underlying assumptions.

Estimation of benefits of measures in the field of recalls

A fundamental obligation that derives from the GPSD is the obligation of producers and distributors to notify the authorities and take the necessary actions for consumer protection, once one of the products that they have placed on the market is identified as dangerous[422]. The limited effectiveness of recalls also leads to consumer detriment, the size of which is estimated in this Annex.

For estimating consumer detriment due to ineffective recalls, we follow the approach explained above, namely to use the value of an unsafe product as a proxy for the detriment it causes to consumers that have bought it (a detailed justification of this approach is provided in the same Annex). When using the value of a recalled product to analyse consumer detriment, two situations can be differentiated:

1. *An unsafe product is recalled and returned to a producer.* The resulting consumer detriment can be approximated as being zero[423];

[422] GPSD Art 5 (3).

[423] In reality, even in this situation consumers incur a detriment due to the time spent for the transaction, e.g., for returning the product by mail or in person to a shop. However, this additional detriment is not considered here, provide a conservative, simplified estimate.

2. *An unsafe product is recalled and not returned to a producer.* In this case the consumer detriment is the value of the product, as discussed.

Under a scenario of improved recall effectiveness, consumer detriment in the EU can be expected to be reduced by more than EUR 400 million per year. As mentioned above, this estimate is based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product caused damage to persons, other goods or the environment. Also, the return rates underlying the improved effectiveness scenario are still relatively low and might be further increased through appropriate measures by producers and authorities, considering e.g., the increased availability of customer data in online transactions. If return rates were to be improved beyond our assumptions, consumer detriment would accordingly be further reduced, compared to the estimate provided.

Methods for other supporting estimations

Other supporting estimations include the analysis of costs of mandatory accident reporting (see Annex IV) and the extrapolation of the number of parcels imported to the EU (Part 1, EQ3, and Part 2 problem analysis). In both cases, baseline data was extrapolated using relevant data sources from international organisations or data from non-EU countries in which comparable measures were taken. For more details on the methodological approach taken in each case, see the relevant section of the report.

Validation and quality assurance of results of analyses conducted

Great care was taken to explore all possible data sources at EU level and from international databases to use the best available data, which is a key element of quality assurance. All analyses were validated internally by different members of the team, to safeguard internal consistency and accuracy. Finally, in major analyses external expertise was involved, either through advisory roles (e.g. an expert of EuroSafe supported the data extraction process related to the IDB), or through providing advice on specific methodological issues. These included the WHO, which was consulted on possible approaches to group ICD-10 codes, and ECHA, which provided advice on the most appropriate method to determine VSLY values.

Sensitivity analysis was used to assess robustness of estimates against different assumptions, where relevant. With respect to the estimation of detriment, we elaborated sensitivity scenarios concerning the cost of premature death and the loss of quality of life. The first scenario to be tested against the main scenario involved using the lower estimate of the VSL to recalculate the costs incurred as a result of premature death. The second scenario involves the opposite recalculation, namely using the high estimate of the VSL and the corresponding QALY value to recalculate the costs incurred as a result of premature death and of lost quality of life. The third and fourth scenarios take into account the fact that the type of the injury as such e.g. injury to muscle, burn etc. does not convey the severity of the injury which may significantly influence the magnitude of the loss. Therefore, to account for the possibility of a mild and severe occurrence of the same type of injury we estimated the loss of quality of life using both low and high QALY losses per each type of injury. The rest of the assumptions (monetary value of a VSL, a QALY) remained the same as in the main scenario. The fifth and final sensitivity scenario involved taking into account for the calculation of the cost of premature death only the fatalities caused by mechanisms relevant for product safety that occur at home keeping everything else constant.

Annex VIII: Interviews conducted

Organisation	Topics covered	Date of interview
DG JUST	Discussion of research items in the TOR and available data	14 April 2020
DG JUST	Availability of data in RAPEX and how it can be best retrieved to address specific research items; notification delays in RAPEX; situations when the Commission needs to intervene in disputes between MS; effectiveness of RAPEX	24 April 2020
DG JUST	Access to the European Injury Database (IDB); potential linkage of environmental risk and the health risk for consumers	6 May 2020
DG CONNECT	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	24 July 2020
DG GROW	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	27 July 2020
DG TAXUD	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	28 July 2020
DG ENV	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	19 August 2020
DG SANTE	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	20 August 2020
DG JUST	Standardisation work under the GPSD: Key evaluation questions provided in the TOR; administrative burdens related to the standardisation process; policy options for revision of the GPSD	15 September 2020
US CPSC	Evidence on unsafe products found online; impact of new technologies; injury data related to product safety incidents, and estimates of related consumer detriment	28 May 2020
Health Canada (Healthy Environments and Consumer Safety Branch)	Evidence on unsafe products found online; impact of new technologies; injury data related to product safety incidents, and estimates of related consumer detriment	27 May 2020
EuroSafe	Availability of injury data related to product safety incidents in the EU; implications for estimation of related consumer detriment, key evaluation questions and options	9 June 2020 and 17 September 2020
The Slovak Trade Inspection	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)*	17 June 2020
DGCCRF	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)*	24 June 2020 (responses received)
Douane (French Customs)	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new	24 June 2020 (responses received)

	technologies (connected devices, products with AI, Internet of Things)	
Financial Administration of the Slovak Republic	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)*	30 June 2020
Danish Safety Technology Authority	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)*	11 June 2020
Danish Customs	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)	17 June 2020
VeiligheidNL	Availability of injury data related to product safety incidents in the NL and EU; implications for estimation of related consumer detriment	23 June 2020
Australian Competition & Consumer Commission	Evidence on unsafe products found online; impact of new technologies; injury data related to product safety incidents, and estimates of related consumer detriment	23 June 2020
Reima Oy	Key evaluation questions provided in the TOR; policy options for potential revision of the GPSD	24 June 2020
IKEA	Key evaluation questions provided in the TOR; policy options for potential revision of the GPSD	24 June 2020
Albert Heijn	Key evaluation questions provided in the TOR; policy options for potential revision of the GPSD	25 June 2020
BusinessEurope	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	26 June 2020
EuroCommerce	Key evaluation questions provided in the TOR; policy options for revision of the GPSD; potential information sources	26 June 2020
WHO	Availability of mortality data related to product safety incidents in the EU; implications for estimation of related consumer detriment	29 June 2020
Allegro	Key evaluation questions provided in the TOR; effectiveness of Product safety Pledge; policy options for potential revision of the GPSD	30 June 2020
BEUC	Key evaluation questions provided in the TOR; policy options for potential revision of the GPSD; information from a campaign carried out by BEUC concerning online marketplaces	1 July 2020
Janssen Fritsen	Products and activity of the company; baseline costs and benefits associated with product safety legislation; recurrent costs; benefits from clarification and harmonisation of regulations; impact of policy options for potential revision of the GPSD	14 July 2020
Dutch market surveillance authority (NVWA)	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)*	16 July 2020
Jeronimo Martins	Products and activity of the company; impact of policy options for potential revision of the GPSD; impacts of COVID-19	17 July 2020

Mattel	Products and activity of the company; impact of policy options for potential revision of the GPSD; costs related to differences in national regulations; implementation of different policy options; impacts of COVID-19	17 July 2020
Dutch customs	Evidence on unsafe products found online; Product Safety Pledge; Customs checks; Risks posed by new technologies (connected devices, products with AI, Internet of Things)	18 July 2020
A.S. Watson	Products and activity of the company; impact of policy options for potential revision of the GPSD; role of suppliers in taking over costs regarding product safety; benefits from better cooperation on market surveillance; impacts of COVID-19	20 July 2020
Abena Produktion	Products and activity of the company; impact of policy options for potential revision of the GPSD, for example regarding additional researching, additional training or more testing; impacts of COVID-19	25 August 2020
Eaton Industries	Products and activity of the company; impact of policy options for potential revision of the GPSD; impacts of COVID-19	1 September 2020
QLEVR	Products and activity of the company; impact of policy options for potential revision of the GPSD; costs resulting from need of tracking of products, impacts of COVID-19	1 September 2020
Bamed	Products and activity of the company; impact of policy options for potential revision of the GPSD; costs of re-testing as a result of policy options; impacts of COVID-19	2 September 2020
Amazon	Key evaluation questions provided in the TOR; effectiveness of Product safety Pledge; policy options for potential revision of the GPSD	3 September 2020 and 7 September 2020
Digital Europe	Key evaluation questions provided in the TOR; effectiveness of Product safety Pledge; specific challenges related to coverage of software; policy options for potential revision of the GPSD	8 Se3ptember 2020
Schneider Electric Industry	Products and activity of the company; need to avoid overlap between GPSD and other directives; cybersecurity; question whether electrical products should be covered by GPSD; need for more efficiency and more coordination in market surveillance; impact of policy options for potential revision of the GPSD; impacts of COVID-19	3 September 2020
Decathlon	Products and activity of the company; impact of policy options for potential revision of the GPSD; impacts of COVID-19	7 September 2020
Bauhaus	Products and activity of the company; costs for legal advice; impact of policy options for potential revision of the GPSD; costs related to differences in national regulations, e.g. labelling; impacts of COVID-19	9 September 2020
ANEC	Standardisation work under the GPSD: Key evaluation questions provided in the TOR; administrative burdens related to the standardisation process; policy options for revision of the GPSD	9 September 2020
Bomb Cosmetics	Products and activity of the company; impact of policy options for potential revision of the GPSD; issues relating to food-imitating products; impacts of COVID-19	24 September 2020

Source: Civic Consulting. Notes: * Member States' market surveillance authorities have also contributed evidence and their views on the evaluation questions/policy options through participation in the surveys conducted for this study.

Annex IX: Summary of views of SMEs and other businesses

Consultation process

For this study, considerable efforts were made to reach out to businesses, including SMEs and their representatives. This included exploratory interviews with EU business associations, in which we pointed out the need to involve their member associations and company members in the study process, to safeguard that the views of SMEs and other businesses were adequately presented.

To reach a representative sample of stakeholders across the EU, we conducted a mapping of stakeholders during the inception phase and used the Civic Consulting stakeholder database, which was complemented through additional web-based research, to include more companies (and business associations of companies) that produce non-harmonised consumer products such as childcare articles, clothing, and furniture across the EU. The survey questionnaires were widely distributed amongst SMEs and other business stakeholders as follows:

- We contacted more than 1000 SMEs and other businesses in all EU27 Member States (plus UK). In parallel, we directly contacted companies that import or distribute relevant products, to obtain their assessment regarding their direct experiences with the application of the requirements of the GPSD and related impacts in terms of compliance costs and administrative burdens;
- We also contacted more than 300 relevant business associations in all EU27 Member States (plus UK) and at EU level (including UEAPME, BusinessEurope, Digitaleurope, EMOTA, EuroCommerce, etc) and in Member States. We asked all organisations to complete the survey, and also to identify among their members companies of different size categories (including SMEs) that could contribute to the consultation, and to contact them with an invitation to participate in the specific survey of companies.

The business surveys were launched on 02 July 2020. Reminders were sent on 8 July 2020 and a second reminder on 24 July 2020. Surveys closed on 9 September 2020. We also conducted phone calls to business associations at EU level for their support in distributing the surveys to their member associations, and phone calls to business associations in MS for their support in reaching out to their member companies (in total several hundred calls). In total, 153 survey responses were received, of which 37 to the survey of business associations and 41 to the survey of companies (of which 6 were SMEs).

In parallel, we conducted a total of 20 interviews with companies (including SMEs) and business associations, which also considered in detail potential impacts of the COVID-19 crisis on their operations (see sections 7.4 and 8.6). In total, 12 companies were interviewed regarding COVID-19, including two SMEs.

Consultation results

In the following, we provide key results of the consultation, separately indicating results of companies in general, SMEs and business associations. As indicated in the following figures, SMEs did by and large provide similar assessments to companies in general. However, SMEs responding to the survey only reported 'minor' additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). In contrast to larger companies, none of the SME respondents indicated 'moderate' or 'significant' additional costs due to differences in the national implementation of the GPSD. A possible reason is that larger companies are more likely to operate in all EU Member States than SMEs, and therefore experience relevant legislative differences more often.

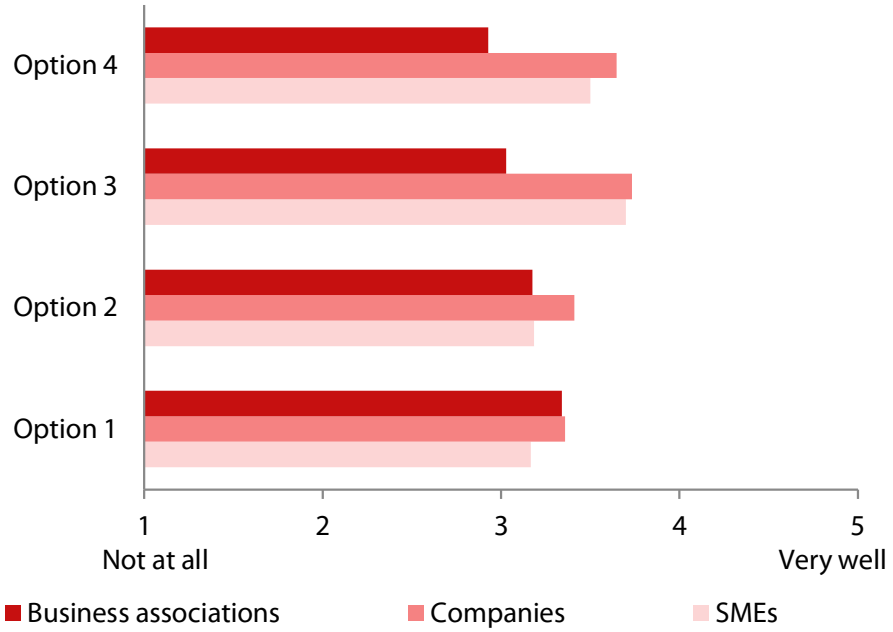
Also notable is that in the assessment of the effectiveness of options, as well as concerning the benefits they bring, business associations often provided considerably lower assessments than companies, including SMEs, especially regarding policy options involving legislative change. This is shown in the following figures.

For each of the four options discussed in sections 8.1 to 8.4, we presented the assessment by stakeholders regarding the extent to which the option would effectively address each of the following five challenges for product safety (on a scale of 1 to 5, from 'not at all' to 'very well'):

- Ensure general safety rules, including for product risks linked to new technologies
- Address safety challenges in the online sales channels
- Make product recalls more effective
- Enhance market surveillance and ensure better alignment of rules
- Address safety issues related to food-imitating products

Figure 33 below provides the assessments of business stakeholders, separately indicating assessments by business associations, companies and SMEs (the figure presents a total score, calculated as average of the assessments regarding the five challenges listed above).

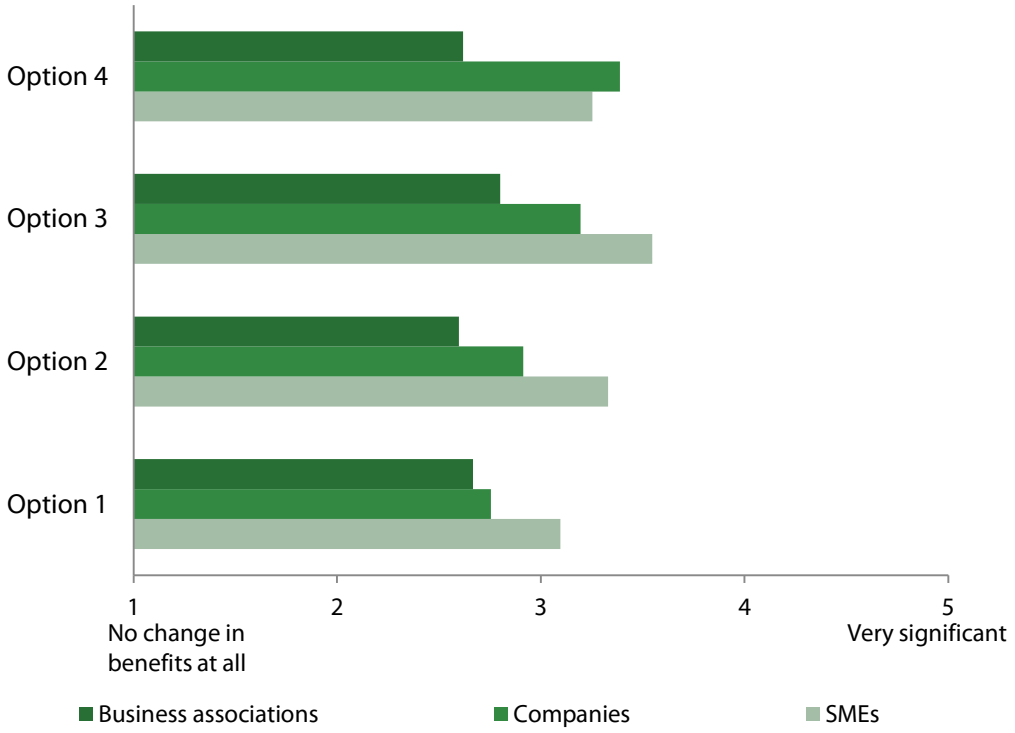
Figure 33: In your view, to what extent would Option [...] effectively address the following challenges for product safety? – Average across all challenges, by business stakeholder group



As Figure 33 illustrates, companies overall, as well as SMEs as specific sub-group, assessed Options 3 and 4 as being most effective, and considered them to 'moderately' to 'well' address the listed challenges. In contrast, average assessments by business associations consider Options 1 and 2 to be most effective. As a result, the overall assessment of business stakeholders (when put together) does not show a considerable variation between the options, and consider all four options to slightly better than 'moderately well' address the challenges (see the corresponding figure in section 8.6).

Not surprisingly, the picture is relatively similar when considering the summary assessment regarding the expected benefits that would result from the implementation of each option, compared to the baseline (Figure 34).

Figure 34: Where do you see the greatest additional benefits that would result from the implementation of Option […]? – Average across all benefit categories, by business stakeholder group



Again, Options 3 and 4 are seen as providing most benefits by companies overall, as well as SMEs as specific sub-group, which assessed these benefits on average between 'moderate' and 'significant'. While SMEs consider Option 2 to also bring more than 'moderate' benefits, companies as a whole and business associations are more sceptical, with an assessment on average across benefit categories of less than 'moderate' benefits regarding Option 2. In general, business associations tend to see less benefits than companies and SMEs. Note however, that the sample of SMEs responding to the survey is very small, so that results have to be interpreted with care.

Impacts of COVID 19

Due to the timing of the survey, no questions concerning COVID-19 were included. Therefore, a special focus was put on this topic in the complementary interviews conducted with companies (including two SMEs). Key messages from the interviews in this respect include:

- Almost all respondents mentioned that their companies were affected by the COVID-19 crisis. In many companies, sales decreased significantly due to store closures, which was particularly detrimental to companies that rely on the classic model of retail stores in the form of "brick-and-mortar" shops. Companies tried to compensate this loss by cost saving measures such as short-time work and unpaid holidays. However, there were also companies that reported to be largely unaffected. An interviewee from a company in the childcare product sector, who only experienced minor effects, indicated as an explanation that "baby articles are needed even in a pandemic situation";

- However, most companies mentioned that they were to some extent able to benefit from increased e-commerce, which compensated some of the losses. One company even mentioned that overall, they benefitted during the COVID-19 crisis as sales of particular products used for do-it-yourself home improvements (such as paints) increased dramatically. Other companies also benefitted from government contracts for the supply of specific goods (such as PPE). Companies mentioned that they were able to shift their suppliers to overcome shortages, or that they launched new assortments during the crisis to compensate shortages.

For more details, see section 7.4. Specific views of the interviewed SMEs include:

- Regarding the question of how the COVID-19 pandemic has in any way affected how product safety in companies is safeguarded and any related supply chain issues, a SME respondent mentioned that testing for new devices is taking longer due to delays related to the pandemic. Such delays for example in supply chain functioning can have a particularly detrimental effect on business activity of SMEs.

- An SME respondent also stated that the pandemic is likely to have an impact on long-lasting, structural changes of the 'new normal' in behaviour and economy that are significant for SMEs. For example, people are expected to buy more sustainable and environmentally friendly products.

- Regarding the question of how the COVID-19 crisis affects the policy options and their expected impacts, one SME respondent stressed that it is a bad time to be bringing in additional regulations for businesses. The interviewee mentioned that many businesses are really struggling, and that this is especially the case for SMEs. He continued that these challenges, including for SMEs, also arise from changing consumer habits.

- However, one SME respondent also argued that better clarification of rules would reduce costs significantly, including Option 1. Cost reductions would take place on the sales level, i.e. less explanation to buyers and insurance companies, and the design and manufacturing level, i.e. less explanation of product safety requirements to engineers. But the SME respondent also stated that one-off costs would generally increase for all regulatory options except for Option 1 due to familiarisation costs occurring in the organisation, i.e. explaining the new rules internally and externally. And these costs are especially significant for SMEs, according to the interviewee.

Annex X: Summary of impact on SMEs

Assessment of businesses likely to be affected

The following table provides an overview of the types of businesses and sectors likely to be affected by a revision of the GPSD, structured according to the specific policy objectives for the revision.

Table 140: Overview of policy objectives for a possible revision of the GPSD and relevance for specific types of businesses and sectors

Specific policy objectives	Most directly relevant for …	Most relevant sectors of business	Relevant for SMEs
Ensure general safety rules, including for product risks linked to new technologies	Businesses producing or selling consumer products incorporating new technologies	Manufacturing Wholesale Retail	Relevant for all size classes of enterprises, including SMEs
Address safety challenges in the online sales channels	Online marketplaces, businesses selling online to consumers	Wholesale Retail	Relevant for all size classes of enterprises, including SMEs
Make product recalls more effective	Businesses producing or selling harmonised and non-harmonised consumer products	Manufacturing Wholesale Retail	Relevant for all size classes of enterprises, including SMEs
Enhance market surveillance and ensure better alignment of rules	Businesses producing or selling non-harmonised consumer products	Manufacturing Wholesale Retail	Relevant for all size classes of enterprises, including SMEs
Address safety issues related to food-imitating products	Businesses producing or selling food-imitating products	Food-imitating products manufacturers and retailers	Producers of food-imitating products are often SMEs (but lack of market data)

Consultation with SMEs representatives

See Annex IX.

Measurement of the impact on SMEs

Recurrent costs

Estimated changes in EU businesses' annual recurrent costs are presented in Table 141 below. Changes in recurrent costs of SMEs (0 to 249 employees) are estimated to be as follows:

- Option 1: EUR 0 million;
- Option 2: EUR 16.6 million;
- Option 3: EUR 99.9 million;
- Option 4: EUR 166.3 million.

Table 141: Estimated changes in EU businesses' annual recurrent costs, EU total under Options 1 to 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Option 1				
Manufacturing sectors	0	0	0	0
Wholesale sectors	0	0	0	0
Retail sectors	0	0	0	0
Total additional recurrent costs (EU27)	***0***	***0***	***0***	***0***
Option 2				
Manufacturing sectors	4.3	5.5	8.9	**18.6**
Wholesale sectors	1.7	1.2	1.8	**4.7**
Retail sectors	3.4	0.6	2.4	**6.4**
Total additional recurrent costs (EU27)	**9.3**	**7.3**	**13.0**	**29.6**
Option 3				
Manufacturing sectors	25.7	32.9	53.2	111.7
Wholesale sectors	10.2	7.1	10.6	27.9
Retail sectors	20.2	3.8	14.2	38.2
Total additional recurrent costs (EU27)	**56.1**	**43.8**	**78.0**	**177.8**
Option 4				
Manufacturing sectors	42.7	54.8	88.7	**186.2**
Wholesale sectors	17.1	11.8	17.6	**46.5**
Retail sectors	33.6	6.4	23.7	**63.6**
Total additional recurrent costs (EU27)	**93.4**	**72.9**	**130.0**	**296.3**

Note: for detailed results and methodology, see sections 8.1 to 8.4. Note that the estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

One-off costs

Estimated changes in EU businesses' one-off costs are presented in Table 142 below. Changes in recurrent costs of SMEs (0 to 249 employees) are estimated to be as follows:

- Option 1: EUR 0 million;
- Option 2: EUR 4.4 million;
- Option 3: EUR 11.3 million;
- Option 4: EUR 20.8 million.

Table 142: Estimated changes in EU businesses' annual one-off costs, EU total under Options 1 to 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
Option 1				
Manufacturing sectors	0	0	0	0
Wholesale sectors	0	0	0	0
Retail sectors	0	0	0	0
Total additional one-off costs (EU27)	***0***	***0***	***0***	***0***
Option 2				
Manufacturing sectors	0.5	0.6	1.0	**2.1**
Wholesale sectors	0.8	0.6	0.8	**2.2**
Retail sectors	1.6	0.3	1.1	**3.0**
Total additional one-off costs (EU27)	**2.9**	**1.5**	**2.9**	**7.3**
Option 3				
Manufacturing sectors	1.2	1.6	2.5	**5.3**
Wholesale sectors	2.1	1.5	2.8	**5.7**
Retail sectors	4.1	0.8	2.9	**7.8**
Total additional one-off costs (EU27)	**7.5**	**3.8**	**7.6**	**18.8**
Option 4				
Manufacturing sectors	2.3	2.9	4.7	**9.8**
Wholesale sectors	3.9	2.7	4.0	**10.6**
Retail sectors	7.6	1.4	5.4	**14.4**
Total additional one-off costs (EU27)	**13.8**	**7.0**	**14.0**	**34.8**

Note: for detailed results and methodology, see sections 8.1 to 8.4. Note that the estimates provided in the table are not precise forecasts, but rather indicate direction and relative magnitude of changes in costs under different policy options compared to companies' current consumer product safety-related costs, while reflecting the uncertainty of firm-level estimates on which they are based.

Discussion of impacts on SMEs

The impact on SMEs is further discussed below, focusing separately on each option. For more details, refer to sections 8.1 to 8.4 of this report.

Option 1

In line with the results presented above, no significant firm level impacts are to be expected due to the implementation of Option 1 for specific types of operators, including SMEs. An exception are SMEs that are manufacturing or distributing food-imitating products. Currently, the Food-imitating Products Directive is applied differently across EU countries, as MSAs can take action on products such as food-shaped shampoos or bath gels, even though no specific risk evaluation has been made (interpretation of the Directive as a per se prohibition of food-imitating products). We expect that a targeted revision to better detail the specific requirements of the Food-imitating Products

Directive and criteria for the evaluation of the risks posed by specific food-imitating products could help manufacturers and distributors to better assess the potential risks of the products offered by them. As both manufacturers and sellers already have to comply with the current Directive, we do not expect additional costs from a revision that merely aims at providing greater clarity and legal certainty respectively. A greater level-playing field regarding the implementation and enforcement of the Food-imitating Products Directive in the EU, as envisaged under Option 1, could lead to minor cost savings on the side of manufacturers and distributors of food-imitating products.

Option 2

The implementation of Option 2 is expected to address some of the current gaps in the product safety regime for non-harmonised products and thereby support the continued free movement of goods in the Single Market[424]. This would likely contribute to positive spillover effects on consumer trust, demand, production and employment, compared to the baseline scenario. As concerns the benefits for SMEs, small companies generally estimate that a revision of the product safety requirements of the GPSD according to Option 2 would bring a variety of at least 'minor' to 'moderate' benefits. Small companies on average estimate that Option 2 would result in significant benefits due to improved quality/lifecycle of products and a deterrent effect on rogue traders. Other areas where SMEs expect relatively strong benefits are increased consumer trust, better supply chain management due to improved traceability of products and better access to the market in non-EU/EEA. These areas are seen as benefits that SMEs assess to be 'moderate' to 'significant'. This is also the case for lower operational risks for businesses and easier compliance with product safety requirements. By contrast, SMEs considered several benefits to be less than 'moderate', including a more level playing field among businesses and greater legal certainty.

Option 2 would impose additional adjustment (e.g. familiarisation cost) as well as compliance costs on SMEs. This is particularly the case for SMEs that (voluntarily) decide to install and operate customer registration systems. Similarly, mandatory elements for product recalls (product description with a photograph, description of risk, instructions on what to do, link to a recall website and free phone number or online service for queries) would increase the cost of SMEs that have put unsafe consumer products on the market.

Option 2 would not entail stricter regulation for a particular type of SMEs, but may entail a higher relative cost burden for manufacturers than distributors. The total additional cost burden for SMEs in manufacturing and distribution sectors is reported in the table above. As indicated in the table, total costs for SMEs manufacturing, wholesale and retail of non-harmonised consumer products in the EU27 in the first year of implementation of Option 2 are estimated at EUR 21.0 million[425]. They would fall in subsequent years to EUR 16.6 million. Compared to the full sample results for the impact of Option 2 on businesses one-off and recurrent costs, SMEs would likely face higher compliance costs than large companies from the implementation of the proposed policy measures[426].

Even though the relative costs increases are generally higher for SMEs, the net impact on SMEs overall costs depends on the benefits that can result from a revised GPSD aligned to the market surveillance rules in Regulation (EU) 2019/1020. We expect that SMEs could save some of the costs that currently arise from inconsistencies in the implementation and enforcement of the GPSD across the EU. Taking into consideration

[424] For a similar assessment, see SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final.

[425] Sum of the firm size categories 0 to 49 employees and 50 to 249 employees, see table above.

[426] Higher relative cost impacts for SMEs compared to large companies are also reported in European Commission (2020), Study on due diligence requirements through the supply chain, Final Report, 20 Febraury 2020.

these benefits and the fact that the changes in SMEs' costs from Option 2 are very small, we expect that the overall net effect from Option 2 on SMEs' costs is rather low and therefore unlikely to affect SMEs' operations.

Option 3

The implementation of Option 3 would be expected to address current gaps in the product safety regime for non-harmonised products and thereby safeguard the continued free movement of goods in the Single Market[427]. This would likely contribute to positive spillover effects on consumer trust, demand, production and employment, compared to the baseline scenario. As concerns the benefits for SMEs, small companies generally estimate that a revision of the product safety requirements of the GPSD according to Option 3 would bring a variety of at least 'minor' to 'moderate' benefits. Option 3 is especially seen as a benefit due to its deterrent effect on rogue traders and as it would result in better information on unsafe products/measures taken by MSAs provided through Safety Gate/RAPEX. In the case of medium-sized companies, Option 3 is seen as a suitable contribution to a more level playing field among businesses. In addition, Option 3 is considered to be a significant benefit when it comes to reducing the occurrence of products presenting health and safety risks and also for contributing to a better functioning of the EU internal market. Finally, moderate benefits are expected regarding the potential to increase business revenue or consumer trust.

As concerns costs for SMEs, the effects from Option 3 will generally have a larger relative cost impact on SMEs than on large companies[428]. Due to their size (e.g. in terms of turnover, profits and staff), SMEs generally bear a larger relative cost burden resulting from regulatory complexity and uncertainty. At the same time, and for the same reasons, SMEs can generally benefit more from policy measures that aim at a greater level of regulatory harmonisation in the EU (greater marginal benefit of reduced regulatory complexity compared to large companies) [429].

Option 3 would not entail stricter regulation for a particular type of SME, but may entail a higher relative cost burden for manufacturers than distributors. The total additional cost burden for SMEs in manufacturing and distribution sectors is reported in the table in the previous section. As indicated in the table, total costs for SMEs manufacturing, wholesale and retail of non-harmonised consumer products in the EU27 in the first year of implementation of Option 3 are estimated at EUR 111.2 million[430]. They would fall in subsequent years to EUR 99.9 million. Compared to the full sample results for the impact of Option 3 on businesses one-off and recurrent costs, SMEs would likely face higher compliance costs than large companies from the implementation of the proposed policy measures.

Even though the relative costs increases are generally higher for SMEs the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a greater level of regulatory harmonisation across the EU27 through the choice of a regulation. Also, the changes in SMEs costs are so small that Option 3 would not be expected to affecting operations considerably. This also implies that under any foreseeable scenario, the expected measures are not expected to leading to the

[427] For a similar assessment, see SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795 final.

[428] SMEs can be disproportionately impacted where new systems and processes need to be put in place to comply with general consumer safety requirements and requirements for the provison of information, since these costs are likely to be higher in relative terms for SMEs. See, e.g. VVA europe (2015), Implementation of the New Regulation on Market Surveillance: Indication of Origin, Final Report, 6 May 2016; European Commisison (2020), Study on due diligence requirements through the supply chain, Final Report, 20 Febraury 2020.

[429] Higher relative cost impacts for SMEs compared to large companies are also reported in European Commission (2020), Study on due diligence requirements through the supply chain, Final Report, 20 February 2020.

[430] Sum of the firm size categories 0 to 49 employees and 50 to 249 employees, see table above.

closing down of either small or medium-sized businesses. This consideration is also true for specific information obligations, such as the obligation for actors across the online supply chain to provide all safety information online that is also required to be provided with a product in 'brick-and-mortar' stores, and the related obligation for online platforms to make sure that third-party sellers, such as SMEs, provide this information. We expect these costs to be relatively low for companies selling consumer products on these platforms, including SMEs.

Option 4

As the previous option, Option 4 would not entail stricter regulation for a particular type of SME, but may entail a higher relative cost burden for manufacturers than distributors. The total additional cost burden for SMEs in manufacturing and distribution sectors is reported in the table in the previous section. As indicated in the table, total costs for SMEs manufacturing, wholesale and retail of non-harmonised consumer products in the EU27 in the first year of implementation of Option 4 are estimated at EUR 187.1 million[431]. They would fall in subsequent years to EUR 166.3 million[432]. Otherwise, impacts on SMEs are expected to be similar to the impacts under Option 3.

[431] Sum of the firm size categories 0 to 49 employees and 50 to 249 employees, see table above.

[432] The notable difference in cost estimates of companies between Option 3 and Option 4 is discussed in detail in section 8. As specified there, a possible explanation for the difference in the assessment of costs provided by businesses is that businesses tend to provide cautious estimates with regard to additional costs from new regulatory obligations that might arise if one single set of rules would apply to harmonised and non-harmonised products. Some respondents also highlighted that changing Regulation (EU) 2019/1020 so quickly after its adoption could have considerable implications on costs.