

FIT FOR FUTURE Platform Opinion

Topic title	New Legislative Framework for Products
	2021 AWP
	Decision No 768/2008/EC and Regulation (EC) No 765/2008 <i>Legal reference</i>
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	Evaluation of the ‘New Legislative Framework for Products’ (Decision No 768/2008/EC on a common framework for the marketing of products and the accreditation and CE marking provisions of Regulation (EC) No 765/2008) <i>Title of the (ongoing) evaluation:</i> <p>The objective of this evaluation is to assess the effectiveness, efficiency, relevance, coherence and EU added value of Decision No 768/2008/EC on a common framework for the marketing of products and the accreditation and CE marking provisions of Regulation (EC) No 765/2008. It should also assess if these instruments are fit for the digital age and a greener economy and if they accelerate our green and digital transition and our economic resilience.</p> <p>The roadmap for this evaluation was published and feedback was received. It took place between 4 November 2020 - 2 December 2020. A public consultation has not yet been launched.</p>
<input type="checkbox"/> Included in Annex VI of the Task force for subsidiarity and proportionality	
	No

	<input type="checkbox"/> Other
	No
Have your say: Simplify!	<i>No relevant suggestions on this topic were received from the public.</i>
Commission follow up	REFIT Scoreboard: New Legislative Framework for Products Have your say portal: Industrial products - evaluation of the new legislative framework Annual Burden Survey: The EU's efforts to simplify legislation

SUGGESTIONS SUMMARY

- Suggestion 1: Maintain the European system for harmonized standards**
- Suggestion 2: Explain regulatory choices**
- Suggestion 3: Don't fix what isn't broken**
- Suggestion 4: Updating NLF to the current and future business environment**
- Suggestion 5: Evaluation of Member state's Notified Bodies**
- Suggestion 6: Supplementary market surveillance activities focused on compliance processes in companies**
- Suggestion 7: Digital information and documentation**
- Suggestion 8: Fit for crisis situations**
- Suggestion 9: One catalogue of obligations for economic operators**

SHORT DESCRIPTION OF THE LEGISLATION ANALYSED

The New Legislative Framework (hereafter NLF) for EU product legislation consists of Decision No 768/2008/EC and Regulation (EC) No 765/2008 aiming to improve the Internal Market for goods and boost the quality of conformity assessment of products. Decision No 768/2008/EC is a template for future Union product legislation which marks a political commitment to align Union harmonised legislation for products with common principles and reference provisions or justify deviation, and more than 20 pieces of legislation are today aligned to the Decision. Since its adoption, businesses and products have undergone a digital and green transformation. Market surveillance provisions in Regulation 765/2008 were recently amended to better reflect and deal with challenges caused by increased global e-commerce. The provisions were lifted out and modernised in Regulation (EU) 2019/1020, where the obligations of economic operators were expanded to fulfilment service providers and further obligations were added. More revisions have been proposed in the General Product Safety Regulation to address online marketplaces.

The purpose of NLF is to ensure compliance of products with the applicable legislation at the time they are placed on the market. Products are increasingly digital and being frequently updated or upgraded after they have been put into service. They may also incorporate technology such as artificial intelligence that could lead to further changes of the product. Remanufacturing of products is an ever-growing business where the objectives of promoting the circular economy and ensuring product safety need to be adequately tackled. It needs to be reassessed whether the NLF continues to be fit for purpose in the current economic reality and changing digital environment. In addition, the conformity assessment procedures must still be fit for purpose in this changing environment to ensure that products placed on the Union market are compliant with the applicable legislation.

Where independent third parties (the so called “notified bodies”) intervene in the conformity assessment procedure, the competence of such bodies needs to be guaranteed. To that end, the

NLF defines the accreditation of notified bodies as the preferred – but not compulsory – means to demonstrate the competence of such bodies, and thus the NLF may play an important role.

PROBLEM DESCRIPTION

Existing evidence suggests the following issues:

The evaluation focuses on whether: i) the NLF is fit to address the way products may be changing during their lifetime to both support the take-up of smart connected or remanufactured products and to ensure safety; ii) the conformity assessment procedures remain fit for purpose and ensure the safety and compliance with the applicable requirements of the products placed on the Union market; iii) the rules for notified bodies are robust enough to ensure the competence of those bodies; iv) the accreditation system functions well and ensures that the competence of the notified bodies intervening in the conformity assessment procedures is sufficiently guaranteed; v) affixing the CE marking and other product information to the product itself continues to be appropriate; and vi) whether the lack of a crisis instrument for urgency situations renders the NLF less effective or efficient¹.

The issues identified by the Commission in its roadmap are relevant. However, the Fit for Future Platform is of the opinion that the scope of the evaluation should be broadened in order to cover all key elements of the NLF. According to the Fit for Future Platform, the evaluation needs to be extended with at least an assessment of: 1) the application of the process for developing harmonized standards; 2) the appropriateness of the existing economic operators; and 3) the possibilities for improving market surveillance. Practitioners at all levels of implementation should be invited actively to contribute to the evaluation.

Harmonised standards

A key pillar of the NLF is the system for harmonized standards, in which legislators define essential requirements for consumer- and environmental protection, while European Standardisation Organisations define the corresponding detailed technical requirements for products and services through voluntary standardisation. Timely delivery of state-of-the-art harmonized standards is a prerequisite for the effectiveness, efficiency, and relevance of the NLF. Furthermore, a robust and efficient European standardisation system is vital to a) the green and digital transitions, b) Europe's competitiveness on the global market, and c) influence on future international standardisation, especially regarding new digital technologies.

Following a ruling from the European Court of Justice in 2016, the Commission has adopted a more legalistic approach to harmonised standards, affecting the standardisation requests, the technical evaluation and the final citation of the standards in the Official Journal of the European Union. This new approach has caused frictions and delays across the system and given rise to concerns among member states, European standardisation organisations and the European business community. Furthermore, there are indications that the Commission is considering alternative ways to develop technical specifications in areas covered by the NLF, thus potentially by-passing the European standardisation system.

¹ Source: [Evaluation roadmap](#);

The current challenges have been addressed in several public statements, most recently by 17 Member States at the COMPET Council on 25 May 2021².

Economic operators

The purpose of the evaluation is to assess the effectiveness and relevance of Decision no 768 and the relevant elements in regulation 2008/765 and to assess whether the NLF is fit for future, particularly in terms of the digital development, green transition and challenges related hereto. The current growth and development in online trade has led to the emergence of new actors in the value chain, particularly online marketplaces, which have only partially been addressed in the new Regulation 2019/1020, while the common assumption was that the e-commerce directive exempted online marketplaces from liability in general. Only the specific role as fulfilment service providers was added to the list of economic operators and an obligation for Information Society Service Providers to cooperate on take-down was added. It remains unclear to what extent the forthcoming General Product Safety Regulation will address online marketplaces, and the current proposal does not add online marketplaces to the list of economic operators.

In the same vein the growth in circular business models has led to 3rd parties remanufacturing, updating and upcycling products without the original manufacturers' involvement, entailing new questions about when 'changes' made to products after they have been placed on the market requires new CE-marking and to what extent. The problem concerning updating is also relevant in relation to the digital transformation, as many digital products are continuously updated by the manufacturer or 3rd parties throughout their lifetime, e.g. software updates after products are put into service. These developments necessitate an assessment of whether the current definitions in the NLF and the division of responsibilities for different economic operators in the product distribution chain is fit for future – even fit for the present. The current NLF does not address fulfilment service providers, online marketplaces and their role in making products from sellers established in third countries available for European consumers. Neither does it address remanufacturers and other 3rd parties who may make changes to products in circular and/or digital business models.

Therefore, it is recommended that the Commission extends its evaluation to include an assessment of whether the current definitions of economic operators and their responsibilities are “fit for future”, are coherent with related legislation, and match the digital and green transformations sufficiently in terms of accounting for new types of distribution chains, new business models and expected future developments.

Furthermore, the proliferation of obligations for economic operators (in regulation 2019/1020 and the General Product Safety Regulation) has made it more difficult for them to navigate and comply with the rules. To facilitate compliance and enforcement, it is recommended that the evaluation consider whether it would be feasible to provide an overview of all obligations for economic operators in one place in the NLF Framework Decision.

² *Joint note on EU industry competitiveness and effective harmonised standardisation.* Link: <https://data.consilium.europa.eu/doc/document/ST-8600-2021-ADD-1/en/pdf>

Market surveillance

A key part of product safety is market surveillance that properly and effectively monitors the market. Therefore, ensuring a framework that allows for the development of supplementary market surveillance activities focused on compliance processes in companies in addition to the traditional product-focused market surveillance could broaden the scope and efficiency of European market surveillance activities.

The Fit for Future Platform has acknowledged the issues raised by the legislation concerned as follows:

Regarding: modernisation and future proofing of existing laws, including via digitalisation, the efficient labelling, authorisation and reporting obligations, the simplification of EU legislation:

Harmonised standards

- Both Member States and stakeholders support the NLF as the legal framework for EU product rules. It is important for the success of the NLF that there is a strong political mandate and support from both the Commission, the European Parliament, Member States and stakeholders. The NLF is an important tool to ensure clarity and transparency in the applicable rules for business and is a key element to ensure the competitiveness for European businesses. The Commission should seek to make it as easy as possible to run a business in the EU. Using the NLF and thereby well-known methods for new product rules is a cornerstone in this endeavour;
- It is crucial for a well-functioning internal market for goods that businesses can easily identify the rules which their product must comply with. The Fit for Future Platform thinks that the NLF is the best tool to develop and ensure an effective internal market for goods. We support that the main principles in the NLF are maintained, keeping the public-private partnership for harmonized standardisation between legislators and industry as the core principle;
- However, the evaluation should draw lessons useful to inform the Commission on how the NLF should be updated, and especially when and where it is necessary in order to support the digital and/or green transition. In this regard, we find it essential that the NLF is technology neutral and fit for future.

Economic operators

- Since the adoption of NLF in 2008, e-commerce has increased significantly and introduced online platforms as a new trading place where consumers and businesses buy products from sellers all over the world. Also, the growth in the circular economy with 3rd parties remanufacturing products has changed the types of products sold today and challenged the linear thinking of the value chain on the basis of which the NLF is designed. The definitions in the NLF should be evaluated with a focus on determining whether the definitions include all relevant economic operators in the value chain and whether the Decision still provides a clear and proportionate distribution of obligations

which corresponds to the role of each operator in the supply and distribution process.³ Accelerating technology changes, the green transition, new product categories and business models have impacted the relationship among the economic operators in the value chain. Since 2008, big changes have happened and it should be evaluated whether the NLF should be updated to better reflect a modern value chain and ensure fair competition on a level playing field, while fostering the development of new innovative business models. Lack of doing so could lead to further “free riding”, as companies might adapt their business models to fit in the least burdensome category in relation to compliance obligations, for example online marketplace instead of importer;

- New obligations of economic operators have been included in Regulation 2019/1020 on Market Surveillance (chapter II), and further obligations have been proposed in the General Product Safety Regulation. This proliferation of obligations on economic operators has made it more difficult for them to navigate and comply with the rules.

Notified Bodies

- Notified Bodies help shape the trust in products sold on the single market by securing a uniform measurement of product safety. However, distinct procedures are allowed to establish the compliance of Notified Bodies with the applicable requirements, namely by having recourse to accreditation and by direct qualification from the notifying authorities. This creates an unharmonized approach to assess the competence of Notified Bodies, further enhanced by the fact that notifying authorities are not obliged to use harmonised standard and do not possess a robust peer-evaluation system between them, as it is the case for accreditation bodies. Although dispositions are under implementation until April 2023 to harmonise the accreditation requirements of Notified Bodies, currently they may vary across EU Member States, among other things because Union Harmonisation Legislation does not stipulate which standard(s) have to be used. This multitude of approaches and requirements creates an un-level playing field for Notified Bodies and, in extension, risks lowering the trust, validity and consistency in the markings they distribute as well as the safety of European consumers.

Market surveillance

- Effective market surveillance is a precondition for a level playing field. Member States that are able to expand their market surveillance activities to also include full company approaches where quality assurance processes are assessed, increase their range and efficiency in ensuring product safety. Furthermore, actively encouraging and cooperating with companies to guide them to comply with relevant legislation is an important voluntary tool, which should be taken into consideration in the evaluation, while leaving it up to the individual member states how to prioritise the supervisory authorities' resources.

³ Recital 19 of the NLF reads: “All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products which are in conformity with the applicable legislation. This Decision provides a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.”

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- Quality assurance processes and procedures as well as autonomous control procedures and self-evaluation are also significant tools for directing the market surveillance efforts towards non-compliance in the Member States in a cost-effective manner and should be taken into account when evaluating the NLF and the responsibilities of the economic operators. Enabling and enforcing market surveillance efforts based on data collection and overall risk analysis does not only support the digital transformation, it increases the general product safety to the benefit of the European consumers.

Digital information and documentation

- The Fit for Future Platform questions whether affixing information and documentation physically to products is still the most effective means of communicating to enforcement authorities in all circumstances. The evaluation could provide a platform for uncovering if there is a potential for reducing burdens for both businesses and authorities through further digitalisation of product information and documentation in the EU without removing information which is mandatory for consumers to view on the product.

Crisis preparedness

- The COVID-19 crises have influenced the internal market for goods. The experiences and lessons learned from the crisis should be a part of the evaluation to ensure that the NLF can perform during crises.

The specific issues encountered at local and regional level are:

- N/A

SUGGESTIONS

Suggestion 1: Maintain the European system for harmonized standards

Description: The evaluation of the NLF should consider the functioning of the European system for harmonized standards, which is currently facing a number of challenges. There is an urgent need to identify joint solutions to bring the system back on track and ensure that it is fit for the future. The Commission should take into account stakeholders' concerns on this issue and ensure that the evaluation of the NLF is coordinated and takes account of coherence aspects, in view of existing and upcoming initiatives on harmonized standards, such as the Commission's upcoming standardisation strategy, which is expected in 2021.

Expected benefits: A well-functioning system for harmonised standards will deliver harmonised standards in time to support new EU legislation. This will help manufacturers and authorities ensure that products and services are compliant with EU law. On a larger scale, a future-proof standardisation system can support the green and digital transitions, Europe's competitiveness on the global market and influence on future international standardisation, especially regarding new digital technologies, reaping the benefits of digitalization and reducing burdens.

Suggestion 2: Explain regulatory choices

Description: The NLF evaluation should consider and draw lessons relevant to confirm and strengthen the mandate of the NLF as a key legal framework for Union harmonised legislation for products. This would mean that when the Commission makes a legislative proposal to ensure the safety of products, the Commission should always consider using the NLF, and weigh it against the benefits of other alternative approaches. The Commission should be committed to explain their regulatory choices.

Expected benefits: The NLF has proven a successful tool to improve the internal market for goods to the benefit of consumers, business, authorities, and the European economy as a whole. Confirming and strengthening the NLF mandate would make it easier for businesses as new EU product rules are adopted using well-known methods and thereby creating as few barriers for business as possible when new EU product rules are adopted. Consistently using the NLF as the legal framework would provide predictability, and it would strengthen transparency if the legislators explained when a proposal does not follow the NLF. This should never come at the expense of safety, as the legislators are free to diverge from the NLF, where appropriate, for example if self-declaration is deemed insufficient in terms of safety and a mandatory requirement for third party assessment is deemed proportional.

Suggestion 3: Don't fix what isn't broken

Description: The basic principles in the NLF should only be changed if necessary. The NLF evaluation and potential update should be done with respect for the principle of better regulation. Based on analysis, any amendments of the NLF should maintain the focus on improving uniform implementation and enforcement of the harmonised product rules and ensure a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, the protection of consumers, the protection of the environment and public security.

Expected benefits: Keeping the basic principles in the NLF will be the best legal framework for businesses, as they are familiar with and recognise the principles in the NLF. At the same time, adapting the basic principles in the NLF where necessary, will ensure a high level of protection of public interests, consumers and the environment in the EU Single Market. A balanced application of the basic principles in the NLF is essential to ensure the competitiveness of the EU.

Suggestion 4: Updating NLF to the current and future business environment

Description: We encourage the Commission to evaluate and update the definitions in the NLF to ensure a clear and proportionate distribution of obligations, which corresponds to the role of each operator in the supply and distribution process, including in the digital and circular economy. The evaluation should cover, whether there is a need to integrate existing definitions from related legislation – such as Fulfilment Service Providers defined in Regulation 2019/1020 – and add new definitions – such as online platforms/marketplaces and remanufacturers.

Furthermore, it should be specified how ongoing and future legislative proposals that include definitions of terms in the NLF can consistently be aligned with the definitions in the NLF.

In particular, there is a need to evaluate the relationships between economic operators in the NLF and clarify the divisions of responsibilities in the digital and circular value chains and ecosystems to ensure trust and fair competition on the internal market for goods and services.

The digital and green transitions pose new challenges in terms of product requirements, as new products are placed on the market. The NLF should be able to accommodate products that undergo changes during their lifetime, such as upgrades, upcycles, updates, and remanufacturing. It might also be necessary to clarify roles and responsibilities across the value chains and ecosystems to cater for these developments, as some economic operators may change their roles and obligations during a product's lifetime.

The Platform encourages the Commission to consider how it can be ensured that e.g. remanufactured, upcycled or updated products meet the relevant product requirements for safety and security without imposing disproportionate burdens on new and sustainable business models. It is important that the NLF makes it easy and attractive for innovative businesses, especially SMEs, to place safe, secure and sustainable products on the internal market. It is important that the NLF does not create a burden for new and innovative business models. This could for instance be achieved by only making repairers responsible for the part of the product they have repaired, rather than for the full product for the rest of its lifetime. This approach is already applied in some Member States, and the experiences should be taken into consideration.

Expected benefits: The modernisation of NLF will ensure that economic operators in digital and circular value chains and ecosystems take appropriate responsibility and that new product types and products that are changed, updated or remanufactured during their lifetime are included properly in the NLF. Further a uniform use of definitions in all EU product legislation will strengthen coherence and create more clear rules for businesses.

Suggestion 5: Evaluation of Member state's Notified Bodies

Description: As multiple approaches to assess the competence of Notified Bodies exist across EU member states, the NLF must facilitate knowledge sharing among the EU's accreditation bodies and supervising authorities so that an approach to assess the competence of Notified Bodies can be reached. This would enhance the foundation upon which the notification is built. An evaluation of the requirements that Notified Bodies have to fulfil, in addition to those contained in harmonised standards, is necessary to provide evidence whether they are still fit or they need to be further detailed and/or supplemented. This would guarantee the trust in and validity of the Notified Bodies, as well as their markings throughout the EU. Therefore, it is proposed that the NLF evaluation examines the current requirements for Notified Bodies in order to confirm that they reflect the current market and society needs.

Expected benefits: It is expected that a more nuanced overview and understanding of the different approaches and requirements for Notified Bodies will create evidence to explore a more robust framework for the conformity assessment procedure and increase the trust towards the Notified Bodies, the certificates issued by Notified Bodies as well as the conformity assessments procedures. This would create a more level and transparent playing field for EU

Notified Bodies. In extension of this, the transparency throughout the different systems would facilitate the practicalities in re-testing or re-certifying to a higher degree, and thus increase the trustworthiness of CE-certificates. Even though the evaluation of the NLF does not consider market surveillance, these benefits spill over to market surveillance, as the CE-marking provides important guidance for market surveillance activities. Reliable and well-functioning market-surveillance is a prerequisite for fair conditions for healthy competition.

Suggestion 6: Supplementary market surveillance activities focused on compliance processes in companies

Description: With an ever-expanding market and further increasing complexity of products, market surveillance activities that have a broader and systemic focus can assist in ensuring the safety of products at an early stage, rather than simply “catching” them at arrival. One way to work towards this goal is to supplement traditional controls of products with a review of internal processes in companies and provide guidance for improving compliance in connection with inspections, where the authorities have the resources available to do so. Therefore, it is suggested that the Commission takes notice in the evaluation of the development in several Member States, who are successfully supplementing the traditional market surveillance – focused on products – with market surveillance activities focused on businesses’ knowledge and ability to ensure safety and, in particular, on the quality assurance process set up internally by economic operators to ensure product safety. It is a prerequisite for these practices that the NLF does not preclude these activities and clearly describes quality assurance processes and procedures as well as autonomous control procedures and self-evaluation.

These supplementary market surveillance activities should not substitute or duplicate other company-based approaches such as the control of production systems that Notified Bodies perform. Notified bodies already operate with a similar but narrower scheme of company-based market surveillance, but notified bodies do not cover all product types within the harmonised area, and their verification primarily covers production systems. Additionally, their range is limited to the standards for the specific product types and only in the manufacturer part of the product’s value chain. However, the aforementioned supplementary market surveillance activities can cover all economic operators.

This approach is not meant to replace the traditional market surveillance focused on products, and it should be remembered that especially large companies can in many scenarios comply more easily with the traditional methods, while SMEs may benefit more from guidance. It is an additional tool that can be used, where relevant, by those Member States that have the resources for such additional measures.

Expected benefits: The main advantages of supplementary market surveillance activities focused on compliance processes in companies, follow from the fact that it is a “full company”-based approach which in principle has an effect on all products handled by the economic operator inspected. This results in improved efficiency and range, as the compliance process controls make it possible to achieve an impact and cover a wide range of products with the same resources, while at the same time positively encouraging businesses to comply with the product safety legislation. Insights from the review of internal processes can be used to enable cost-effective, data-driven prioritization of further market surveillance activities, based on overall

risk assessments per company. Not least, compliance process-oriented market surveillance can be a lighter option which facilitates dialogue and guidance towards especially SMEs. In addition to being easier to comply with for SMEs, this approach is more fit for surveillance of new green and digital business models, where changes to the product occur throughout its lifetime.

Suggestion 7: Digital information and documentation

Description: We recommend that the Commission evaluates carefully and draws lessons relevant to explore whether product information and documentation could be given digitally as a default (digital-by-default), except when the product information is mandatory for consumers. This information should always be physically available on the product. We recommend that the Commission identifies where and when it could be encouraged that information provided on the product could also be provided digitally. Digitizing documentation and other information may improve the efficiency of enforcement and thus safety. The Commission should in this context take other ongoing initiatives on digitalisation of labels, information and documentation into consideration and ensure coherence, e.g. with the upcoming product passport. A situation with many different digital labels (for example QR-codes) on a product should be avoided.

Expected benefits: It would be beneficial to evaluate if allowing for digital information and documentation by default would potentially alleviate companies and enforcement authorities from a significant burden and enable seamless access to information to support new business models and market surveillance tools.

Suggestion 8: Fit for crisis situations

Description: We support that the evaluation also includes whether NLF is adequate to perform urgently during crisis, such as during the COVID-19 crises. In this regard it might be relevant to consider an instrument for emergency situations, while considering potential overlaps with existing instruments. However, the Commission must also consider whether a better implementation and enforcement of existing instruments could have an impact as well.

Expected benefits: Including an emergency instrument in the NLF would strengthen the resilience of the internal market for goods and prepare the NLF for possible future crises.

Suggestion 9: One catalogue of obligations for economic operators

Description: New obligations of economic operators have been included in Regulation 2019/1020 on Market Surveillance (chapter II), and further obligations have been proposed in the General Product Safety Regulation. We would like this evaluation to consider whether it would be feasible to provide an overview of all obligations for economic operators in one place in the NLF Framework Decision.

Expected benefits: To gather all responsibilities of economic operators – or an updated catalogue of these – in the same legal act, i.e. the NLF Framework Decision would be a clearer and more logical set-up and could thus simplify compliance for both business and authorities.
