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EVALUATION

of the

New Legislative Framework

{SWD(2022) 365 final}

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Glossary

Term or acronym	*Meaning or definition*
AI	Artificial intelligence
CAB	Conformity Assessment Body
CEN	European Committee on Standardization
Cenelec	European Committee on Electrotechnical Standardization
CBA	Cost-Benefit Analysis
CPR	Construction Products Regulation (EU) No. 305/2011
DoC	Declaration of Conformity
DoP	Declaration of Performance
DSM	Digital Single Market
EA	European Cooperation for Accreditation
EC	European Commission
ECT	Treaty establishing the European Community (Nice consolidated version)
EMCD	Electromagnetic Compatibility Directive 2014/30/EU
EO	Economic operators
ESO	European standardisation organisation (CEN, Cenelec, ETSI)
ETSI	European Telecommunication Standards Institute
F4F	Fit for Future Platform
GDPR	General Data Protection Regulation (EU) 2016/679
GPSD	General Product Safety Directive
GPSR	Proposal for a General Product Safety Regulation
IA	Impact Assessment
IoT	Internet of Things. IoT system architecture is generally divided into three layers: the perception layer, the network layer and service layer (or application layer)
ICSMS	Information and Communication System for Market Surveillance
IVDR	In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746
LVD	Low Voltage Directive 2014/35/EU
MD	Machinery Directive 2006/42/EC

MDR	Medical Devices Regulation (EU) 2017/745
MS	Member State
MSA	Market Surveillance Authority
NA	Notifying Authority
NAB	National Accreditation Body
NANDO	New Approach Notified and Designated Organisations Information System
NB	Notified Body
NLF	New Legislative Framework
ODM	Original Design Manufacturer
OEM	Original Equipment Manufacturer
OPC	Open Public Consultation
PO	Policy option(s)
RAPEX	Rapid Exchange of Information System
RED	Radio Equipment Directive 2014/53/EU
SBS	Eurostat's Structural Business Statistics (SBS), which shed light on relevant classes of connected Radio Equipment and Wearables.
SCM	Standard Cost Model
TFEU	Treaty on the Functioning of the European Union
TSD	Toys Safety Directive
WTP	Willingness to Pay – the maximum amount that consumers are willing to pay for internet- connected radio equipment e.g. for products with, and without security features.

1. INTRODUCTION

1.1. 1.1. Purpose and scope of the evaluation

The New Legislative Framework (hereafter NLF) for EU product legislation consists of Decision No 768/2008/EC[1] and Regulation (EC) No 765/2008[2] aiming to improve the Internal Market for goods and boost the quality of conformity assessment of products. Hence, the internal market **legal basis** is used for both the Decision and the Regulation (Article 95 ECT, which corresponds to Article 114 TFEU, Approximation of laws). Besides Article 95 ECT, the legal basis of the Regulation is also Article 133 ECT (corresponds to Article 207 TFEU under the title Common Commercial Policy).

Decision No 768/2008/EC contains a template for future Union product legislation. This Decision lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for legislation revisions or recasts[3]. Currently, there are 23 pieces of legislation and one delegated act aligned to the NLF.[4]

Regulation (EC) No 765/2008 established an overall framework of rules and principles related to accreditation, market surveillance, conformity assessment and the CE marking. The market surveillance provisions of this Regulation were replaced by Regulation 2019/1020[5], which started to apply on 16 July 2021.

The key concepts used for the evaluation of the NLF are the following:

- **New Approach:** The New Approach is a legislative technique used to ensure the free movement of industrial products. This technique is inspired by the *Cassis de Dijon*[6] judgment of the Court of Justice and its key element is the reduced content of legislation to cover only the essential protection requirements which the Court had indicated were the only valid reasons for a national authority to block a product from another Member State. The asset of the New Approach is its flexibility. Keeping the directives and regulations free from detailed specifications has facilitated a flexible legal framework, which is technology-neutral and serves as a catalyst for innovation and growth. It has allowed keeping legislation slim, without frequent adaptations to technical progress, which is an important factor in a business environment characterised by fast developing technologies,
- **Notified bodies:** Conformity assessment is a responsibility of the manufacturer. However, depending on the risks of the products, the relevant legislation may require that a third party is involved in the conformity assessment procedure. The conformity assessment bodies involved in a third-party conformity assessment procedure based on the EU product

[1] Decision No 768/2008/EC the European Parliament and the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L 218, 13.8.2008, p. 82–128

[2] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30–47.

[3] Recital (2) of Decision 768/2008/EC.

[4] List of the 23 NLF-aligned directives, regulations and delegated act(s): https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en

[5] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, started to apply on 16 July 2021.

[6] Judgment of 20 February 1979, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein*, C-120/78 EU:C:1979:42

legislation need to be designated for such conformity assessment activities. These bodies must be chosen, i.e. designated by the authorities of the Member States on the basis of certain minimum criteria (competence, impartiality, integrity, etc.), which are set out in the NLF. They are then "notified" to the Commission, after which they may carry out conformity assessment activities according to the procedures set out in the EU product legislation.

- **Accreditation:** The notified conformity assessment bodies may also be accredited. Accreditation is an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements. To avoid that different approaches and differing systems are used throughout the EU for the accreditation of conformity assessment bodies, the NLF developed a comprehensive framework for accreditation and laid down at EU level the principles for its operation and organisation.
- **CE marking:** The New Approach introduced a common marking of conformity, which had become its most visible and well known element. The CE marking is in effect a declaration by the manufacturer that the product conforms to all the essential requirements of the relevant legislation and that it has been subject to the applicable conformity assessment procedures. Since products bearing the CE marking should be in compliance with the applicable directives and regulations and hence benefit from free circulation, the CE marking operates as a "passport" to the whole EU market.

Since the adoption of the NLF, industry and products have transformed radically, in particular due to the digital and the circular economy aspects. It needs to be reassessed whether the NLF continues to be fit for purpose in the current economic reality and the conformity assessment procedures still ensure that products placed on the Union market are safe and compliant with the applicable legislation. In addition, it is necessary to assess whether the NLF is also sufficiently able to cope with an increasing demand for integration of environmental aspects into product legislation.

The main purpose of this evaluation is to bring forward an informed analysis of the current performance of the NLF, assessing the effectiveness, efficiency and its relevance in particular given the technological development, the coherence with similar initiatives and the overall EU added value of certain aspects of the NLF.

In particular, the assessment focuses on whether:

a) 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;
b) 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;
c) the rules for notified bodies are robust enough to ensure the competence of those bodies;
d) the accreditation system functions well and ensures that the competence of the notified bodies intervening in the conformity assessment procedures is sufficiently guaranteed;
e) affixing the CE marking and other product information physically to the product itself continues to be appropriate; and
f) the lack of a crisis instrument for urgency situations renders the NLF less effective or efficient.

Although the focus of the evaluation is retrospective, **a forward-looking dimension** is unmissable to assess the relevance of the NLF and its fitness for purpose. The evaluation takes into account the

ongoing regulatory developments serving **the digital transition**. Legislative proposals that are relevant for the evaluation include the Proposal of the AI Act[7], the Proposal of the Machinery Regulation[8], the Proposal for the regulation on batteries and waste batteries and Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products. Regarding the **green transition and the circular economy**, this evaluation takes into consideration also the Circular Economy Action Plan[9] and the regulatory pressure it created to integrate environmental aspects into product legislation. The evaluation also takes into account the Proposal of the General Product Safety Regulation (GPSR)[10], which sets up a new horizontal framework for product safety of consumer non-food products in the EU. This evaluation is prepared with a view to provide a solid basis for a possible future impact assessment.

Consequently this evaluation includes an evidence-based assessment of the extent to which the NLF might be able to accommodate the following developments in product markets and in manufacturing processes:

- **Ability of products to change after they have been placed on the market**, for instance due to software, firmware or hardware updates and upgrades, or through the continuous learning capabilities of machine learning systems.
- **Increasing digitalisation and complexity of products**, internet connectivity of certain products raises considerations regarding cybersecurity and product safety.
- **Changes in manufacturing value chains and emergence of alternative means of production** (e.g. 3-D printing) resulting in the blurring of delineations between economic operators, as well as between products and services.
- **Circular economy developments**, including increasing focus on placing on the market of products following their repair, refurbishment, and remanufacturing.

Scope of the evaluation

The **material scope of this evaluation** does not include the provisions of Regulation (EC) No 765/2008 relating to market surveillance, which were already subject to an evaluation and review[11] and have since been replaced by Regulation 2019/1020.[12]

This evaluation conducts an evidence-based review of the performance of the NLF in the following key areas:

[7] Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts.
[8] Proposal for a Regulation of the European Parliament and of the Council on machinery products.
[9] Communication from the commission to the European Parliament, the Council, the European and Social Committee and the Committee of the Regions COM/2020/98/final- A new Circular Economic Action Plan for a cleaner and more competitive Europe
[10] Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council.
[11] The market surveillance provisions of Regulation (EC) No 765/2008 were already subject to a REFIT evaluation (SWD(2017) 469 final). Since then, a new Regulation (EU) 2019/1020 has been adopted and replaced those provisions as of April 2021.
[12] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

- **Alignment of Union harmonisation legislation** to the NLF's common principles and reference provisions.
- **Conformity assessment** rules and procedures.
- Framework and rules for the **accreditation** and notification of conformity assessment bodies.
- **CE marking** and administrative requirements.

The material scope of the evaluation is extended to the specific pieces of EU product legislation that had been aligned with the NLF, in order to demonstrate the performance and impact of the NLF through the main evaluation criteria.

The evaluation **does cover the aspects of harmonised standards** relevant to the NLF, such as having technologically neutral essential requirements and relying on harmonised standards for presumption of conformity. **However, it does not address the EU standardisation system beyond those aspects.** The Evaluation of the standardisation system should be a stand-alone process.

The recently adopted Standardisation Strategy announces a launch of a separate evaluation of Regulation (EU) 1025/2012 to assess whether it is still fit for purpose.

This evaluation builds upon and complements an earlier evaluation for the internal market legislation on Industrial products.[13] The scope of this earlier evaluation was overarching and broad in nature, covering many New Approach directives, but only a few pieces of product legislation had been aligned to the NLF.

The **temporal scope of the evaluation** covers the period from 2014 to 2020. As already mentioned, Decision No 768/2008/EC only contains reference provisions to be integrated into the different pieces of product legislation. The Package of ten Directives[14] to be aligned with the reference provisions and approaches outlined in the NLF was adopted in 2013-2014.[15] Regarding the **geographical scope**, the evaluation covers EU Member States as well as the three additional State Parties to the EEA-EFTA Agreement (Iceland, Lichtenstein, Norway). It corresponds to the geographical scope of the NLF, considering that both the Decision and the Regulation are incorporated into the EEA Agreement.[16]

[13] This evaluation will build upon, and complement the SWD/2014/023 Evaluation of the Internal Market Legislation for Industrial Products, and on COM/2014/025 A vision for the internal market for industrial products.

[14] Alignment of ten technical harmonisation directives to Decision No 768/2008/EC.

[15] Although the Toys Safety Directive revised by Directive 2009/48/EC of 18 June 2009 was the first product legislation fully aligned with the Decision, the Alignment Package of ten technical harmonisation directives with the NLF was adopted in 2013 – 2014. This was the first set of aligned legislation, able to manifest the effectiveness and consistency brought by the NLF into the EU product legislation (1. Pyrotechnic Articles Directive (2013/29/EU) - OJ, L 178, 28.06.2013.; 2. Recreational craft and personal watercraft Directive ((2013/53/EU) - OJ, L 354, 28.12.2013.; 3. Low Voltage Directive (2014/35/EU); 4. Electromagnetic Compatibility Directive (2014/30/EU); 5. ATEX Directive (2014/34/EU); 6. Lifts Directive (2014/33/EU); 7. Simple Pressure Vessels Directive (2014/29/EU); 8. Measuring Instruments Directive (2014/35/EU); 9. Non-automatic Weighing Instruments Directive (2014/31/EU); 10. Civil Explosives Directive (2014/28/EU), these directives are published in OJ, L 096, 29.03.2014.

[16] Decisions of the Joint Committee No 126/2012 of 13 July 2012 amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement.

Methodological approach

This Staff Working Document builds on the Study that was carried out for the European Commission – DG GROW by the Centre for Strategy & Evaluation Services (CSES), supported by the Centre for Industrial Studies (CSIL)[17].

The Study has been conducted using a number of different research tools that have allowed for a verification and cross-checking of the evidence in accordance with triangulation principles.

It was challenging but necessary to methodologically design the evaluation in such a way that the effects of the horizontal NLF framework can be clearly distinguished from the effects of the product-specific legislation.

The assessment of the performance of the NLF is indeed almost inseparable from the performance of the specific pieces of EU product legislation, which sets limitation to the assessment of costs and benefits attributable to the NLF and especially to their quantification. Nonetheless, the case studies and all the evidence collected is carefully selecting the information relevant for the performance of the NLF.

The methods used include: an extensive desk research; consultations (both targeted and public consultations); direct interactions with stakeholders (via interviews and a validation stakeholder workshop); case studies.

A detailed description of the methodology and main sources of information for this evaluation are provided in Annex II.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

1.2. 2.1. Description of the intervention and its objectives

1.2.1. 2.1.1. How the intervention fitted in the wider policy framework?

In 1985 the Commission proposed the so called New Approach. Instead of setting out detailed technical requirements in product legislation according to the Old Approach, the New Approach directives limit themselves to defining essential requirements in relation to issues such as health, safety, consumer protection and the protection of the environment.

On the basis of the feedback received from the stakeholders in a public consultation on the functioning of the New Approach, in March 2003, the Commission adopted a Communication entitled "Enhancing the implementation of the New Approach directives[18]", setting out the main elements for the review:

1. Lack of confidence in notified bodies and in the whole notification process;
2. Weaknesses in market surveillance and efficient and consistent enforcement of the directives;
3. Inconsistencies between different directives;
4. Misunderstanding of the value and role of CE marking.

[17] Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008), Final Report, Centre for Strategy & Evaluation Services (CSES) and CSIL, May 2022

[18] Communication from the Commission to the Council and the European Parliament COM(2003) 240 final

Following this, the Impact Assessment of 2007 accompanying the NLF Regulation and the Decision was prepared in 2007.[19]

The broader EU policy and legal context in which the NLF was developed is also important to mention. Besides the EU Industrial Policy-related interventions and goals, such as having an efficient and effectively functioning internal market in which European manufacturers, and in particular SMEs, can thrive, the Better Regulation agenda was also important. There was a need to strengthen regulatory coherence across the EU harmonisation legislation, but also to reduce the burden of red tape to promote efficiency savings for industry.

1.2.2. 2.1.2. Problems and needs that the intervention aimed to address

In the Impact Assessment of 2007, there were six **key needs** and problems facing the EU that the NLF sought to address. These are detailed below.

- **Recognition that the New Approach to harmonisation legislation needed to be updated**. Although it supported the implementation of individual pieces of harmonisation legislation, the New Approach required a modernisation to become a more common approach across the EU product legislation, to strengthen coherence and consistency among the different pieces of product legislation.
- **Need to ensure the free movement of goods within the Single Market in the most efficient and effective way.** Setting general principles and a horizontal framework was seen as a means of removing the remaining obstacles to the free movement of goods.
- **Need to surmount inconsistencies among the different pieces of legislation developed over a 30-year period.** This necessitated the introduction of a horizontal regulatory framework to provide as much commonality across the legal framework as possible, whilst allowing flexibility for some divergence where necessary for specific sectors.
- **Need to enhance cooperation and a more uniform approach to monitoring compliance with Union harmonisation legislation** through more effective and better coordinated market surveillance and enforcement activities. This is mentioned as it constitutes part of the overall picture. However, as already explained, market surveillance is outside the scope of this evaluation.
- **Conformity assessment practices in 2008 were perceived unsatisfactory, with insufficient attention across the EU to ensuring the high quality of conformity assessment services** at national level. Therefore, strengthening the quality of accreditation procedures for conformity assessment bodies (including notified bodies) was an imperative.
- **Need to enhance the credibility of CE marking.** Whilst the CE marking was widely recognised internationally contributing to the development of the single market, industry stakeholders perceived that the CE marking was being undermined by low levels of compliance with the applicable EU legislation that allows the manufacturer to affix the CE marking, especially among some manufacturers in third countries.[20]

[19] Impact assessment {COM(2007) 37 final SEC(2007) 173}accompanying the proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products and a Decision on a common framework for the marketing of products (i.e. the NLF)

[20] See for instance the upcoming Evaluation of the Electromagnetic Compatibility Directive, supporting the Study published in 2021; Evaluation of the Low Voltage Directive, 2019.

1.2.3. 2.1.3. General and specific objectives of the intervention

The general objectives set out in the Impact Assessment of 2007 of the NLF are to ensure a high level of protection of public interests and the free movement of goods throughout the EU within a flexible and innovation-friendly legal framework,

The specific objectives that are covered by the scope of this evaluation foreseen to achieve these general objectives of the NLF are the following:

1) To reinforce the implementation of the New Approach, such as setting technology-neutral essential requirements and leaving detailed technical aspects of implementation to the development of non-mandatory harmonised standards.

The NLF was expected to fill in the gaps and simplify implementation to reinforce its capacity to ensure a high level of protection and the free movement of goods throughout the EU within a flexible and innovation-friendly legal framework.

2) To strengthen the consistency and coherence of Union harmonisation legislation

The NLF was expected to provide economic operators with a clear and consistent legal framework to ensure better overall coherence of EU legislation and to simplify its implementation. This objective was to be achieved thanks to the regulatory toolbox established by the NLF to revise existing and to develop new Union product legislation.

3) To strengthen the quality of conformity assessment services through the improved accreditation of notified bodies and improve the monitoring of notified bodies by national authorities

The rules of the NLF relating to the operation of notified bodies and accreditation were expected to ensure equal conditions for conformity assessment bodies and avoid unfair competition which undermines the quality of conformity assessment.

4) To strengthen the efficiency and effectiveness of the enforcement of EU legislation to reduce the incidence of non-compliant products on the market

This objective relates to the NLF's role in improving market surveillance in different ways. Whilst outside the scope of this evaluation, this is a crucial element of the NLF.

5) Clear meaning and enhanced credibility for CE marking.

The NLF was expected to reinforce the importance and enhance the clarity of the CE marking through setting out general principles and reference provisions to be integrated in new and revised EU product legislation.

1.2.4. 2.1.4. The intervention logic

The **NLF's intervention logic** aims to examine the inter-relationships between the different components relating to the NLF:

1) The **needs and problems;**
2) The **general** and **specific** objectives that it seeks to achieve;
3) The **inputs** (e.g. human and financial resources) required in order to achieve these objectives, the **activities and implementation processes** and the **expected effects.** The intended causal chains, seen from a theoretical perspective, have been integrated into the mapping. These are shown in terms of the linkages between the general and specific objectives of the NLF, and the **outputs (shorter-term outcomes), results (intermediate**

outcomes) and **impacts** (**longer-term outcomes)** that are expected to be achieved through the NLF.

The following figure provides a visual overview of the intervention logic:

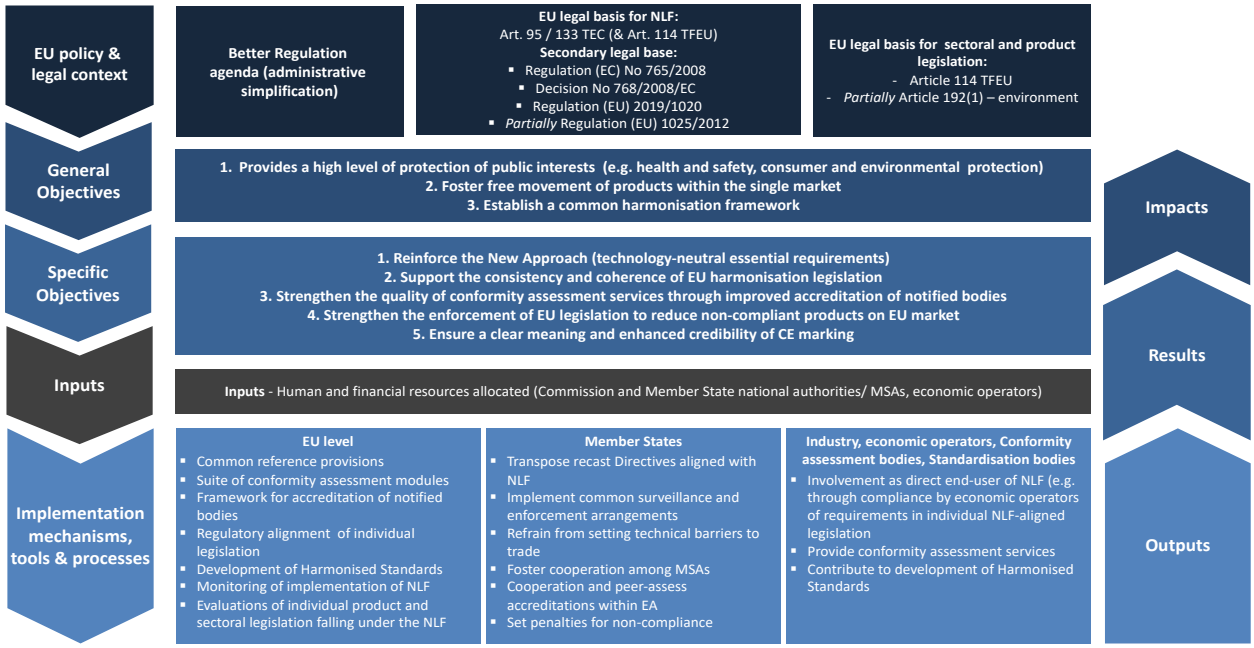

Figure 1 Intervention logic

1.3. 2.2. Points of comparison

In this section we will look back to the situation in the area of EU product legislation before the intervention – the adoption of the NLF.

The separate points of comparison in this section are structured around the specific objectives against which the intervention is assessed, while the description of the pre-intervention state-of-play relies on the findings of the Impact Assessment of 2007.

1.3.1. 2.2.1. Reinforcement of the New Approach

The Impact Assessment of 2007 report explained that the harmonisation legislation and the New Approach could still be improved.

The New Approach directives are based on **technological neutrality**. They contain only the **essential requirements** the product has to fulfil, while products manufactured according to **harmonised standards** are deemed to be compliant with those essential requirements. Technical specifications, in the form of standards[21] allow products to meet the essential requirements needed and are considered as an 'easy' way to meet compliance with the legislation (presumption of conformity). The use of standards guarantees the required level of safety of products, but the use of harmonised standards is voluntary and a manufacturer may use any other technical solution which demonstrates that his product meets the essential requirements.

[21] Harmonised standards are developed by the recognised European Standardisation Organisations (ESOs) CEN, CENELEC and ETSI in line with specific mandates from the Commission.

If a product is not manufactured along the harmonised standards, the manufacturer has to demonstrate the compliance of the product with the legal essential requirements. This New Approach and technical harmonisation have successfully contributed to eliminating some barriers to trade, but there were still weaknesses in the legislative framework, which prevented consumers and enterprises from fully exploiting the benefits of the Internal Market.

The then existing rules were often criticised as **burdensome or for being uncertain or inconsistent**. Also, within the 25 New Approach directives confusion has arisen due to inconsistencies in the requirements for the various elements making it increasingly difficult for all market players and national authorities to comply.

This has resulted in a **lack of credibility and confidence in the system.**

1.3.2. 2.2.2. Supporting the consistency and coherence of EU harmonisation legislation

According to the Impact Assessment of 2007, inconsistencies and legal uncertainty in the pre-NLF regulatory framework were significant.[22]

This represented a problem especially in case of **products that had to comply with different pieces of EU product legislation**[23].

Another problem in this context was the **discrepancy of conformity assessment procedures**. The individual directives have not always stuck to the text of the decision, which was confusing to manufacturer of a products covered by several different pieces of product legislation.[24]

Differences also existed regarding the information which had to be contained in the **declaration of conformity**. This led to **different interpretations in the Member States** which jeopardised the free movement of goods in the Community.

1.3.3. 2.2.3. Strengthening the quality of conformity assessment services through improved accreditation of notified bodies

Product legislation sometimes requires that a product is tested, inspected or certified by an independent third party, a "notified body", before it is placed on the market. Notified bodies hence played an important role already within the New Approach system to guarantee the safety of products on the market. Their competence and capacity to carry out their tasks correctly has always been crucial. The Impact Assessment of 2007, however, identified a lack of confidence in notified bodies and in the whole notification system. The main issues were the following:

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[22] Problems were often experienced with **simple expressions** used in the legislation, such as "manufacturer" or "placing on the market"[22]. Numerous pieces of legislation used these terms without defining them, others contained definitions, but these definitions differed from one legal instrument to the other. The existing definitions and concepts did not always took account of the developments. Sometimes definitions were not sufficiently precise and left room for diverging interpretations.

[23] For example, electrical products, which are (and were then as well) often covered by the Low Voltage Directive, Directive on electromagnetic compatibility, environmental requirements set out in the "ROHS"[23] and "WEEE"[23] directives and, in addition, energy labelling provisions may have also applied to the product.

[24]For example, outdoor machinery was covered by four different directives: the machinery directive, the directive on electromagnetic compatibility, the directive on emission from non-road machinery and the directive on noise emissions from outdoor equipment.

- **Uneven level of conformity assessment services provided by notified bodies**

The interpretation of safety and procedural requirements often varied significantly from body to body.[25] Problems experienced with notified bodies were also relevant in an **environmental context**.[26]

- **Lack of transparency and different approaches in the competence assessment and monitoring of notified bodies**

Industry, public authorities and notified bodies themselves **doubted that all notified bodies actually possessed the required competence to carry out the tasks for which they are notified**.[27] 60% of participants in the public consultation supporting the IA 2007 considered that notified bodies were **not sufficiently monitored**.

- **Unnecessary burdensome requirements in the notification procedure**

The notification procedure was significantly simplified and accelerated due to the introduction of "NANDO-Input"[28], a web-based application designed for the direct notification of conformity assessment bodies, which has been operational since April 2006.

However, the pre-NLF legal framework obliged the Commission **to publish a list of notified bodies in the Official Journal of the European Communities** for information purposes before encoding them in the NANDO database. The lists were typically published once per year, whereby there was sometimes a significant time period between the notification of a body and the publication of a new list.

- **Lack of an EU framework for accreditation and the legal status of the European Cooperation for Accreditation (EA)**

Different approaches and differing systems for accreditation existed throughout the EU causing an uneven level of rigour throughout Member States[2930].

Member States co-ordinated their accreditation activities through the framework created by a pan-European organisation known as EA[31]. However, **the position and influence of EA was limited** by its legal status and its recognition by public authorities varied from Member State to Member State,

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[25] This resulted in forum shopping for conformity assessment bodies based, for instance, on low prices or less rigorous services.

[26] A few directives had already addressed environmental aspects and foreseen the intervention of notified bodies in the conformity assessment process. Consequently, the downgrading of quality in the service delivered by notified bodies could have seriously hampered the effective functioning of this control mechanism and result in products on the market which are harmful to the environment.

[27]Evaluation of the application of the Lifts Directive, Final Report for DG Enterprise, 2004; Report on the functioning of the medical devices directive 20002; Impact assessment on the proposal for a Directive on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations http://ec.europa.eu/governance/impact/docs/ia_2005/sec_2005_1498_fr.pdf,

[28]NANDO = New Approach Notified and Designated Organisations

[29]Accreditation of testing and certification bodies, KAN report 30e, June 2003.

[30] Most Member States used accreditation for evaluating the competence of a notified body and considered it as a useful qualification element for granting notification. However, since accreditation has been regulated at national level, due to different designation, accreditation and monitoring policies, notified bodies were operating under uneven conditions inside the EU.

[31]EA is a non-profit association established in November 1997 and registered as an association under Dutch law in June 2000. EA results from the merger of EAC, European Accreditation of Certification, and EAL, European co-operation for Accreditation of Laboratories.

due to the lack of common legal basis and of regulation on accreditation at EU level and a harmonised accreditation policy.

1.3.4. 2.2.4. Ensuring a clear meaning and credibility of CE marking

By affixing the CE marking to the product the manufacturer declares that the product is in conformity with all applicable directives providing for the CE Marking. A product bearing CE marking, benefits from the free movement of goods inside the Union. However, **pre-NLF legal texts did not give a definition or explained the meaning of the CE marking**.

The CE marking was well known in the marketplace but **its meaning was often unclear**.[32]

CE marking represented the whole system of product conformity under the New Approach, and therefore **weaknesses in the functioning of the system undermined the confidence in the CE marking.** Lack of confidence in the CE marking had negative repercussions on industry. Manufacturers needed to have enhanced recourse to additional marking/testing to ensure the confidence of the market place in their products.

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

This section will outline the evolution of the EU product legislation following the adoption of the NLF. The state of play is presented focusing on outputs, results and impacts. To ensure a logical flow that is easy to follow, the presentation of the developments is structured around the specific objectives of this evaluation, similarly to the points of comparison in the previous section (see subtitles 2.2.1. – 2.2.4.).

1.4. 3.1. Current state of play

1.4.1. 3.1.1. The NLF and the reinforcement of the New Approach

Specific objective: Reinforcement of the New Approach
Output (immediate short-term outcomes): Number of NLF-aligned legislation
Results (intermediate outcomes, linked to the achievement of specific objectives) ➢ Availability of the regulatory toolbox to facilitate the revision of existing and drawing up of new Union harmonisation legislation; ➢ Availability of common definitions for sectoral product legislation; ➢ A framework that allows for technological evolution with technology neutral legislation setting only essential requirements.

Thanks to the NLF, the New Approach gained ground in NLF-aligned EU product legislation, which ensured the uniform application and reinforcement of the New Approach. **The reference provisions, often called as a regulatory toolbox**, set out in Decision No 768/2008/EC ensured the **availability of common definitions for the sectoral product legislation**.

[32] Studies have demonstrated that consumers in particular had a poor understanding of the role of CE marking. It was often perceived as an indication of origin or as a proof that CE marked products have been tested and approved by some kind of authority. For more information see: CE - A study of consumers' and retailers' knowledge of the CE mark, The Swedish Research institute of Trade, 2004

The NLF-aligned legislation is therefore reflecting the same structure and content of the common regulatory toolbox and its reference provisions. The regulatory toolbox, a model for revised and new product legislation, became available to facilitate the revision of existing and drawing up of new Union harmonisation legislation[33].

The reinforcement of the New Approach via the NLF also comprises the **emphasis of technological neutrality of product legislation and the presumption of product compliance with the essential requirements set out in the legislation and expressed in technical terms in the harmonised standards.**

The Study of the CSES showed that this feature of the NLF is highly appreciated.

However, when harmonised standards are not available, the manufacturer may only rely on third-party assessment to prove that the product meets the essential requirements laid down in the legislation (See Chapter 4.1.1.).

1.4.2. 3.1.2. Supporting the consistency and coherence of EU harmonisation legislation

Specific objective: Supporting the consistency and coherence of EU harmonisation legislation
Output (immediate short-term outcomes): Integration of the common reference provisions into the aligned product legislation
Results (intermediate outcomes, linked to the achievement of specific objectives) ➢ Better alignment of the requirements for economic operators and of the approach to marketing products on the internal market; ➢ Reduced divergences and clearer administrative requirements; reduced costs of compliance (i.e. costs of familiarisation with Union harmonisation legislation and costs of conformity assessment procedures).

Definitions and common reference provisions are integrated in all NLF-aligned legislation. The aligned legislation may depart, totally or partially, from the common principles and reference provisions laid down in Decision No 768/2008/EC on account of the specificities of the sector concerned. However, any such departure should be justified.[34]

Following the adoption of the NLF, the gradual alignment of EU product legislation started and still continues. For example, although the Machinery Directive has not yet been aligned to the NLF, the recent Proposal of the Machinery Regulation does envisage alignment.

The number of the product legislation aligned with the common framework of the NLF from 2008 is 23 and on delegated act and they are presented in the table below:

[33] Chapter R1 of Annex I of Decision No 768/2008/EC provides a common structure for the presentation of definitions within Union harmonisation legislation, as well as 17 common definitions, covering key product legislation-related terms. More specifically, these definitions cover:
Relevant stakeholders, including 'national accreditation body', 'conformity assessment body', and 'economic operators', as well four different types of economic operators (the manufacturer, the authorised representative, the importer, the distributor); and
Other key terms related to products, such as 'making available on the market', 'placing on the market', or conformity assessment procedures, such as 'CE marking' and 'accreditation'.
This catalogue of definitions is supplemented by Article 2 of Regulation (EC) No 765/2008, which includes additionally the definitions of accreditation, national accreditation bod and peer evaluation.

[34] Recital 6 of Decision No 768/2008/EC.

EU Legislation	Description
Directives	
Toy Safety Directive	Directive 2009/48/EU
Transportable Pressure Equipment Directive	Directive 2010/35/EU
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive	Directive 2011/65/EU
Pyrotechnic Articles Directive	Directive 2013/29/EU
Recreational Craft and Personal Watercraft Directive	Directive 2013/53/EU
Civil Explosives Directive	Directive 2014/28/EU
Simple Pressure Vessels Directive	Directive 2014/29/EU
Electromagnetic Compatibility Directive	Directive 2014/30/EU
Non-automatic Weighing Instruments Directive	Directive 2014/31/EU
Measuring Instruments	Directive 2014/32/EU
Lifts Directive	Directive 2014/33/EU
ATEX Directive	Directive 2014/34/EU
Radio Equipment Directive	Directive 2014/53/EU
Low Voltage Directive	Directive 2014/35/EU
Pressure Equipment Directive	Directive 2014/68/EU
Marine Equipment Directive	Directive 2014/90/EU
Regulations	
Construction Products Regulation**	Regulation (EU) No 305/2011
Cableway Installations Regulation	Regulation (EU) 2016/424
Medical Devices Regulation	Regulation (EU) 2017/745
Personal Protective Equipment Regulation	Regulation (EU) 2016/425
In vitro Diagnostic Medical Devices Regulation	Regulation (EU) 2017/746
Gas Appliances Regulation	Regulation (EU) 2016/426
EU Fertilising Products Regulation	Regulation (EU) 2019/1009
Delegated acts	
Commission Delegated Regulation on unmanned aircraft systems and on third-country operators of unmanned aircraft systems	Commission Delegated Regulation (EU) 2019/945

Table 1 Aligned EU legislation and non-legislative acts of general application

In general, the **alignment of product legislation to the NLF has resulted in limited differences** across the 23 pieces of NLF-aligned legislation and one delegated act, which have been partly removed through further horizontal harmonisation brought by Regulation (EU) 1025/2012 and Regulation (EU) 2019/1020. This perspective is clearly illustrated by the responses to the targeted consultation.

The legislative mapping included in the Study of CSES compares the legal text of the 23 NLF-aligned legislation with the NLF reference provisions. This exercise demonstrates that there are **only minor differences across the entire body of the NLF-aligned legislation** (please see Annex X – Mapping of the NLF aligned legislation).

Union harmonisation legislation imposes an obligation on the manufacturer to draw up and sign an **EU Declaration of Conformity** before placing a product on the market. The model for this declaration is contained in Annex III of Decision No 768/2008/EC. The NLF-aligned product legislation either refers to that model declaration or the model is directly annexed to the sectoral Union harmonisation legislation at stake.[35]

[35] The standard EN ISO/IEC 17050-1 has been drawn up with the objective of providing the general criteria for the declaration of conformity, and it can also be used as a guidance document provided it is in line with the applicable Union harmonisation legislation. Where several pieces of Union harmonisation legislation apply to a product, the manufacturer or the authorised representative has to provide a single declaration of conformity in respect of all such Union acts. The model of the EU declaration of conformity is used in all NLF-aligned legislation, except the

The integration of common reference provisions resulted in **better alignment** of the requirements for economic operators and of the approach to marketing products on the internal market. In addition, the Study of CSES shows that in the past ten years regulations are representing a growing trend comparing to directives as harmonisation instruments. Considering that regulations are directly applicable and do not need transposal to the national systems of the Member States, this choice of instrument is also preferred by the industry because it allows less scope for ambiguity and divergence in interpretations and implementation.[36]

1.4.3. 3.1.3. Strengthening the quality of conformity assessment services through improved accreditation of notified bodies[37]

Specific objective: Strengthening the quality of conformity assessment services through improved accreditation of notified bodies
Output (immediate short-term outcomes): Common conformity assessment system and accreditation framework
Results (intermediate outcomes, linked to the achievement of specific objectives) ➢ Clearer and more robust rules on the conformity assessment system; ➢ Higher quality and more consistent third-party conformity assessment services.

To ensure a uniformly high level performance of notified bodies and their fair competition throughout the Union, the legislation that follows the NLF set out obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services[38]. To guarantee a consistent level of quality in the performance of conformity assessment, the legislation that follows the NLF set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of bodies. The system of notified conformity assessment bodies set out in Decision No 768/2008/EC is complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Although not mandatory for all notified bodies, accreditation is the most preferred means of verifying the competence of conformity assessment bodies. It provides an authoritative statement of the competence, professional integrity and impartiality of the bodies to be notified to the Commission and the other Member States.

The NLF strengthened the supervisory role of notifying authorities. When it ascertains that a notified body no longer meets the requirements set out in the relevant directive or regulation or is

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Construction Product Regulation and the Transportable pressure equipment directive, which do not provide for the obligation of the manufacturer to draw up such declaration. Some of the NLF legislations that are covering products with a higher safety risk and more complex conformity assessment depart slightly from the model, requesting more safety related and details on the notified bodies taking part in the different modules of the conformity assessment (Lift Directive, Pressure Equipment Directive, Recreational craft and personal watercraft Directive, Cableway Installations Regulation, Medical Devices Regulation, *In vitro* diagnostics Medical Devices Regulation). The Lifts Directive also requires different forms for manufacturers of safety components for lifts (Annex II.A) and installers of lifts (Annex II.B).

[36] The Study of the CSES enumerates several pieces of EU harmonisation legislation that were converted from directives to regulations following their revision, such as the Construction Products Regulation, the Regulations on Medical Devices and on *In Vitro* Diagnostic Medical Devices, the Gas Appliances Regulation. In addition, the Proposal for the Machinery Regulation, published in April 2021, aims to replace the Machinery Directive and continue this trend

[37] More details on the System of notified conformity assessment bodies in included in Annex VI – Conformity assessment – State of Play.

[38] Recitals 37-39 of Decision No 768/2008/EC

failing to fulfil its obligation, the notifying authority may restrict, suspend or withdraw the notification[39].

The notification system also became simpler. The notified bodies encoded in the NANDO database do not need to be published previously in the Official Journal of the EU.

The adoption and practical implementation of the EU legal framework for accreditation is a very important achievement under the objective of strengthening the conformity assessment system in Europe.

The NLF created the European system for accreditation of conformity assessment bodies. Regulation (EC) No 765/2008 recognised **the EA** as a single organisation at European level and introduced a mandatory membership of the national accreditation bodies in the EA. The EA is responsible for the peer evaluation for its members (national accreditation bodies).

The conformity assessment system detailed in the NLF[40] underpins the entire internal market, as it represents the means by which economic operators demonstrate the compliance and conformity of their products with the essential requirements laid down in specific product legislations.

1.4.4. 3.1.4. Ensuring a clear meaning and enhanced credibility of CE marking

One of the key needs of the internal market at the time when the NLF was developed was to clarify and enhance the meaning of the CE marking.

The CE marking indicates that a product is declared by the manufacturer as in conformity with Union harmonisation legislation. CE marking is the visible consequence of a whole process comprising conformity assessment in a broad sense.

Member States are not allowed to restrict the placing on the market of CE marked products, unless such measures can be justified on the basis of evidence of the non-compliance of the product. This also applies to products made in third countries which are sold in the EU.

Regulation (EC) No 765/2008 lays down the definition, the format and the general principles governing the CE marking, while Decision No 768/2008/EC provides for the reference provisions to be integrated into product legislation on the general principles of CE marking (Article R11) and the rules and conditions for affixing the CE marking (Article R12).

The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate[41].

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[39] Based on the NANDO database, the evaluation established the following: Besides the *expired* and *withdrawn* notification, from 2013 the category of *suspended* notification has been introduced. While expired and non-extended notifications are not necessarily attributable to any monitoring activities of the notifying authorities, suspended and withdrawn notifications are clearly related to the controls conducted by the notifying authorities. The number of suspended and withdrawn notifications suddenly raised from 2013. While this number is between 2 and 4 per year in 2010-2012, it is 72 in 2013, 64 in 2014, 72 in 2015, 160 in 2016, 40 in 2017, 28 in 2018, 40 in 2019 and 37 in 2020. Therefore, we can conclude that due to the requirements set by the NLF, the notifying authorities strengthened the supervision of the notified bodies.

[40] Annex II of Decision 768/2008/EC sets out in details 8 different overarching modules from module A, which does not include a third-party assessment, to module H, which is based on a full quality assurance.

[41] The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant Union harmonisation acts. The CE marking replaces all mandatory conformity markings having the same meaning, which existed before harmonisation took place. Such national conformity markings are incompatible with the CE marking and would constitute an infringement of the applicable European legislation in question.

Several pieces of Union harmonisation legislation foresee additional markings that are complementary and non-overlapping to the CE marking[42].

4. EVALUATION FINDINGS (ANALYTICAL PART)

1.5. 4.1. To what extent was the intervention successful and why?

This chapter will outline the success of the NLF in terms of its effectiveness (fulfilling expectations and meeting the objectives), efficiency (in terms of the proportionality of its cost and benefits) and coherence (internal and external).

The evaluation matrix in Annex 2 of the underlying Study, which is also included in Annex 3 of this SWD, lists the data and information sources and evidence base, as well as the assessment methods of the general and specific objectives of the NLF. The methods used for assessing the specific objectives are desk research including legal mapping, targeted survey and the interview program. RAPEX-Safety Gate and NANDO were also used as a source of information when relevant.

In general, according to the majority of stakeholders, the NLF has provided a satisfactory benchmark for sectoral legislation that has been revised or modified since 2008, particularly considering the omnibus alignment of ten sectoral directives adopted in 2014 (see in Chapter 1.1., footnote 14 and 15).

Respondents to the consultations were likely to consider the NLF to have been effective in achieving its general objectives: The reinforcing of the free movement of products within the single market and ensuring a high level of protection of public interests. Based on the triangulation of the results of the consultations and interviews, stakeholders consider that it also succeeded in achieving of its specific objectives, which are the reinforcing of the technology neutral approach, better coherence, strengthened conformity assessment and enforced visibility and clarity of the CE marking system.

1.5.1. 4.1.1. Effectiveness

a) Reinforcement of the New Approach

The NLF ensured the **reinforcement of the New Approach** thanks to the creation of the regulatory toolbox and common definitions. All the NLF-aligned legal instruments are using the same definitions such as ‘manufacturer’ or ‘placing on the market’. This aspect of the effectiveness of the NLF is highly appreciated particularly when products are covered by more than one product legislation. The evidence used for the assessment was based on desk research including the legal mapping[43] and confirmed in the targeted surveys, interviews and validation workshop.

The NLF also managed to **reinforce the technology-neutral approach to setting essential requirements for the EU product legislation**.

The results of desk research are complemented here by the results of the targeted survey, interview program and stakeholders’ workshop. The majority of stakeholders throughout all stakeholders groups in the targeted consultations (84.1%, 174/207) considered the use of **harmonised standards**

[42] For example, the EU energy label for energy-related products; the specific marking of explosion protection required for equipment and protective systems intended for use in potentially explosive atmospheres; the supplementary metrology marking required for measuring instruments and non-automatic weighing instruments.

[43] More information is available in the Study: Section 4.1.2. Achievement of the NLF’s general objectives and Annex 7 Mapping of NLF-aligned legislation.

to have been effective **as a voluntary mechanism for achieving of conformity** with the essential requirements. They consider that as a technologically neutral regulatory framework based upon essential requirements, the NLF is perfectly suited to cope with the **higher speed of technical innovation** and customization coming with digitization, avoiding the stiffness and inflexibility of technical provisions fixed in laws.

Stakeholders in the interviews and targeted consultations often stress, however, that the effectiveness of the NLF might be jeopardized by reasons that despite not stemming from the NLF, may have a serious impact on its implementation. If harmonised standards are not available the moment when the new EU product legislation starts to apply (see title 3.1.1. above), manufacturers do not have recourse to harmonised standards and cannot rely on the presumption of conformity with the essential requirements. National competent authorities pointed out that **the success of the NLF depends heavily on having a quick and effective standardisation process**. If the citation of harmonised standards is too slow (or, effectively, non-existent), this renders **market surveillance more difficult**, to the detriment of the level-playing field for companies.

On one hand, the demonstration of conformity in the absence of harmonised standards represents a **more serious financial burden**[44] for manufacturers, because they may only rely on third-party assessment instead of harmonised standards to prove that the product meets the essential requirements laid down in the legislation. They would need to have recourse to documenting compliance with different generations of standards, which leads to additional costs.

On the other hand, the delay in adopting new standards is **hindering innovation**[45], because the manufacturers that are departing from the standards to introduce innovative solutions are not able to rely on the presumption of conformity with the essential requirements. In that case, the presumption of conformity with the standards might become a double-edged sword: If the harmonised EU standards lag behind the newest international standards representing the state of the art, the NLF is not able to perform as expected. The presumption of conformity with a legal provision conferred by conformity to a harmonised standard would not seem to support innovation.

Specific product legislation should, wherever possible, avoid going into technical details. It should limit itself to the expression of essential requirements. However, where health and safety, the protection of consumers or of the environment, other aspects of public interest, or clarity and practicability so require, detailed technical specifications may be set out in the legislation concerned. [46] Nonetheless, industry stakeholders are highlighting that there is a trend in the new legislative proposals of EU product legislation to incorporate more granular technical requirements. Better implementation of the NLF, without technical details included in the product legislation whenever it is not absolutely necessary would help ensure the technological neutrality of the framework. According to these stakeholders, the impact of this tendency is reduced flexibility of the NLF-aligned legislation and of the framework to deal with changes in the market, an erosion of the

[44] An example: A large European association active in the digital sectors cited the example of the entry into force of the Radio Equipment Directive. All manufacturers of radio equipment hast to undergo a third-party conformity assessment, if the harmonised standards are not used. However, approximately a third of the updated RED standards were not cited in the OJEU when the Directive started to apply. The huge amount of certification request was on one hand challenging to handle for the notified bodies, while on the other hand added costs and delays for placing products on the market.

[45] A renowned pump manufacturer stressed when the market is moving faster than the development of standards that are used as a reference by the notified bodies to perform their service, the innovative products cannot benefit from the presumption of conformity with the applicable product legislation. This viewpoint was confirmed by a renowned manufacturer of garden machinery who had a deceptive experience in resorting voluntarily to a NB to have a second opinion on innovative ideas. Therefore, the industry often perceives that standards, technical specifications or procedures do not match market needs, and could ultimately constitute a barrier to trade or to innovation.

[46] Recital 8 of Decision No 768/2008/EC

principle of technological neutrality, resulting in negative impacts on innovation and competitiveness.

The performance of the NLF regarding its general objective to ensure the safety of products through the EU has been demonstrated in the Study of the CSES relying on the RAPEX-Safety Gate database (Annex IX). Nonetheless, the attribution of the results of this analysis is significantly impacted by the different market trends and changes for different products (including the increase of e-commerce from third countries) and also by the different practices of the national market surveillance authorities. These factors strongly influence both the number of unsafe products identified and reported via Safety Gate, and their proportion by product category from one Member State to another.

Based on the triangulation of the evidence collected in this evaluation **we conclude that the NLF shows a high level of effectiveness in ensuring the reinforcement of the New Approach, relying on the technological neutrality of legislation containing only essential product requirements.** Nonetheless, the full achievement of this approach requires consistency of the legislator not to include more detailed requirements into EU product legislations than necessary. It also requires the prompt delivery of harmonised standards, which is outside of the scope of the NLF.

b) Supporting the consistency and coherence of EU harmonisation legislation

The mapping of NLF-aligned legislation in Annex X corroborates the results of the surveys that the NLF showed a high level of effectiveness in regard of the **alignment of EU product legislation[47].** The majority of respondents perceive that the NLF has been effective in facilitating the consistency and coherence of different EU harmonisation legislation.

44.8% of stakeholders (94 respondents) consider that, overall, the NLF has been effective to a great extent in **facilitating the consistency and coherence of different EU harmonisation legislation for products**, while 32.9%, (69 respondents) consider it to have been effective to a moderate extent.

However, views varied considerably by stakeholder type. Among the larger groups of stakeholders (types with over ten responses), national accreditation bodies were most likely to consider that the NLF has been effective in facilitating the consistency and coherence of different EU harmonisation legislation for products 'to a great extent': 80% held this view (16 responses). National notifying authorities were least likely to share this view (26.3%, five responses), just behind notified bodies / conformity assessment bodies (27.9%, 17 responses) and MSAs (28.6%, six responses). The reason for the differences in views of accreditation bodies on the one hand and notifying authorities on the other hand may lie in the different level of harmonisation of accredited and non-accredited notified bodies. The accreditation framework established by the NLF relies on accreditation standards and peer evaluation conducted by the EA. In some Member States only accredited conformity assessment bodies may become notified bodies, while in others accreditation is not mandatory for the notification. Desk research and the interviews conducted by the contractor showed[48] that the common reference provisions in the aligned sectoral legislation led to **reduced divergences** among those legislations. Businesses are able to find the same types of provisions in the different pieces of product legislation: definitions; the obligations of economic operators (manufacturers, authorised representatives, importers, distributors); conformity of the product; EU declaration of conformity; general principles and rules on CE marking; notification and rules on notified bodies and safeguard

[47] More information is available in the Study: Section 4.1.1.1. Level of alignment of product harmonisation legislation with the NLF.
[48] More information is available in the Study: Section 4 *To what extent was the NLF successful and why?*.

procedures. The obligations of the economic operators are **clear and repetitive from legislation to legislation,** therefore the efforts of familiarisation with the harmonisation legislation are less burdensome. Furthermore, Annex II of Decision No 768/2008/EC contains the different types of conformity assessment modules (from self-assessment to various types and rigour of third-party assessments) among which the legislators of the sectoral legislation may choose, depending on the risk related to specific products.

The 2014 Evaluation of the Internal Market Legislation for Industrial Products already concluded that the NLF provided a clearer definition of the obligations for different economic operators and supported administrative simplification across many areas of the legal framework[49] (e.g. through the common suite of conformity assessment modules and the declaration of conformity template). The evaluation results were reported in the context of the Commission Communication 'A vision for the internal market for industrial products'.

The better alignment was further improved by the Guide to the implementation of directives[50] based on the New Approach and Global Approach, published in 2000, which was updated in 2016. The Blue Guide explains the provisions of the Decision and the Regulation to ensure their consistent interpretation throughout the body of the EU product legislation. The latest revision of the Blue Guide was adopted on 13 June 2022. Nevertheless, certain **divergent requirements have been identified** in the Study[51] during the desk research and interviews between NLF-aligned legislation and the NLF reference provisions, as well as between different pieces of Union harmonisation legislation. In this respect, the targeted consultation was seeking for an answer from economic operators and industry associations to what extent they had experienced problems because of divergent requirements between EU product legislation in the following areas: administrative obligations; sectoral-specific requirements; conformity assessment modules and procedures; definitions of economic operators; and safeguard clauses.

Across all areas combined, most respondents have experienced problems[52] from a small to a great extent because of divergent requirements between one or more pieces of EU product legislation. Economic operators and industry associations identified administrative obligations (e.g. mandatory registration / labelling / declarations) as the aspect most likely to be problematic to a great extent. Conformity assessment modules and procedures were most likely to cause problems to them 'to a moderate' extent.

Although, from the perspective of each individual piece of legislation, the differences with the NLF reference provisions are minor, industry stakeholders and conformity assessment stakeholders in particular have commented in the interviews and targeted consultations on the **cumulative impact of numerous smaller differences**. These stakeholders highlight that, when a product is subject to multiple Union harmonisation legislations, any increase in the complexity of conformity assessment, due to an accumulation of minor differences in rules, **also increases the costs of compliance**.

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[49] More information is available in the 2014 Evaluation of the Internal Market Legislation for Industrial Products: Section 2.3.1 Regulatory simplifications and clarification measures.

[50] European Commission, Directorate-General for Enterprise and Industry, *Guide to the implementation of directives based on the new approach and the global approach*, Publications Office, 2000

[51] More information is available in the Study: Section 4.1.1.1 Level of alignment of product harmonization legislation with the NLF.

[52] More information is available in the Study: Section 4 *To what extent was the NLF successful and why?*, Figure 4-3: Problems experienced because of divergent requirements between one or more pieces of EU product legislation (Question 16, N=50)

The mapping of the NLF aligned legislation in Annex X lists the 23 pieces of NLF-aligned legislation, pointing to the provisions departing from the NLF.

In terms of definitions set out in the NLF, the majority of stakeholders perceive that these definitions are clear and have brought greater coherence to the application of legislation and its interpretation when enforced by Member State authorities.

Desk research showed that some EU legislations contain definitions to impose obligations on specific economic operators in the supply chain, whose role is not defined in the NLF, when it is necessary to ensure the safety of certain products[53]. Nonetheless, industry reports about difficulties experienced due to inconsistencies caused by unnecessary divergences of legislation from NLF principles. To avoid unnecessary divergences, some stakeholders stress that proposals for EU product legislation should be scrutinized from the perspective of alignment with the NLF principles, whereby, as suggested at the stakeholders' workshop, any divergences should be justified and explained in the recitals of the legislation as they may cause unnecessary financial burden and generate legal uncertainty.

Based on the triangulation of the evidence collected in this evaluation, **we conclude that the NLF has been effective in facilitating the consistency and coherence of different EU harmonisation legislations.** Among the important achievements are reduced divergences, in large extent thanks to the clear and repetitive obligations of economic operators. Nonetheless, the cumulative impact of minor smaller divergences may increase the costs of compliance.

c) Strengthening the quality of conformity assessment services through improved accreditation of notified bodies

The NLF **set clear and robust rules for notified conformity assessment bodies**. Overall, most stakeholders across all groups have stated that the NLF approach ensures the safety and compliance of products placed on the single market. The desk research showed that NLF has positively impacted the implementation of the conformity assessment system and the process for notification of conformity assessment bodies. Industry noted during the interviews[54] that the continuity in conformity assessment procedures between the New Approach and the NLF is positive. This stems not only from the adoption and implementation of the rules for the accreditation of conformity assessment bodies stipulated in Regulation (EC) No 765/2008, but also from the reference provisions for specific product legislation on conformity assessment, including the suite of conformity assessment modules, and the notification procedure for conformity assessment bodies.

The frequency with which industry stakeholders use the services of NBs/CABs (whether required or not) was examined through the targeted consultation. 36 out of 82 industry respondents (individual economic operators or industry associations) reported that they or their member organisations use NBs / CABs 'Always' (12 responses) or 'Often' (24 responses). Only 3 respondents out of 82 reported that they 'Never' use the services of NBs / CABs.

Among **the NLF's most beneficial aspects**, stakeholders frequently mentioned during the interviews the harmonised conformity assessment and accreditation system, which enables the free movement of goods within the EU. Others suggested that the NLF's main advantage is that it

[53] For example, Article 2(6) of the Directive 2014/33/EU on lifts defines the installer as economic operator, to impose responsibilities on the person who makes a product operational and ready to use. Hence, the installer is a person who assumes responsibilities which in the context of other Union harmonisation legislation are typically assigned to the manufacturer.

[54] More information is available in the Study: 4.1.1.2. Conformity assessment of the accreditation framework.

determines **the requirements for bodies assessing the conformity of products**, which increases trust in their competence and the quality of their work. In relation to conformity assessment, industry representatives clearly stated that they perceive **module 'A'** (internal production control, without a mandatory involvement of a third party)**, in combination with effective market surveillance**, to provide a good and fair level playing field for manufacturers.

In terms of the NLF's effectiveness at providing **rules for notified bodies**, stakeholders' views varied. 54,8% (74/130) of the respondents in the targeted consultations agreed, to a great extent, and 26,9% (35/130) to a moderate extent that the NLF provides an adequate set of requirements to ensure the independence of notified bodies.

When it comes to the question of **personnel and real activity that the NB has to perform by itself without outsourcing**, only 22% (34/135 responses) agreed in the targeted consultations to a great extent that the NLF is sufficiently clear on that issue. 22.2% (30/135) considered this sufficiently clear to a moderate extent; 27.4% (37/135) to a small extent; 5.9% not at all, while 17.7% did not know.

Some stakeholders participating in the interview program were wondering **if there is a limitation regarding the tasks of notified bodies that must be performed by an employee of the notified body**. More precisely, whether the certification decision should be taken by a person who is employed in the notified body. Such requirement is set in Section 3.2.7 of Annex VII of the Medical Device Regulation (EU 2017/745): "*The personnel with overall responsibility for final reviews and decision-making on certification shall be employed by the notified body itself and shall not be external experts or be subcontracted.*"

Desk research and interviews showed that some Member States established the same requirement for their notified bodies in all areas and not only under the Regulation on medical devices, while in the others the decision-making can also be subcontracted. It is reported to be a common practice in global organization groups that the decision-maker is a contracted staff in a third country and therefore the whole certification activity of the notified body takes place in a third country.

The Blue Guide explains that a notified body *must have appropriate personnel* and equipment and be able to carry out all necessary tests and evaluations according to the requirements of the modules itself. It is not possible to subcontract a task for which the notified body has no competence itself. The notified body cannot under any circumstances subcontract all of its activities, as that would make the notification meaningless.

Assessing **whether the rules for notified bodies are robust enough to ensure their competence**, 78.5% of stakeholders (106/135 respondents) in the targeted consultations considered that, at least to a moderate extent, the overall requirements set by the NLF are robust enough to ensure the **competence of notified bodies**, including 46.7% (63/135 respondents) who considered this to be the case to a great extent.

Nonetheless, when it comes to **subcontracting of substantial technical tasks of notified bodies,** certain difficulties have been identified based on desk research. The Evaluation of the Internal Market Legislation for Industrial Products[55] also noted that ensuring the quality of services when the subcontractor is located outside the EU is already a challenge and existing subcontracting practices make this even more problematic, particularly in relation to products where third-party certification is mandatory.

[55] More information is available in the Evaluation of the Internal Market Legislation for Industrial Products: 4.3.2 Regulation of Notified Bodies

The stakeholders addressed problems related to the subcontracting of the activities to foreign subsidiaries, such as the **difficulties to monitor subsidiaries of notified bodies in another EU or non-EU country**. The Commission service dealing with marine equipment observed that in this sector there is a tendency for non-EU owned conformity assessment bodies to set up subsidiaries in the EU which are then formally notified as notified bodies. In some cases, these have been found to be mere **letterbox companies**, **with no permanent full-time staff in the notifying Member State.** There is an example for both, accredited and non-accredited notified bodies owned by a third-country company, without any staff or employing one person in the Member State. For the actual work, these companies are fully dependent on the services subcontracted from their non-EU based mother companies. This results in a situation where, for example, a manufacturer established in a third country can obtain access to the EU market by relying entirely on a third country conformity assessment infrastructure, raising questions about the EU's autonomy in this area.

Most of these problems are due to **insufficient monitoring activities of the subcontracted tasks and subcontractors** if these activities are outsourced outside the European Union. The notifying authority/accreditation body has to assess the extent to which the notified body wants to rely on subcontractors and the authority may withdraw and limit the scope of the notification.

It is important to highlight that if the notifying authority /accreditation body is not capable of **ensuring effective monitoring of the competence of the body responsible for the tasks subcontracted by the notified body, it should not allow the subcontracting**. Nonetheless, in 2020 the Commission received information from national market surveillance authorities and industry associations questioning the practices of an accredited notified body, with respect to the certification of FFP masks. Although the notified body cannot outsource all its activities and restrict them to purely administrative function, in that specific case the activities of the notified body were minimalized and the extent of outsourcing seemed to approach the entire activity of the notified body. The high number of RAPEX-Safety Gate notifications also indicated that the subcontracted tasks were threatening to undermine the quality of such services and raising the question of unfair competition and a level playing field. Following the correspondence between the Commission and the accreditation body, the notification of the notified body was not extended after its expiry.

The notified body cannot in any circumstances subcontract all of its activities and restrict its engagement to only administrative tasks. Better implementation of the existing rules on subcontracting by the notifying authorities/accreditation bodies could most probably improve the current situation and eliminate those subcontractors that cannot be effectively monitored and the so called 'letter-box' notified bodies fully dependent on the services subcontracted to their non-EU based mother companies. Nonetheless, stakeholders seem to agree that the NLF does not provide enough clarity on the mandatory staff, on the extent of the mandatory real activity of the notified body and possible limitations of the tasks to be subcontracted.

In terms of the effectiveness of the accreditation framework, the overall feedback from all stakeholders consulted, including prominent industry associations, suggests that the **accreditation system functions well and ensures that the competence of the accredited notified bodies** intervening in the conformity assessment procedures is sufficiently guaranteed.

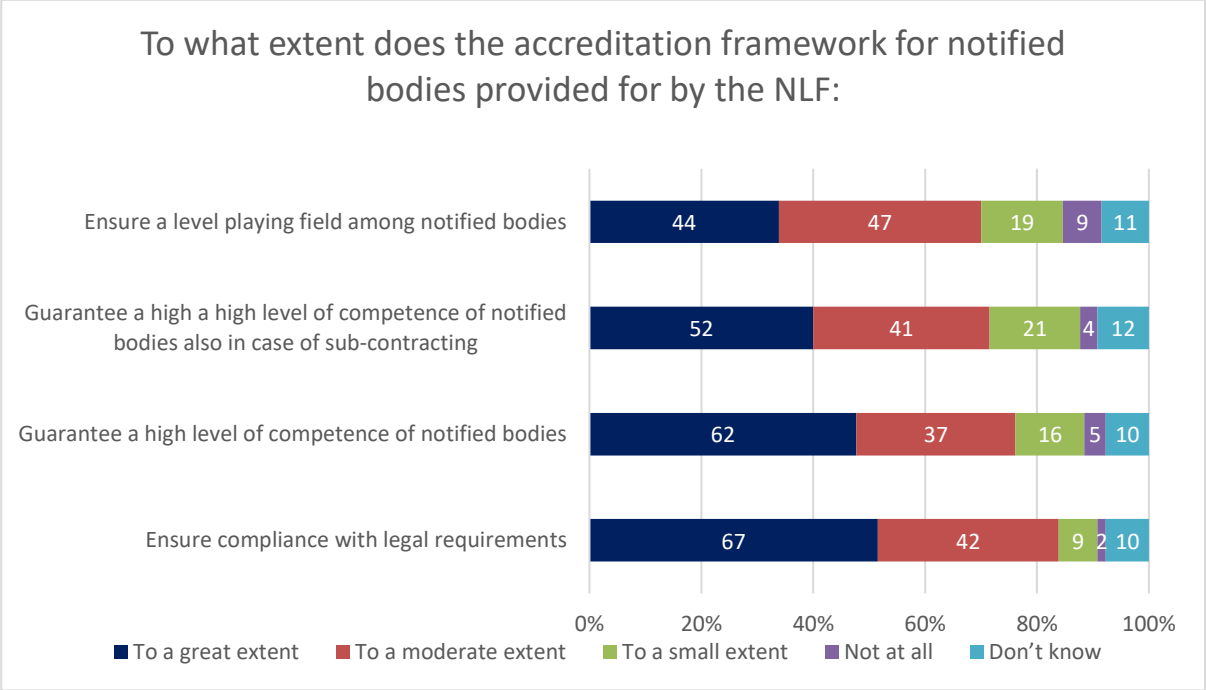

Figure 2 Targeted consultations: Effectiveness of the accreditation framework set-up by the NLF (Question 27, N=130)

In support of that feedback, the most frequent arguments are that the NLF has improved both, the mutual confidence in test reports and certificates of conformity for cross-border trade and reducing the process associated with notification and designation. Industry stakeholders further highlighted that this reduction of differences in the activities carried out by notified bodies has increased fair competition between businesses.

As already explained in chapter 3.1.3., **accreditation**[56] is the preferred means of verifying the competence of conformity assessment bodies, but it **is not mandatory**. Therefore not all notified conformity assessment bodies are also accredited conformity assessment bodies. Even if conformity assessment bodies can be notified as accredited or non-accredited notified bodies, based on the data available in the NANDO database, we can see that the number of accredited notified bodies significantly outweigh those that are not accredited: 82% (2125) of all notified bodies (2589 in June 2022) are accredited, while only 18% (464) are not accredited.

43.8% (53 of 130) of the respondents in the targeted consultation agreed that the **NLF does not ensure that the procedures for monitoring non-accredited notified bodies are sufficiently reliable and appropriate for the purposes of notification**. In contrast, only 15.4% (20/130) of respondents, 9 of which were national notifying or competent authorities, considered these procedures to be reliable and appropriate.[57]

[56] More details on the **accreditation process** and the challenges identified in the European system for accreditation are included in Case Stydy No. 2 in Annex VIII.

[57] Results of Question 30 (N=130): While accredited notified bodies are monitored by the accreditation body, the monitoring of non-accredited notified bodies is ensured by national notifying authorities using alternative means. Does the NLF ensure that these alternative procedures for monitoring the non-accredited notified bodies are sufficiently reliable and appropriate for the purposes of notification? This question was asked to: economic operators, industry associations, national accreditation bodies, national competent authorities and national notifying authorities.

Furthermore, 46.9% (61 of 130) of the respondents in the targeted consultations noted that the **existence of non-accredited notified bodies does not remain appropriate**; 27.6% (36 respondents) stated that the existence of non-accredited notified bodies was 'not at all' appropriate.[58]

Some stakeholders see **mandatory accreditation**[59] as the only way to ensure the appropriate and equal high level of competence of notified bodies, while others point to the significant amount of time and costs needed for accreditation comparing to its benefits. The Evaluation of the Internal Market Legislation for Industrial Products pointed out[60] that despite mixed views on the accreditation procedure and its effectiveness, there appears to be significant support towards mandatory accreditation across the EU. As presented on pg. 47 of the underlying Study and in Case Study No. 2 in Annex VIII of this SWD, consumer associations and industry associations interviewed have suggested that accreditation should become mandatory to create a true level playing field for notified bodies, based on competence. Nonetheless, there are a range of challenges related with mandatory accreditation that stakeholders have highlighted. According to notified bodies, mandatory accreditation is not considered the optimal solution, but could help ensure the best possible alignment in the notification processes and competencies of the assessing body (accreditation body) to be somewhat aligned through peer assessment and with that, ensure a level playing field in terms of requirements put on the Notified Bodies.

Notified bodies in charge of the Lifts Directive pointed out that in countries where the national accreditation body related to the technical directive and the notifying authority are the same body, the difference between relying on a notified body having accreditation compared to a non-accredited notified body is not significant as the technical expertise is similar. Therefore, it is difficult to say whether mandatory accreditation would make much difference. For example, in Germany, there is a national accreditation body for each NLF-aligned directive or regulation and there is also a notifying authority. If a notified body chooses one of the German inspection bodies, with or without accreditation, the same inspectors perform the audit, but the day rates charged are different.

Several categories of stakeholders consider **the definition of accreditation too vague**. Certification bodies expressed the view that although the accreditation system is harmonised across all EU Member States, the definition of accreditation refers to unspecific "harmonised standards and where applicable additional requirements", leaving room for varying interpretations[61].

This situation may distort the EU level playing field between conformity assessment bodies with consequences for economic operators.

The Commission considers that the definition of accreditation in Regulation (EC) No 765/2008 referring in general to *'harmonised standards and, where applicable, any additional requirements'* that the conformity assessment body should meet to obtain an attestation by a national accreditation body allows flexibility, instead of being vague. The EA is a body recognised under Regulation (EC) No 765/2008 and the mandatory membership of national accreditation bodies in the EA is also

[58] Results of Question 28 (N=130): To what extent does the existence of non-accredited notified bodies remain appropriate to ensure the competence required by the NLF? This question was asked to: economic operators, industry associations, national accreditation bodies, national competent authorities, and national notifying authorities.

[59] Stakeholder views on the question of whether accreditation should become mandatory are presented and discussed in Case Study No. 2 in Annex VIII.

[60] More information is available in the Evaluation of the Internal Market Legislation for Industrial Products: 4.4.2 Compulsory accreditation

[61] More details on the views of stakeholders about the definition of accreditation is included in Case Study No. 2. Annex VIII.

ensured by Regulation (EC) No 765/2008. The EU is financing the activities of the EA in connection with the application of Regulation (EC) No 765/2008, such as the coordination of accreditation activities and the processing of technical work linked to the operation of the peer evaluation system (Article 32 of Regulation (EC) No 765/2008). Consequently, the better implementation of the accreditation rules achieving more harmonised practices in the area of accreditation of conformity assessment bodies is rather seen via the coordination and accentuation of this aspect in the peer evaluation activities of the EA than through a possible amendments of the NLF, enumerating the relevant harmonised standards in the NLF.

Based on the triangulation of the evidence collected in this evaluation, **we conclude that the rules of the NLF on notified conformity assessment bodies are clear and sufficiently robust to ensure safety and compliance of products, as well as the competence of notified bodies**. Nonetheless, the NLF-rules show a **lack of clarity when it comes to outsourcing of the services of notified bodies to third-country conformity assessment bodies**. Considering, however, that in such cases ensuring the quality of the services is challenging due to difficulties in monitoring, the NLF foresees the possibility for the notifying authority not to allow subcontracting by the notified conformity assessment body if there are no means to ensure an adequate monitoring. The evaluation shows that **the NLF does not provide for sufficiently reliable procedures of monitoring of non-accredited conformity assessment bodies. Concerning the effectiveness of the accreditation framework, the general conclusion is that it functions well and ensures the competence of the accredited notified bodies.**

d) Ensuring a clear meaning and enhanced credibility of CE-marking

The issue of the performance of the NLF provisions related to the CE marking was most recently examined in the 2014 Evaluation of the Internal Market Legislation for Industrial Products. As summarised in the 2017 report on the implementation of Regulation (EC) No 765/2008[62], the assessment "show[ed] an overall satisfaction with the CE marking, which is considered appropriate and effective. The assessment also showed that there is no need for any fundamental change in CE marking, although there is a need for greater consistency and to avoid having different requirements for different pieces of legislation and address the issue of products with multiple parts"[63].

Most stakeholders consulted for this evaluation maintain that the CE marking holds significant value and works well. Overall, the provisions on CE marking are clear, enhance its clarity and credibility, increase industry attention on CE marking requirements, strengthen the visibility of CE marking, and iron out minor inconsistencies between different pieces of legislation. Stakeholders consider that it is a trustworthy indicator that a product will function safely and as intended.

For instance, 64.1% of respondents to the targeted consultation (100 of 156 respondents) perceive the NLF to have been either somewhat effective (34.6%, 54 respondents) or very effective (29.5%, 46 respondents) in **strengthening the visibility and use of the CE marking system**. In particular, stakeholders have highlighted the CE marking's strong global reputation and the global benefit of having a common approach.

[62] More information is available in the 2017 Report on the implementation of Regulation (EC) No 765/2008: Section 3 CE marking

[63] Report on the implementation of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, COM(2017) 789 final.

However, in this context, a **few challenges have been highlighted by stakeholders**. Consumer associations, for instance, still share concerns with regard to understanding the purpose of the CE marking among consumers. They stated that consumers may perceive it to be a quality or certification marking, rather than a compliance marking. Furthermore, industry stakeholders have highlighted challenges stemming from global trends related to product markings.

Based on the triangulation of the evidence collected in this evaluation **we conclude that the NLF strengthened the visibility and clarity of CE marking, nonetheless, consumer associations consider that there is still room for raising awareness of consumers on the meaning of CE marking**.

To conclude, **the NLF has been effective in achieving its all four specific objectives**. Thanks to the regulatory toolbox set out in the NLF, the provisions are repetitive in every single piece of NLF-aligned legislation, whereby divergences are reduced in the EU product legislation. Technological neutrality supports innovations and should be preserved in the future as well, by avoiding to include more detailed product requirement in the legislation than necessary. The effectiveness of the NLF may depend on factors outside of its scope, such as the prompt delivery of standards.

1.5.2. 4.1.2. Efficiency

a) Reinforcement of the New Approach

Two third of the surveyed economic operators and industry associations agreed that the NLF increased the overall efficiency of Union product legislation through simplification and burden reduction.

According to the stakeholders, the **positive effects of the NLF, considering both monetary and non-monetary benefits, strongly outweigh the costs**. The NLF comprises very few direct costs, as most costs associated with the framework of EU product legislation stem directly from compliance with individual pieces of NLF-aligned legislation. However, a wide range of cost savings and other benefits have been highlighted by stakeholders. For economic operators, these benefits included reduced costs in familiarisation with legislative requirements by economic operators due to the implementation of common provisions; greater regulatory certainty; greater harmonisation of obligations; reduced market barriers; and, as a result, enhanced industrial competitiveness. A further strategic benefit was the enhanced global recognition of the CE marking stemming from its prominence within the NLF.

In terms of **specific benefits of the NLF**, two-third of the economic operators and industry associations agreed that **the NLF has reduced the costs of familiarisation** with different EU product legislation, while a great majority reported that the NLF **has reduced divergence**[64] between different pieces of EU product legislation, leading to cost savings in the conformity assessment procedure. For example, Case Study No. 4 in Annex 4 of the Study, which is also included in Annex VIII demonstrates that none of the costs identified for economic operators can be entirely and directly attributed to the NLF. According to the Study of CSES, the benefits of the NLF

[64] The scope of the evaluation from 2014, 'A vision for the internal market for industrial products', COM(2014) 25 final, was overarching and broad in nature, covering many New Approach directives. Among the key findings were that the NLF "provides a clearer definition of the obligations for different economic operators" and supported administrative simplification across many areas of the legal framework (e.g. through the common suite of conformity assessment modules and the DoC template). The evaluation results were reported in the context of the Commission Communication 'A vision for the internal market for industrial products'.

are rather strategic[65], such as fostering the free movement of goods in the internal market and increase in industrial competitiveness.

It should also be noted that the coherence and consistency of the NLF aligned legislation, the conformity assessment and CE marking are also the elements of the New Approach, which were supposed to be improved through the NLF. Consequently, the efficiency and performance of the NLF related to the other three specific objectives at the same time corroborate the efficiency of the NLF in reinforcing the New Approach.

Based on the triangulation of the evidence collected in this evaluation **we conclude that the NLF is efficient in achieving the objective of enforcing the New Approach.** The NLF has reduced divergences among the different pieces of legislations and therefore also the costs of familiarisation with EU product legislations.

b) Supporting the consistency and coherence of EU harmonisation legislation

In terms of efficiency of the NLF in supporting the consistency and coherence of EU product legislation, based on the surveys, respondents highlight that the enhanced regulatory certainty is a positive result of the NLF's functioning**.** Reduced uncertainty over applicable rules, thanks to the common approach brought about by the NLF, is a direct benefit attributed to the NLF. If assessed against a counterfactual scenario characterised by regulatory fragmentation (by piece of legislation and/or by country), this benefit's relevance is further underscored.

According to the results of the public consultation, 83% of the respondents (78) stated that the NLF has had **a positive or very positive impact in terms of regulatory certainty and ease of compliance with EU product legislation**. This positive opinion is in line with the wide consensus observed on this point during the interview programme.

Due to its very nature, a quantification or monetisation of this benefit cannot be achieved. At the same time, in light of the increase in NLF-aligned pieces of legislation, the conclusion can be drawn that over the 2014-2020 period the extent of this benefit has grown, compared to the pre-2014 baseline scenario.

Based on the triangulation of the evidence collected for this evaluation, **we conclude that the NLF is efficient in supporting the consistency and coherence of EU harmonisation legislation**. Although it is not possible to quantify the benefits over the costs of the NLF under this objective, stakeholders agree that the NLF brought regulatory certainty into the EU legislative framework for products and has facilitated compliance.

c) Strengthening the quality of conformity assessment services through improved accreditation of notified bodies

The efficiency of the conformity assessment procedure based on the same principle in the NLF-aligned product legislation and structured by modules is appreciated by the stakeholders. They report that the **costs linked to the familiarisation with the procedures and preparation of the conformity assessment** are also reduced.

In the targeted consultations 85.5% (47 of 55 responses) of economic operators and industry associations agreed that the NLF has reduced the costs of familiarisation with different EU product legislation to a great or moderate extent.

[65] More information is available in the Study: 4.2.4.1 Benefits of the NLF: Results (linked to specific objectives)

The opinions of stakeholders strongly support the argument that the NLF has brought about savings in terms of **facilitated familiarisation and administrative simplification.** Due to the growing number of pieces of legislation that have been aligned to the NLF over the 2014-2020 timeframe considered in this study, it can also be safely concluded that this cost saving has increased over time, compared to the pre-2014 scenario.

Case Study No 3. in Annex IV of the Study, which is included in Annex VIII of the SWD on the assessment of the NLF-related costs and benefits under an NLF-aligned legislation (the EMCD) explains that in a hypothetical scenario without the NLF, the EMCD would probably still contain a conformity assessment procedure, with less similarities with the conformity assessment provided in other product legislation. The costs of familiarisation with the procedures would likely be higher in the absence of the NLF model of conformity assessment procedures, due to lack of harmonisation. Generally, the cost of complying with the EMCD corresponds to 5-15% of total costs of production[66]. Administrative and reporting costs therefore represent only a minority share of the total production costs borne by manufacturers. The self-certification approach made possible by the EMCD, in particular, contributes to keeping costs relatively low and grants a certain level of flexibility to economic operators. Some benefits, such as increased market efficiency and improved industrial competitiveness can be attributed to some extent to the NLF.

The Study of CSES shows that cost savings generally do not primarily concern the main bulk of conformity assessment costs (i.e. tests and the involvement of notified bodies), but **focus on the costs related to technical documentation**. Although the details included in the documentation depend on the nature of the product, the general requirements referring to the contents of the technical documentation that are relevant for proving the conformity of the product with the applicable harmonisation legislation are set out in the rules which follow Annex II of Decision No 768/2008/EC. In the case of the EMCD, the Directive's evaluation reported costs of technical documentation as part of the conformity assessment procedure being in a range between 1,000 and 10,000 euro per product. In terms of staff resources required in relation to the documentation, most stakeholders providing an estimate indicated a cost between 4 and 10 man-days.

The most important costs reported in the targeted consultation by economic operators and industry associations were related to the **involvement of notified bodies** (rated by 60.7% – 34 of 56 responses – as high or very high) and the **performing of laboratory tests** (rated by 53.6% – 30 responses – as high or very high). Overall costs of conformity assessment procedures were deemed high or very high by a minority of respondents (35.7% – 20 responses).[67] Most of the costs deriving from the conformity assessment procedure for the products covered by an NLF-aligned product legislation may only be partially attributed to the NLF (see Case Study No. 4 in Annex 4 of the Study, which is also included in Annex VIII of this SWD on the assessment of the NLF-related costs and benefits under an NLF-aligned legislation (the TSD).

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[66] **For manufacturers:** Costs during product development (engineering costs; purchasing standards; pre-testing); Conformity assessment costs (preparing technical documentation; laboratory tests; involvement of notified body); Costs during production process (e.g. EMC-relevant measures); Familiarisation with legislative requirements. **For public authorities:** Enforcement costs.

[67] These considerations are also supported by past evaluations of NLF-aligned pieces of legislation. As noted in the 2020 evaluation of the Toy Safety Directive (TSD), an EC-type examination carried out by a notified body is more expensive than laboratory testing, as at least the costs for the review of the technical documentation are additional (typically around 500 Euro). Moreover, if test methods or protocols have to be developed (e.g. in light of innovations), costs increase further. In the case of the Electromagnetic Compatibility Directive (EMCD), according to its 2021 evaluation, the overall cost of a notified body's involvement ranges between 3,000 and 20,000 Euro.

The cost of testing is high in itself: Under the EMCD, for instance, the daily fees of third-party laboratories in the EU is reported to be in the range 800-1,500 Euro.[68] The Evaluation of the Toys Safety Directive also states that testing of toys entails considerable laboratory costs. This includes the operation and maintenance of the laboratory and its equipment as well as costs for hiring the appropriate staff. Tests need normally sophisticated, specialised equipment and machines and, in the case of chemical tests, a permanent input of chemicals, some of which can be very expensive[69].

However, based on the interviews conducted for the Study of CSES, the view of individual companies and business associations concerning conformity assessment procedures is in general positive, as the framework of the modules for assessing compliance, as well as the individual modules, are considered to function well and are not considered excessively costly. Moreover, **since the principles of conformity assessment have not changed significantly with the introduction of the NLF in 2008, no additional costs are identified compared to the previous conditions**. In any case, the specificities of the conformity assessment procedures for different products (even if they use the models provided by the NLF) are included in NLF-aligned sectoral legislation.

Annex VII of the SWD contains an elaboration prepared by the contractor[70] of the main costs and benefits identified by the evaluations of certain NLF-aligned EU product legislation, (i.e. Evaluation of the CPR in 2019, Evaluation of the LVD in 2019, Evaluation of the TSD in 2020, Evaluation Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive in 2021, Evaluation of the EMCD in 2021).

Regarding the efficiency of the NLF in relation to the accreditation framework it introduced, the resources spent by conformity assessment bodies on the accreditation framework, including examination fees and maintenance fees, represent inputs to the NLF's functioning and an important novel element of the 2008 NLF legal texts. As such, they are attributed to the NLF.

To obtain an accreditation, conformity assessment bodies face a range of costs, which include: the examination fee to an accreditation body; annual fee to an accreditation body **(continuous monitoring costs, or maintenance fee)**; **cost of developing and maintaining a quality management system; insurance (in most cases)[71][72].**

National accreditation bodies, national competent authorities, national notifying authorities, and notified bodies were also asked to assess the **burden they experienced resulting from the introduction of the accreditation framework**. 42.3% of respondents (47 responses) reported the burden to be high or very high, while a further 27% (30 responses) considered it to be moderate.

[68] The EMCD evaluation also highlighted the considerable flexibility provided to economic operators in terms of how to comply with the essential requirements, in particular having a choice of conformity assessment procedure, which is widely seen as reducing undue burden and appreciated by industry. In the TSD evaluation, the cost of testing was estimated to represent 16% of the total man-hours required for manufacturers to comply with the Directive's requirements when developing a toy (7% testing the quality and compliance of raw materials for the toy; 9% testing the toy itself). Generating the conformity assessment represented 6%; obtaining an EC-type examination certificate 5%; generating the EC declaration of conformity 5%; and generating the technical documentation 12%.

[69] Evaluation of the Toys Safety Directive, pg. 61.

[70] More information available in the Study: Section 4. To what extent was the NLF successful and why?

[71] The origin of this clause is Decision No 768/2008/EC, Article R17, clause 9, which states that "Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment." In the different Member States, and across different pieces of NLF-aligned legislation, this provision has been implemented and transposed differently.

[72] More details on the cost of accreditation are available in Case Study No. 2. Of Annex VIII.

However, there was **some variation between stakeholder types**: notified bodies were most likely to report that the burden was high or very high (53.8%, 21 responses), while responses from the other groups were more mixed.

Asked to identify and explain the main kinds of **costs and burdens related to the introduction of the accreditation framework for conformity assessment bodies**, three notified bodies / conformity assessment bodies commented in more detail. One said that the cost depends on the scope of accreditation and level of assurance addressed. It could range between €50k and €500k in capital expenses (CAPEX) and around €500k in operating expenses (OPEX). Another respondent referred to the costs of the audit of the accreditation body and the considerable time and overall operating costs of the auditee during the accreditation process. The respondent estimated this cost to be around €72k for an accreditation period of five years.

A third respondent reported that it is difficult to estimate the change in costs related to the introduction of the accreditation framework for conformity assessment bodies as accreditation and (some sort of) notification already existed prior to 2008. Costs occur for both becoming accredited and for maintaining the accreditation.

The general estimation is what a NAB representative consulted for the Study of CSES stated, that the **cost of accreditation does not represent an excessive burden**, as the most important cost to receive the accreditation is the cost to have the necessary equipment and to ensure a good level of competences and supervision of the technical experts. As such, in his opinion, the cost of accreditation should not be seen as a burden.

However, notified bodies engaged in **smaller sectors** who participated at the validation workshop see the cost for accreditation as a rather challenging problem. In case accreditation is made mandatory, this would create significant problems in terms of affordability. To solve the problem of different level of competence of notified bodies, they suggest a **peer-assessment system for notified bodies, similar to the one in accreditation.**

Most respondents were positive about **the benefits that have been achieved as a result of the NLF**. Regarding cost savings due to facilitated familiarisation with different EU legislation (e.g., due to common definitions, reduced market fragmentation etc.), 47% of the stakeholders agreed that strong benefits had been achieved (45 responses), while a further 30% thought there were at least some benefits (28 responses). Respondents were only slightly less positive regarding cost savings in the process of demonstration of conformity across different EU product legislation: 41% agreed that strong benefits had been achieved (39 responses), while a further 28% thought there were some benefits (27 responses).

Looking to efficiency in terms of possible simplification, in the targeted consultations 74.5% of the respondents thought that the efficiency of the conformity assessment procedure would improve to a great extent (35 responses) due to **digitalisation of the declaration of conformity / technical product information / technical file**, without hindering market surveillance activities, while a further 12.8% (six responses) thought it would improve to a moderate extent.

Another possibility for simplification would be seen in the broader application of the **remote assessment techniques** by the notified conformity assessment bodies, where it is appropriate (for more details, see Remote conformity assessment).

Based on the triangulation of the evidence collected for this evaluation, **we conclude that** easier familiarisation with the procedures and preparation of the conformity assessment, as well as the administrative simplification brought by **the NLF led to cost savings. The modules provided in the NLF for assessing compliance are efficient**, and since they have not changed significantly with the introduction of the NLF in 2008, there are no additional costs identified comparing to the

pre-NLF period. **The accreditation framework is considered efficient** in the context of balance between costs and benefits. Except in the smaller sectors, the general opinion is that the costs of accreditation do not represent an excessive burden for the conformity assessment bodies. Digitalisation and remote assessments are identified as the way forward for a possible simplification.

d) Ensuring a clear meaning and enhanced credibility of CE-marking

In terms of the efficiency of the CE marking, economic operators and industry associations were asked in the targeted consultations to assess the scale of the burden deriving from the NLF's communication obligations. The **burden of printing out product information** to accompany the product (e.g. safety documentation, instruction manuals, guidance on reasonably foreseeable use etc.) was most likely to be rated high or very high (83%, 39 responses). **Affixing the CE marking visibly** and indelibly on the product, as well as other traceability information such as the postal address of the manufacturer/importer was deemed the least burdensome: only 36.2% (17 responses) rated it as high or very high. Nonetheless, industry stakeholders highlighted that the need to indelibly mark products costs to manufacturers and limits the flexibility of economic operators to respond to market developments globally, as certain 'marked' stock can only be sold in the specific regions or countries they are marked for.

Very few stakeholders attempted to quantify the costs related to their NLF information obligations. Most answered that it was not possible for them to estimate these costs. In relation to CE marking, a few respondents put the cost at "mere cents". Others said that it would depend on the product, where it is marketed and under which circumstances.

Translating a manual into an EU language was said, by one stakeholder, to cost approximately €10,000 per language, while printing the manual was estimated at around €10 per copy. Administrative costs were said by another stakeholder to range between €5,000 and €20,000 per product.

The Study of CSES stresses that since no significant changes concerning CE marking were introduced with the 2008 NLF, the incremental costs compared to the previous conditions are nil. This is acknowledged in previous evaluations, too. For instance, the evaluation of the NLF-aligned Lifts Directive does not consider the cost of CE marking as relevant in its analysis, as similar requirements were already present in the previous Directive[73].

As part of the stakeholder consultations, one of the key impacts widely agreed upon by interviewees was the enhanced **global relevance of EU regulations**, which in turn supports the standing of the EU in global commerce, thanks to the ability of EU legislation to elevate its model worldwide and shape international practices (named the 'Brussels effect'). The NLF, in several interviewees' opinion, clearly contributed to this benefit. A related element, in this regard, is the **enhancement of Europe's industrial competitiveness**, in terms of comparative competitiveness between European manufacturers and third country counterparts.

According to evaluations of some NLF-aligned pieces of legislation, such as the Lifts Directive evaluation, the CE marking is increasingly perceived as a standard of quality by industry beyond EU borders: buyers in Asia and the US are reported to prefer products with a CE marking; also, the harmonised regulatory framework has reportedly helped companies implement a stronger internationalisation strategy in third countries. The EMCD evaluation reached similar conclusions.

[73] At the same time, the evaluation states that this element is not burdensome for lift installers.

Based on the triangulation of all data collected during the survey, we may conclude that the benefits of the CE marking clearly outweigh its costs.

In this respect, stakeholders from all groups agree that digitalisation offers a potential solution for simplification of administrative obligation related to product information requirements and CE marking.

This view is strongly supported by a study conducted for study conducted for DigitalEurope and the Mobile & Wireless Forum[74], which examined the costs and benefits associated with digitalising certain compliance information in the consumer electronics sector. Quantitative estimates on e-labelling were provided on three segments of the European consumer electronics market: telephony, computing, and TV, radio and multimedia[75]. According to the study, under the current system the total annual costs of indicating compliance in these three fields are about 800 million Euros[76]. These costs are deemed to be high or very high by about half of the companies consulted as part of the study. Against this background, the study proposes an e-labelling scheme designed as an optional approach to a physical label and consisting of a label displayed electronically for devices with built-in screen, a QR code for equipment without screen, and a temporary label (e.g. film label) to allow consumers and market surveillance authorities to see product regulatory markings at the time of purchase or check without switching on the device. The study estimates that the e-labelling scheme would reduce costs of indicating compliance by around 15% (120 million Euros per year), due to lower costs associated with updating compliance information of products already on the market, lower costs linked to differences in national compliance procedures, as well as lower administrative costs linked to addressing requests from national market surveillance authorities.

After extrapolating the cost savings figure to other sectors under NLF scope, the cumulative cost saving related to the e-labelling scheme can be estimated to be at least **490 million Euro per year**[77].

The possible simplifications of the CE marking and other obligations by digital means is discussed below in more details under the assessment of the relevance of the NLF.

Based on the triangulation of the evidence collected for this evaluation, **we conclude that the NLF has been efficient in ensuring the clear meaning and enhanced credibility of the CE marking.**

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[74] Research into e-labelling schemes outside the EU - DIGITALEUROPE

[75] Selected NACE coverage: NACE 26.20 Manufacture of computers and peripheral equipment; NACE 26.30 Manufacture of communication equipment; NACE 26.40 Manufacture of consumer electronics.

[76] Calculated as 0.4% of the turnover of the industry under scope. In turn, the share of 0.4% is the result of a multiplication of the total cost of compliance (2% of annual turnover, based on previous literature) by the share of the total cost compliance related only to the cost of indicating compliance with EU harmonisation legislation (20%, based on stakeholder consultation).

[77] Although no precise correspondence between NACE codes and NLF scope can be established, a list of 17 NACE codes were first selected to approximate the sectors under NLF scope. These are: 26.10, 26.20, 26.30, 26.40, 26.50, 26.60, 26.70, 26.80, 27.10, 27.20, 27.30, 27.40, 27.50, 27.90, 32.40, 32.50, and 32.90. For each of them, 2019 turnover data were then extracted from Eurostat SBS. In cases where 2019 data were not available, turnover data from previous years were used for the approximation. In the case of NACE code 32.40 (Manufacture of games and toys), for which no turnover data were available on Eurostat, data from the recent Commission evaluation of the Directive were used. The cumulated annual turnover of the 17 NACE codes selected is equal to 816.28 billion Euro. This annual turnover was then multiplied by 0.4% (i.e. the cost of indicating compliance with EU harmonisation legislation, according to the 2018 study on behalf of DigitalEurope and the Mobile & Wireless Forum) to estimate the annual cost of indicating compliance, corresponding to 3.27 billion Euro. Adopting the same share of cost reduction due to the proposed e-labelling scheme as indicated in the 2018 study, i.e. 15%, the cumulative cost saving can be estimated at 489.77 million Euro per year. It should be noted that this figure likely represents an underestimation, due to the exclusion from the NACE sectors considered of some further product types under NLF-aligned legislation, e.g. construction products.

CE marking does not represent a serious burden for manufacturers, while often perceived as a standard of quality even outside of the EU. Digitalisation of CE marking and other product information obligations is nonetheless seen as a possible simplification. Having regard to the increasing number of intangible products such as software, this seems to be inevitable in the near future.

To conclude, the NLF has been efficient in achieving its all four specific objectives. Most of the benefits of the NLF are strategic, such as increasing Europe's industrial competitiveness and the global relevance of EU regulation, fostering the free movement of goods in the internal market and increasing industrial competitiveness. Reduced divergences, facilitated familiarisation with the rules, ease of compliance regulatory certainty are benefits that are stressed by all stakeholders. Although their quantification is not possible, these benefits are vital for the everyday smooth functioning of the internal market and its reliability.

Some of the costs and benefits cannot be directly attributed to the NLF as a framework. Two case studies in Annex VIII of the SWD conducted by the contractor on recently evaluated directives, the EMCD and the Toy Safety Directive (TSD), investigate the issue of attributing effects to the NLF or to the sector-specific legislation. They show also that drawing a line between NLF-related impacts and impacts that should be attributed only to the individual legislation is not straightforward.

For example, we are not able to conclude that costs related to the conformity assessment under the Electromagnetic Compatibility Directive 2014/30/EU (EMCD) (such as the costs of preparing technical documentation, performing laboratory tests and potentially using a notified body) are directly attributable to the NLF to a large extent because these costs stem from the integration of NLF rules into the EMCD. The EMCD would probably also contain some kind of conformity assessment even without the NLF. However, that procedure would probably have fewer similarities with the conformity assessments provided in other product legislation. Therefore, familiarisation costs and administrative burden would likely be higher in the absence of the NLF model of conformity assessment procedures, particularly in case of products covered by the EMCD and some other product legislation, which could also envisage a completely different conformity assessment procedure in the absence of the NLF legal framework and its toolbox.

1.5.3. 4.1.3. Coherence

The assessment of the coherence of the NLF as a framework reinforcing the New Approach with other relevant legislations will focus on both, the internal and external coherence of the NLF.

The **internal aspect** considers the coherence between Decision No 768/2008/EC and Regulation (EC) No 765/2008. This aspect also takes into account the extent to which the NLF's provisions are clear to EU policymakers, national authorities and economic operators involved in its implementation, and whether the NLF's scope is considered to be appropriate.

The **external aspect** focuses on the extent to which there are any gaps, loopholes, inconsistencies, or duplications in relation to the NLF and its interaction with the different pieces of product legislation.

As mentioned earlier, 23 different directives and regulations and a delegated act have been aligned with the NLF. Considering that strengthening the consistency and coherence of Union harmonisation legislation is one of the specific objectives of the NLF, the effectiveness and efficiency of the NLF in ensuring coherence with the NLF-aligned product legislation is analysed under the subtitles devoted to the effectiveness and efficiency of the NLF.

In the assessment of external consistency of the NLF with other pieces of EU legislation, we consider the coherence of the following as well:

- **Horizontal legislation** – The coherence with Directive 2001/95/EC on general product safety (GPSD)[78] and Directive on product liability 85/374/EEC[79];
- **Other relevant legislation and legislative proposals,** although the future-proofing coherence of the NLF is elaborated under the assessment of the relevance of the NLF;
- **NLF aligned product legislations with the non-NLF aligned legislation;**
- **NLF and its alignment role for international trade agreements of the EU.**

In terms of internal coherence, as the Study of CSES explains, there is a plenty of risk for inconsistencies and overlaps between the NLF legal texts, as many of the same issues are discussed in both pieces of legislation. For instance, while the general principles of the CE marking are stipulated in Regulation (EC) No 765/2008, the reference provisions to be included into the specific pieces of product legislation are contained in Annex I to Decision No 768/2008/EC (Articles R11-R12). Similarly, the rules on accreditation are set out in Chapter II of Regulation (EC) No 765/2008, while the reference provisions are contained in Annex I to Decision No 768/2008/EC (Articles R21-R23).

Nonetheless, stakeholders did not raise any issues regarding the internal coherence and consistency of the NLF. In both, targeted and public consultations the number of stakeholders considering that there were inconsistencies, overlaps or gaps between the different provisions of the NLF (i.e. between and within Decision No 768/2008/EC and Regulation (EC) No 765/2008) was very low: 1 answer out of 125 in the public consultations and 5 answers out of 122 in the targeted consultations[80]. Regulation (EU) 2019/1020, which replaced the market surveillance part of Regulation (EC) No 765/2008 introduced new definitions, such as 'fulfilment service provider', 'information society service provider', 'distance sales' and 'online interface', to capture the new roles associated with the emergence of online marketplaces. Stakeholders welcome this recent revision and consider that these definitions could serve as a blueprint for refining the conformity assessment procedures applicable to these new types of economic operators in the distribution chain and contribute to the overall coherence of the NLF model.

Regarding the clarity of certain obligations set out in the NLF, 18,5% of stakeholders out of 200 (without important differences throughout the stakeholders group) found unclear the obligations and **administrative requirements for economic operators placing products on the market following their substantial modifications**. A more detailed assessment of this aspect is included in Chapter 4.3 under the evaluation of the relevance of the NLF.

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[78] OJEC L 11 of 15.01.2002.

[79] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products L 210 of 07/08/1985.

[80] Among the few stakeholders who identified inconsistencies, one national accreditation body said that the inconsistencies are not so much in the legal framework, but in the expectation laid down in the Blue Guide. For instance, the requirement related to the conformity assessment bodies and their personnel and facilities in the Member States.

An industry association agreed that there are no striking inconsistencies within the original NLF. However, the adjustments made by Regulation (EU) 2019/1020 on market surveillance (which amended Regulation (EC) No 765/2008) introduced new concepts beyond the existing NLF (e.g. Articles 4, 5, 6 in relation to placing a product on the market).

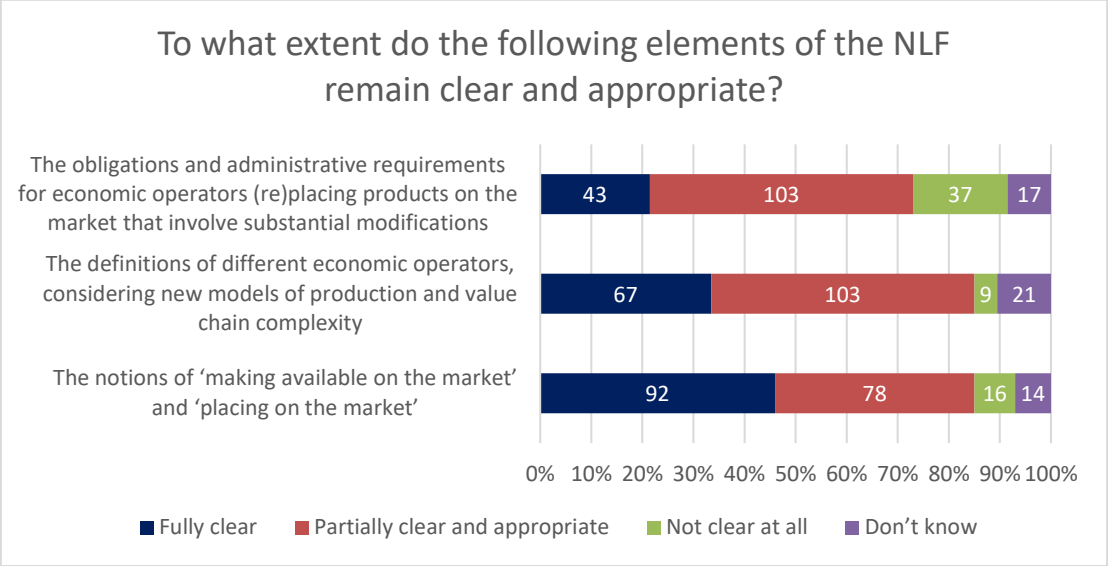

Figure 3 Targeted consultations: Extent to which elements of the NLF remain clear and appropriate (Question 52, N=200)

Similarly to the feedback from stakeholders on internal coherence, a significant number of respondents **did not know** whether the NLF is coherent with other EU legislation that may apply simultaneously or in complementarity with NLF-aligned legislation (**external coherence**). Among those respondents expressing an opinion, the majority believe that the NLF is partially (rather than fully) coherent with horizontal policy and legislation, environmental legislation and other types of relevant legislation.

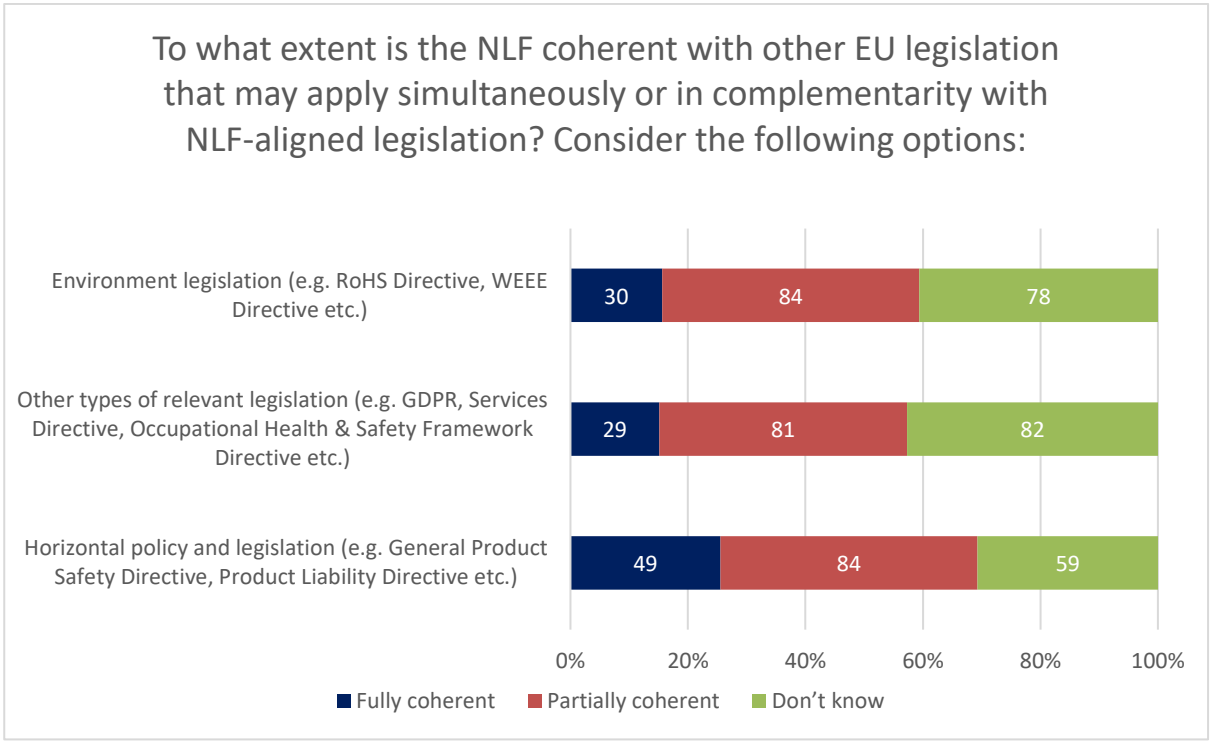

Figure 4 Targeted consultations: Extent to which the NLF is coherent with other EU legislation that may apply simultaneously or in complementarity with NLF-aligned legislation (Question 61, N=192)

The horizontal coherence of the NLF

Directive 2001/95/EC on general product safety (GPSD)[81] is intended to ensure product safety throughout the EU for all non-food consumer products to the extent that they are not covered by sector-specific EU harmonisation legislation. The GPSD also complements the provisions of sector legislation in some aspects. On 30 June 2021, the Commission adopted the Proposal for a new general product safety regulation, to replace the GPSD. Some elements of the Proposal are analysed as part of the section devoted to the relevance of the NLF, in Annex XI.

Directive on product liability 85/374/EEC[82] establishes a system of strict liability, i.e. liability without fault, for producers when a defective product causes physical or material damage to an injured person. The Directive is an important element of the EU product safety legislation framework. It underpins product safety legislation by giving producers incentives to comply with it, as well as legal certainty. This Directive is currently under revision.

Most stakeholders (110 out of 192, i.e. 57,2%) in the targeted consultation are of the view that horizontal policy and legislation, as the General Product Safety Directive and the Product Liability Directive are coherent with the NLF, while the remaining 42,7% do not know (please see the table above demonstrating the results of the targeted survey).

Coherence of other relevant legislations and legislative proposals with the NLF

There are examples in the body of EU legislation where terms defined in the NLF are redefined or have a slightly different meaning. One of such examples is the definition of 'placing on the market'. According to Decision No 768/2008/EC, Annex I, Article R1(2) the 'placing on the market' is defined as the first making available of a product *on the Union market.*[83] Directive (EU) 2019/904 on single-use plastics, based on Article 192(1) TFEU, nonetheless defines the placing on the market in its Article 3(6) as the first making available of a product *on the market of a Member State*. The restriction in the definition set out in Directive (EU) 2019/904 on single-use plastics may require further clarification for economic operators who are familiar with the definition of placing products on the market as set out in the NLF.

Some industry associations expressed their concern at the interplay and the lack of coherence among some EU legislations that are currently being revised, reviewed, or newly proposed and the NLF. When it comes to proposals on general product safety, AI, and cybersecurity, respondents stressed the importance of consistency. **The NLF should be the "leading legislation" for horizontal definitions.**

To further respond to the need for future-proofing coherence of the NLF as regards upcoming legislation that will address the use of products after their placing on the market and first use, some stakeholders suggest introducing additional definitions for 'maintenance', 'repairer', 'disassembler', 'recycler', 'service provider', 'refurbisher' and 'remanufacturer'. Some of these questions are discussed in more details below, under the relevance criteria.

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[81] OJEC L 11 of 15.01.2002.

[82] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products L 210 of 07/08/1985.

[83] Blue Guide, Title 2.3. Placing on the market: When made available on the Union market, products must be in compliance with the Union harmonisation legislation applicable at the time of placing on the market. Compliant products once they have been placed on the market may subsequently be made available along the delivery chain without additional considerations, *even in case of revisions to the applicable legislation or the relevant harmonised standards*, unless otherwise specified in the legislation.

Coherence of the NLF-aligned product legislation with the non-NLF aligned legislation

23 pieces of EU product legislation and a delegated act have been aligned with the NLF, nonetheless there is a lack of coherence between the NLF and other types of legislation in some cases. This increases compliance and enforcement costs for economic operators, notified bodies and market surveillance authorities. In addition, differences in the combined implementation of EU legislation between Member States could prevent the full potential of a well-functioning internal market from being achieved. Case study No.1 in Annex 4 of the Study, which is also included in Annex VIII demonstrates the problem in more details.

NLF and its alignment role for international trade agreements of the EU

The European Commission represents the European Union for the purposes of administering the notification, recognition, challenge, suspension and withdrawal of conformity assessment bodies under the international agreements concerning the recognition of conformity assessment results. The Commission service responsible for negotiating international trade agreements highlighted that the process of notification, recognition, challenge, suspension and withdrawal of conformity assessment bodies under the international agreements concerning the recognition of conformity assessment results is administratively extremely burdensome.

The NLF toolbox shows a high level of effectiveness as a model for EU product legislation with respect to notification and withdrawal of conformity assessment bodies, while the Commission is lacking a similar set of rules when implementing bilateral mutual recognition agreements on conformity assessment. The lack of a modern set of rules to be employed when implementing international trade agreements concerning the recognition of conformity assessment results often leads to incoherence in the implementation.

Based on the triangulation of the evidence collected for this evaluation, **we conclude that the NLF has been an effective tool to achieve both, internal and external coherence**. **Lack of clarity appears related to** those obligations set out in the NLF that are impacted by the **expansion of the circular economy** (e.g. placing products on the market following their substantial modification). The importance of the NLF in creating coherence in the EU product framework is unarguable. An inconsistent use of NLF definitions in a legislation by determining them differently from the meaning used in the NLF leads to confusion among economic operators and authorities who are familiar with the NLF and therefore to additional costs.

1.6. 4.2. How did the EU intervention make a difference?

This chapter will focus on the results of the NLF and assess if they are beyond of what would have been achieved by the Member States acting alone and considering the extent to which the effects (i.e. outputs, results, impacts) achieved through the NLF could have been achieved using alternative means.

The vast majority of stakeholders considered that the **common legal framework provided by the NLF delivered high added value** compared to what could have been achieved through the development of product legislation in its absence.

Regarding the **overall EU added value of the NLF**, stakeholders interviewed across all groups were overwhelmingly positive about its role in avoiding regulatory divergence from emerging in EU product legislation, particularly during the first 10 years of its implementation. Stakeholders perceive the NLF to have had a positive impact across all its key objectives. More specifically, the NLF has added value through:

- General principles and common reference provisions for drawing up EU legislation in the form of a regulatory toolbox designed for EU regulators;

- Implementation of the conformity assessment system, the accreditation framework for CABs and the rules on notification of CABs;
- Reinforcing the principles initially embedded in the New Approach, such as setting non-technical essential requirements, whilst leaving the detailed specifications to harmonised standards;
- Strengthening the visibility of CE marking, thereby heightening its role and importance,[84] although the core CE marking requirements already existed under the New Approach as these were gradually introduced in product specific legislation starting with the Low Voltage Directive in 1973[85].

Collectively, through these different aspects, the NLF has contributed positively to supporting the free movement of products within the internal market and providing a high level of protection of public interests, especially in respect of product health and safety, for both workers and consumers.

Stakeholders considered that **repealing the NLF** (and having different obligations in different pieces of legislation) **would generate diverging interpretations, overlaps and contradictions**. Also, a system with detailed technical specifications (as per the Old Approach) would decrease the flexibility that the current NLF system provides. Stakeholders further highlighted that a more divergent set of sectoral requirements would be expected to bring with it an increased burden both for economic operators and authorities.

Some stakeholders expressed their concerns that the NLF's added value could be watered down unless awareness is strengthened within the Commission itself regarding the regulatory toolbox and the NLF's general principles. To avoid that, a range of stakeholder groups (including consumer organisations and certification bodies) believe that the NLF needs to be updated in order to better contribute towards achieving the objectives of the circular economy and close up to the digitalized environment.

Regarding the **counterfactual assessment[86],** the question of what would have happened in the absence of the NLF has been analysed. There are different dimensions to this. Firstly, there is the question of what would have happened regarding the evolution of individual pieces of EU product legislation without the NLF. As shown in the legal mapping to assess the "before" and "after" situation in respect of NLF-aligned legislation, there would have remained divergence in the administrative requirements for economic operators, with more anomalies and inconsistences in the legislation, many of which were relatively minor, but which nonetheless undermined the overall coherence of the body of EU legislation applicable to products that manufacturers and other economic operators follow.

However, a more significant added value in the views of many industry associations and individual manufacturers was that **the NLF prevented regulators from introducing divergent requirements**

[84]Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits): https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31993L0068

[85] Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31973L0023

[86] For more details please see Section 5 of the Study.

across sectoral legislation that went against the NLF's core principles. This was seen as being the case at least in the 10-year period from 2008. This has also considerably reduced national "red tape" measures.

A major EU industry association commented that **if the NLF were to be repealed,** this would be a disaster for industry as the NLF has helped to provide stability and predictability in the regulatory regime. This finding is validated by the targeted consultation results. Almost half of the stakeholders (49.6%, 59 responses) considered that the **common legal framework provided by the NLF delivered high added value** compared to what could have been achieved through the development of product legislation in its absence. A further 29.4% (35 responses) considered that the framework had delivered some added value.

Based on the triangulation of the evidence collected for this evaluation, **we conclude that the common EU product framework created by the NLF brought a high level of EU added value** compared to what the Member States could have achieved without the NLF. Repealing the NLF would generate diverging interpretations, overlaps and contradictions.

1.7. 4.3. Is the intervention still relevant?

Under this title we analyse if the objectives of the NLF still reflect current and future needs (continuing relevance), mainly in the light of digitalization and the circular economy objectives.

Considering the question of **whether the NLF remains relevant**, the findings point to the following main conclusion:

The NLF legal framework, as set out in Regulation (EC) No 765/2008 and Decision No 768/2008/EC, was relevant in addressing the problems identified in the 2007 impact **assessment**, prior to the adoption of the NLF. Although significant progress has been made towards addressing these needs, stakeholders clearly feel that **these needs and the overarching framework implemented by the NLF remain relevant** moving forward.

However, **key developments in product markets have emerged since 2008 that have resulted in new needs and problems to be addressed by the EU legal framework for products**. These developments, which primarily stem from the digital and circular economies, directly impact the provisions of the NLF, but also the wider EU legal framework for products.

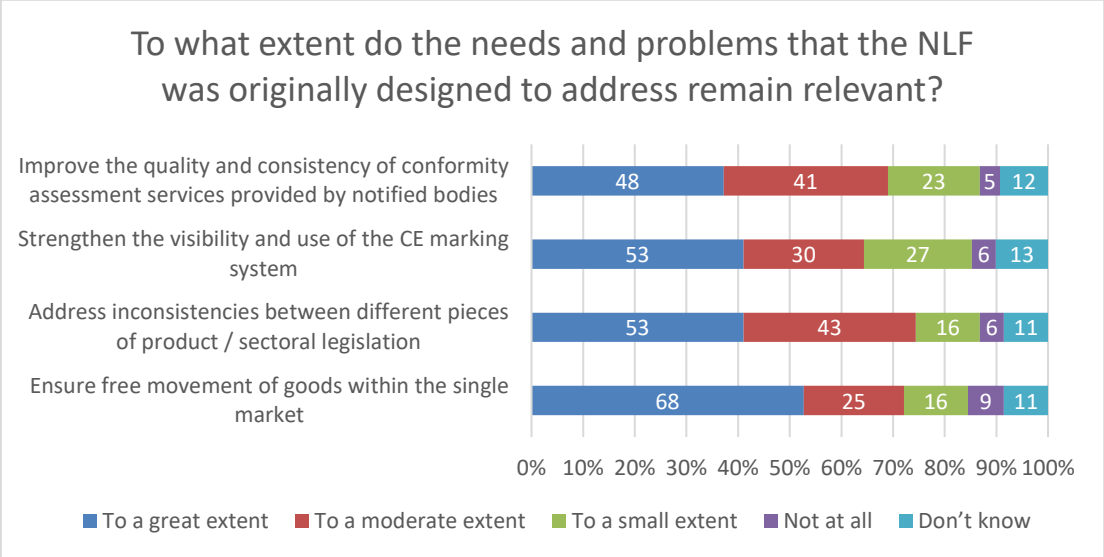

Figure 5 Targeted consultations: Extent to which the needs and problems that the NLF was originally designed to address remain relevant (Question 51, N=129)

The relevance of the definitions set out in the NLF

The analysis provided by the Study of the CSES explains the reasons why the definitions of the NLF might sometimes be lacking relevance today. It explains that **the set of definitions of the NLF reflects the legislator's main concern, stemming from the 1970s, to improve the free circulation of goods within the single market**. Given this focus on the internal market in 2008, the NLF did not take much consideration of the emerging globalisation of trade, which has had a considerable impact on: i) documenting and assessing compliance for economic operators and conformity assessment bodies; and ii) enforcing legislation on products imported from outside the EU.

For instance, the definition of the "importer" referred more to an intra-EU cross-border importer than to an international trader importing products from all over the world, therefore the NLF requires that the importer is established in the EU. However, nowadays, as reported to the Commission by Toys Industries of Europe, the EU-establishment criteria might lead to a less favourable treatment of EU-established importers comparing to e.g. online marketplaces sending products to the EU. In cases of online sales from third countries, there is no economic operator established in the EU (which could qualify as an importer), therefore in such cases there is no economic operator with the responsibility of an importer.

Another definition that may need rethinking is the **definition of accredited NBs**. According to Regulation (EC) No 765/2008, conformity assessment bodies can be accredited. The Regulation does not mention the possibility of accreditation of natural persons. Nonetheless, Regulation 1221/2009[87] (EMAS) defines as environmental verifier "any natural or legal person, or any association or group of such persons, which has obtained a licence to carry out verification and validation….." while it also sets out (Article 2(30)) that "accreditation body means a national

[87] Article 2 (20) (b) of Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC

accreditation body appointed pursuant to Article 4 of Regulation (EC) No 765/2008 which is responsible for the accreditation and supervision of environmental verifiers".

Furthermore, during the past years, there has been a **gradual shift in the legislator's priorities in designing NLF-aligned sectoral legislation**, from ensuring the free movement of goods to reinforcing the level of confidence in the market in relation to core EU policy objectives applying not only to the products themselves but also to the way they are used.

Since the entry into force of the NLF in 2008, manufacturers have significantly **changed their business models** by making their products available on the market increasingly as a part of a customer-oriented solution. This involves numerous services, such as installation and putting into service[88], regular monitoring and maintenance, software and performance updates, training, repair and refurbishing, and even take back and recycling. Such changes have brought them into competition with third-party servicing companies that were already involved to various extents in similar activities, such as machine, equipment and tool rental companies. Therefore, the dividing line between goods and services and the responsibility of different economic operators became blurred.

Interviewed stakeholders recognised the increasing blurring between products and services through the phenomenon known as **servitisation**. *"As the complexity and variety of business activities grow and digitalisation spreads, the boundaries between services and manufacturing become increasingly elusive"*.[89] However, the NLF does not define **new aspects in the value chain**, such as the increased role of services within products (either bundled or add-on services), and what this means from a regulatory perspective in terms of ensuring product safety at the point in time of placing on the market but especially post market placement, as services are typically provided once the product is in operation.

While historically the NLF was essentially focused on the free circulation of goods and compliance with a high level of safety, it has gradually expanded to cover compliance with **environmental protection rules and other core EU interests**. This requires consideration of the whole life cycle of a product, in addition to its 'placing on the market'. The same logic applies to the consideration of safety and privacy aspects related to the marketing of digital solutions and systems involving products.

Many stakeholders across all groups recognise the need for clarification of the **roles and responsibilities of stakeholder categories that were not recognised in the NLF**, but are playing increasingly important roles in the market. These include stakeholders, such as software and application developers, and online marketplaces.

Consequently, it seems that there is a potential need for updating and adding new definitions within the context of the NLF as a result of market trends and emerging Union legislative proposals.

Substantial modification of a product

The NLF is based on assessing the safety and compliance of products at the time they are placed on the market. It does not address changes that may occur to products after they are put into service.

[88] Currently the concept of "putting into service" is introduced in several pieces of Union harmonisation legislation. It also may differ according to specific Union harmonisation legislation, such as the legislation on medical devices. As regards lifts and equivalent products, the putting into service should be considered to take place at the moment when the first use within the Union is possible.
[89] Hojnik, J. (2016) The servitisation of industry: EU law implications and challenges.

Today, it is encouraged that products are reused, refurbished or even remanufactured rather than discarded after being in use for certain time. Consequently, the NLF may not cover all the questions related to the safety of products under the new circumstances. It has therefore been argued that a more 'dynamic notion' of a product compliance is needed to reflect the changing reality in terms of how products evolve post-market placement, for example due to software updates and upgrades.

The conformity assessment procedures are correspondingly ensuring compliance when the product is placed on the market, but not necessarily in the changing environment. The objectives of promoting the circular economy and ensuring product safety should be equally addressed in the conformity assessment procedure.

Re-manufacturing may be seen as a driver of the circular economy, and is supported by key EU initiatives and strategies, such as the 'European Innovation Partnership on Raw Materials' (EIP-RM) which contributes to the objectives of the Innovation Union and Resource Efficient Europe initiatives and provides opportunities for the creation of highly skilled jobs and economic growth.[90] The main environmental argument for remanufacturing is that it results in dramatically less energy and material use than production of new products from virgin materials.[91]

Remanufacturing involves practices in a wide range of industrial sectors, but is best suited for industries that are capital-intensive and produce products that have a long product life-cycle[92]. Industries which have been shown to be particularly suited to re-manufacturing include: aerospace, automotive, electrical and electronic equipment, furniture, heavy duty and off-road equipment, machinery, marine, medical devices and rail, among others. Although about 90% of remanufacturing activity is in the business-to-business sphere[93], it is increasingly being applied to consumer products.

However, **despite remanufacturing becoming a growing industry and a linchpin of the circular economy**, the rules in terms of guaranteeing the safety and compliance of goods that are remanufactured are perceived to be unclear.

Most stakeholders consider the absence of the concept of a '**substantial modification**' in the NLF a **prominent legal gap,** as the increased complexity of value chains is also inherent to circular economy business models. The NLF does not determine when a product to be considered modified to the extent where it becomes a new product and therefore should be subject to conformity assessment procedures prior to being placed on the market again. Since the NLF pre-dates the significant increase in refurbishing and remanufacturing, it does not include any definitions of economic operators involved in such modifications either, such as repairers, refurbishers or remanufacturers with their role in the value chain or stipulate any obligations.

The reference provision in Article R6 of Annex I of Decision No 768/2008/EC sets out the cases in which obligations of manufacturers apply to importers and distributors. According to this provision an importer or distributor should be considered a manufacturer subject to the obligations of the

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[90] European Commission. (2020). Innovation Union.

[91] Re-defining Value – The Manufacturing Revolution | Resource Panel

[92] The circular economy dimension within European manufacturing has grown significantly in the past decade. The European Remanufacturing Council has estimated the market to be worth approximately €30 billion annually in Europe. This was viewed as being relatively small as only about 2% of products that *can* be remanufactured *are* presently being remanufactured. This is likely to grow both as a result of the trend towards circular business models in some industries, but also as a result of the Sustainable Products Initiative[92] (SPI) extending the requirements in the current Ecodesign Directive[92] to include not only energy efficiency, but also materials efficiency.

[93] Remanufacturing Market Study

manufacturer, ***where they modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected.***

Chapter 2.1. of the Blue Guide contains the following explanation on **when a modified product should be considered as a new one** and the responsibility of the person who carries out such modification: '*A product which has been subject to important changes or overhauls aiming to modify its original performance, purpose or type may be considered as a new product. The person who carries out the changes becomes then the manufacturer with the corresponding obligations.'* The Blue Guide also explains that a product, which has been subject to important changes or overhaul after it has been put into service must be considered as a new product if: i) its original performance, purpose or type is modified, without this being foreseen in the initial risk assessment; ii) the nature of the hazard has changed or the level of risk has increased in relation to the relevant Union harmonisation legislation; and iii) the product is made available (or put into service if the applicable legislation also covers putting into service within its scope). This has to be assessed on a case-by-case basis and, in particular, in view of the objective of the legislation and the type of products covered by the legislation in question.

As is the case for physical repairs or modifications, a product should be considered **as substantially modified by a software change** where: i) the software update modifies the original intended functions, type or performance of the product and this was not foreseen in the initial risk assessment; ii) the nature of the hazard has changed or the level of risk has increased because of the software update; and iii) the product is made available (or put into service where this is covered by the specific Union harmonisation legislation).

Some stakeholders (a trade association) believe that the clarification provided in the Blue Guide is sufficient for manufacturers and authorities to understand their responsibilities and cope with their respective duties while preserving flexibility in doing so, depending on the level of risks involved. Others, however, oppose the non-binding status of the Blue Guide and the related risk of misinterpretation.

Stakeholder feedback on the NLF's ability to accommodate the circular economy was gathered through the interview programme.

Some stakeholders interviewed from the refurbishing and remanufacturing sectors perceived that the NLF is outdated and not in line with current market practices and realities. However, there were differences of opinions regarding the best way forward in dealing with this question.

Some stakeholders were in favour of building on wider initiatives instead of changing the NLF, such as:

- The revisions of the Blue Guide: The Blue Guide provides a definition of a substantial modification, and explains the role of refurbishers, remanufacturers and repairers as new economic operators within value chains.
- The development of harmonised standards that provide specific definitions and concepts relevant to the circular economy. Examples of relevant harmonised standards mentioned were: TR 45550[94] – definitions relevant to the circular economy and EN 45559 on material efficiency[95].

The lack of a common definition and the concept of 'substantial modification' may result in **incoherence** among the legislations trying to cope with the increased complexity of value chains

[94] CLC/TR 45550, Definitions related to material efficiency
[95] EN 45559:2019 - Methods for providing information relating to material efficiency aspects of energy-related products

and accommodate the circular economy business models. Some of the revised NLF-legislations and recent legislative proposals contain different definitions as to what constitutes a substantial modification or fully refurbishment. In any instance, **all industry stakeholders consulted agreed on the need for the EU legislator to harmonise all the proposed definitions of substantial modification**, to ensure a common understanding between all parties. Where needed, stakeholders considered that sector-specific, complementary provisions could be necessary to facilitate its application and ensure legal certainty for economic operators.

The examples in Annex XI demonstrate that there is a **diversity in terminology** to describe the modifications of products following their placing on the market in such a way that compliance with the applicable requirements is affected (e.g. refurbishment, remanufacturing, repurposing, substantial modifications).

It is important to keep in mind that the new legislative initiatives aim to modernise the EU's legislative framework, as an integral part of the EU's Green Deal[96]. They build on commitments and reports adopted by the European Commission, including the New Circular Economy Action Plan[97] and the New Industrial Strategy for Europe[98].

In the **context of the UN Sustainable Development Goals (SDGs)**, the NLF is supposed to address responsible consumption and production. More specifically, it should contribute 1) to substantially reduce waste generation through prevention, reduction, recycling and reuse, by 2030 (target No. 12.5) and 2) to encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle (target No.12.6).

Based on the triangulation of the responses in the survey it seems that the NLF is able to respond to the current and upcoming needs of product legislation and preserve its relevance if it is able to provide a general framework for dealing with the challenges of the complex value chains. The NLF needs to accommodate the principles set out in the New Circular Economy Action Plan and therefore enable and foster remanufacturing and high-quality recycling of products. The NLF will be able to retain its effectiveness and efficiency as an important general framework for product legislation if it manages to keep up with the objectives of the circular economy. The NLF has been identified as a decisive cohesion tool in EU product legislation. Thanks to it, the **highest possible level of coherence has been achieved** in the EU's product legislation. Although Decision No 768/2008/EC only provides for a template specific legislation, it tremendously facilitates the drafting of EU product legislation and ensures the uniformity of the body of EU product legislation. If it does not contain framework provisions that are expected to be integrated in a modern EU legislative framework, the drafters of new legislative initiatives will necessarily look for inspiration anyplace else. Without the necessary updates of this general framework, the NLF may lose its actuality and become obsolete.

General relevance of the NLF in the light of digitalisation

Besides the **CE marking** that must be affixed on the product visibly, legibly and indelibly, the NLF requires that **traceability information** is indicated on the product or, where that is not possible, on its packaging or in a document accompanying the product.

[96] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal (COM (2019) 640 final)
[97] A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM/2020/98 final
[98] Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery, COM(2021) 350 final

The NLF also provides that the manufacturer has to draw up and upon a request of the market surveillance authorities provide the **technical documentation** and **EU declaration of conformity**[99]. Manufacturers also have to ensure that the product is accompanied by **instructions** and **safety information,** in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Relatively few stakeholders (between 15.2% and 20.2%, depending on the trend in question, out of 198 responses) took the view that **the NLF is able to accommodate key trends related to digitalisation and the integration of new technologies** in products 'to a great extent', although even fewer (between 3.5% and 7.1%) consider that this was 'not at all' the case. Stakeholders were most likely to consider that the NLF is able to accommodate the key trends identified to a small or moderate extent, or to answer that they don't know.

A series of questions were posed to the stakeholders related to the **appropriateness** of the CE marking, which must be visibly and indelibly affixed to the product and other product information and documentation that must be provided in a hard copy.

As indicated above in Chapter 4.1.4 devoted to the assessment of the efficiency of the CE marking and other product information obligation, industry estimates the **affixing of the CE marking** visibly and indelibly on the product as well as other traceability information such as the postal address of the manufacturer/importer less burdensome (36.2%, i.e. 17 responses) than **printing out product information** to accompany the product (83%, 39 responses).

Economic operators, industry associations, consumer associations, MSAs and national competent authorities were asked in the targeted consultations **whether they consider that the NLF's general information obligations addressed to consumers remain necessary and appropriate**. Respondents were far more likely to agree that affixing the CE marking visibly and indelibly on the product, as well as other traceability information was, to a great extent, necessary and appropriate, compared to printing out information to accompany the product.

Industry respondents were in favour of moving towards **digital-only CE marking, product compliance and user information as soon as possible**. This was seen as potentially reducing costs, but only if hard copy versions were no longer required. However, **none of the national competent authorities shared this view**.

[99] Blue Guide, Title 3.1. Manufacturer: Upon a reasoned request, the manufacturer has to provide the competent national authority with all the information and documentation necessary to demonstrate the conformity of a product, in a language which can be easily understood by that authority. This would include, for example, the declaration of conformity, the relevant part of the technical documentation, or certificates issued by Notified Bodies. *If agreed with market surveillance authorities, this information may be transmitted electronically*.

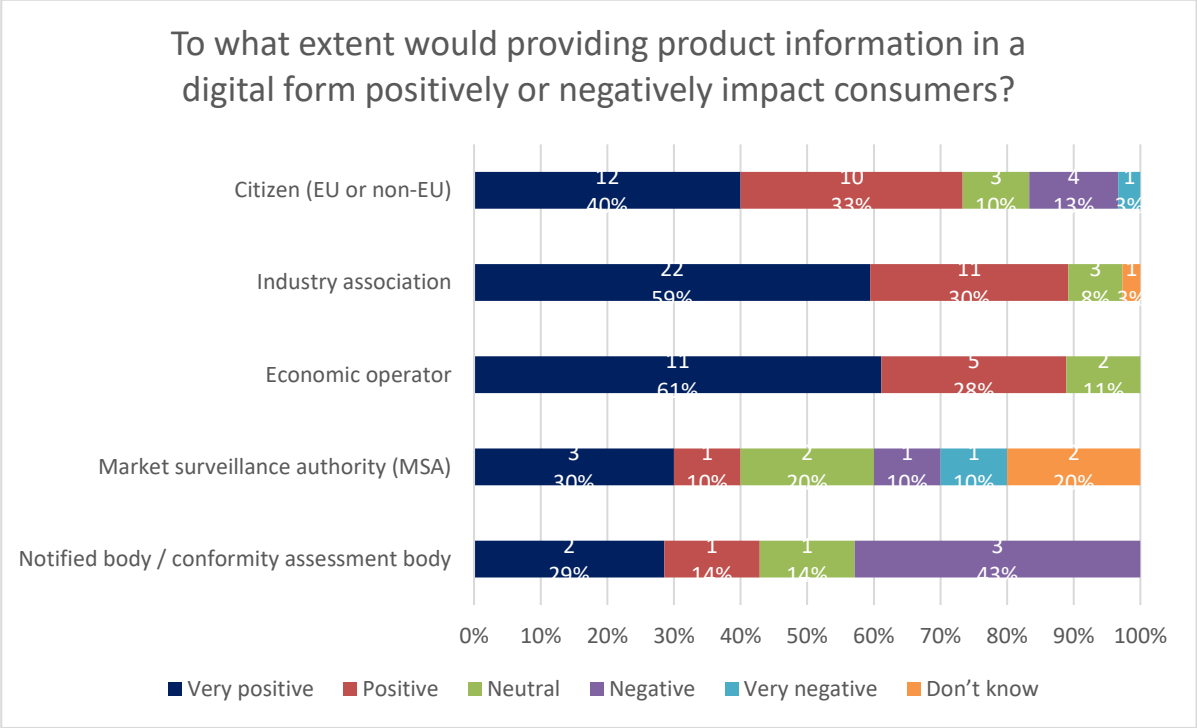


Figure 6 Public consultations - Impact on consumers of providing product information in a digital form (disaggregated by stakeholder type, N=102)

Respondents that viewed digitalisation positively argued that it should always be possible to provide and access information, regarding whether a product carries the CE mark, and in relation to its declaration of conformity or the technical file, in digital format rather than on paper.

Triangulating these findings with the views of interviewed stakeholders, a general consensus emerged across all stakeholder groups regarding the potential benefits of digitalising the obligations that require information to be printed.

Most stakeholders believe that digitalisation could facilitate and speed up compliance by simplifying the way in which manufacturers meet information obligations. **Digitalisation** would serve two objectives: **simplification and environmental protection**.

Based on the public consultations, 45,5% of the stakeholders would appreciate a digital CE marking, 63,2% would appraise positively the digital traceability information (e.g. postal address of the manufacturer/importer), while 72% took the view that providing safety documentation and instruction materials in a digital form would be beneficial.

The primary challenge for the digitalisation of these obligations is the potential impact on **users that are less digitally adept**. Economic operators, industry associations, consumer associations, MSAs and national competent authorities were asked in the targeted consultations about the extent to which the **digitalisation of CE marking / traceability / product information would jeopardise the right of consumers** to be duly informed. There was **some divergence in the responses of the different stakeholder types**. Industry associations (71%, 22 responses) and economic operators (43.8%, seven responses) were most likely to answer that digitalisation would 'not at all' jeopardise the consumer's right to be informed. However, none of the national competent authorities shared this view. While some acknowledged that they preferred 'a digital way forward', it was also accepted that not all consumers are digitally adept. Stakeholders explain that **providing information in a digital format of documents** such as the EU declaration of conformity or the

instruction accompanying the product, **could be an 'either/or' option**, and not an additional requirement. The development of common standards and specification for the content and format of the required product information would further facilitate the fulfilment of administrative obligations.

The Proposal of the machinery regulation foresees that manufacturers provide **digital instructions and the declaration of conformity**. Nevertheless, a paper format is mandatory upon request. (Essential health and safety requirements, 1.7.4). This Proposal explains that one of the problems identified were the monetary and environmental costs due to extensive paper-based documentation. On allowing digital formats for documentation, almost all the stakeholder groups representing the industry indicated that are in favour. Most Member States and consumers organisations are in favour of ensuring also paper format.

Using a **digital product passport** that would include an electronic declaration of conformity and the description of the conformity assessment procedure is often seen as possible simplification and means of lifting administrative burden of the economic operators. A digital passport could also facilitate market surveillance, reduce the costs and improve the effectiveness of the enforcement.

Some recent legislative proposals such as the Proposal for the regulation on batteries and waste batteries and the Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products provide for a digital product passport.

The Proposal for the regulation on batteries and waste batteries provides for an electronic record for industrial batteries and electric-vehicle batteries and a Battery Passport, for each individual battery placed on the market. The Battery Passport would be unique for each battery, to be identified through a unique identifier. The battery passport would be linked to the information about the basic characteristics of each battery type and model stored in the data sources of the system established by the Proposal and should be accessible online.

The Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products would apply to any physical goods placed on the market or put into service[100], including components and intermediate products. The proposal foresees a digital product passport to electronically register, process and share product-related information amongst supply chain businesses, authorities and consumers. Recital (26) of the Proposal explains that the product passport should not replace but complement non-digital forms of transmitting information, such as information in the product manual or on a label. In addition, it should be possible for the product passport to be used for information on other sustainability aspects applicable to the relevant product group pursuant to other Union legislation.

The Proposal for a Regulation laying down harmonised conditions for the marketing of construction products, amending Regulation (EU) 2019/1020 and repealing Regulation (EU) 305/2011 in its Article 78 foresees an EU construction products database or system. This system or database would build on the digital product passport established by the Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products.

Establishing the model for the product passport by the NLF in the future could be beneficial to retain its aligning function and ensure coherence among the different pieces of product legislations. The new legislative initiatives will most probably tend to keep up with the digitalisation, while the existing legislation will also be revised to meet the modern market trends. **Without a general**

[100] Except food, feed, medicinal and veterinary medicinal products, living plants/animals/microorganism, products of human origin, products of plants and animals relating directly to their future reproduction (Article 1(2) of the Proposal).

model offered by the NLF, product legislations will most probably create their own models of product passport.

None of the product legislations and legislative initiatives have departed from the NLF when it comes **to CE marking**, even if, for example, the Medical Devices Regulation, *In vitro* diagnostics Medical Devices Regulation foresee that software, as a standalone product can be a medical device/*in vitro* diagnostic medical device (Article 2(1) of both Regulations). If such product is a downloadable software and being sold without any data carrier, affixing the CE marking to an intangible product can be hardly imagined.

Similarly, the Proposal of the AI Act in Article 3(1) defines that the 'artificial intelligence system' (AI system) is a software, but the CE marking provisions of the AI Act refer to the relevant provisions of the NLF.

A possible future impact assessment on the NLF should consider introducing the possibility of the digital CE marking to ensure the use of CE marking in the digital environment.

Relevance of the conformity assessment procedure

68,9% of stakeholders (73 respondents) in the targeted consultations considered that, at least to a moderate extent, the **NLF requirements for notified bodies remain appropriate**, including 34% (36 respondents) who considered this to be the case to a great extent.

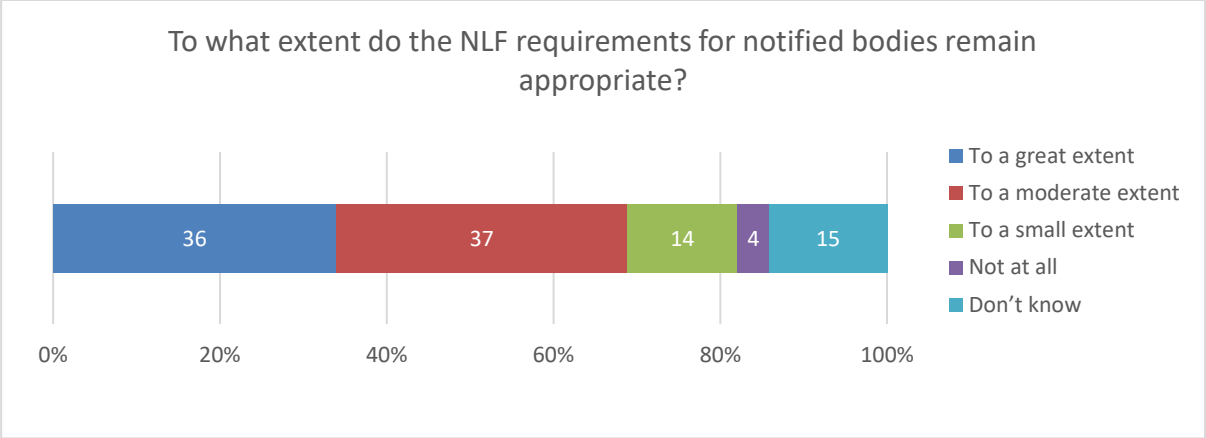


Figure 7 Targeted consultations: Extent to which the NLF requirements for notified bodies remain appropriate (Question 25, N=106)

These overarching findings are validated by the targeted consultation results. 2/3 of the stakeholders (74/96 respondents) perceive that the **suite of conformity assessment modules remains fit for purpose** to at least a moderate extent to ensure that products placed on the Union market comply with relevant EU legislation.

Industry associations evaluate very positively the conformity assessment modules set out in Decision No 768/2008/EC and that the modules, although containing more or less phases depending on their complexity, are based on the same steps.

The majority of industry stakeholders believe that the use of **module A** (internal production control, without a mandatory involvement of a third party) should remain a cornerstone in the new product legislation and revised regulations. Industry stakeholders point out that several of the current legislative proposals tend to require third party conformity assessment for products over self-assessment, **disregarding the risk-based approach for selecting conformity assessment modules**

mentioned above. Module A is linked to faster time-to-market, which is an important element for the competitiveness of European manufacturers.

Economic operators, industry associations, and national competent authorities were also asked in the targeted consultations and interviews to consider **the extent to which the current conformity assessment modules are adapted to the latest manufacturing practices** and were presented with three scenarios. Only a minority agreed that the modules were adapted to the latest practices to a great extent. Stakeholders were most likely to say that the modules are 'not at all' adapted to the latest practices in a scenario in which 'if the product is modified following its placing on the market, it will remain safe and compliant during its lifetime'. As mentioned earlier, the focus of the NLF is the moment when the product is placed on the market and therefore the conformity assessment is also focusing on that moment, whereby the modifications done to the product following its placement on the market are not covered by the existing modules.

Under the NLF, manufacturers are required to undertake a risk assessment as part of the conformity assessment, prior to placing a product on the market. In addition, risks should be adequately considered in the technical documentation (i.e. in the technical file to support the DoC).

However, there remain outstanding questions as to **whether the NLF addresses specific risks relating to the integration of new technologies into products**, as there are no specific rules or guidance on these aspects. This gap already appears to have led to recent legislative proposals moving beyond the common provisions of the NLF and introducing additional regulatory requirements. For instance, in the Proposal of the machinery regulation, as well as the Proposal of the AI Act, manufacturers that are integrating AI technologies and systems into machinery would be required to perform a risk assessment of potential risks associated with the AI that may emerge post-market placement (given the autonomous learning capabilities of AI) before they place a product on the market.

The aim of these regulatory developments is to tackle market challenges that did not exist when the NLF was adopted and improve the robustness of risk assessment if increased risks are identified linked to particular new technologies. The Commission has indeed identified a need to introduce regulatory measures to address the specific risks and challenges posed by AI systems due to their specific characteristics. At the same time, most industry associations and large manufacturers interviewed expressed concerns about the concept of introducing risk assessment requirements linked to the use of specific new technologies, especially AI. The main concern is that this **diverges from the technology-neutrality principle** of the NLF (and earlier the New Approach), which states that "specific product legislation should, wherever possible, avoid going into technical detail but should limit itself to the expression of essential requirements"[101].

Certification stakeholders noted that, in the context of the changes brought by the digital and green transitions and more specifically the trend that products are modified, refurbished and being placed on the market as new products, there **may be room for an additional conformity assessment module**. Such an additional module could focus on validation and verification of a product's compliance of its entire lifecycle.

Directive 2013/53/EC on recreational craft and personal watercraft provides for a separate conformity assessment for products subject to substantial modification. This conformity assessment procedure is focused on the post-construction assessment of a product (Annex V, module PLC). The modified product must bear a plate with the words 'post-construction assessment'. A future possible

[101] Recital 8, Decision No 768/2008/EC on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

impact assessment may explore whether including a similar additional module to the NLF would render it more responsive to the modern supply chains and needs of the circular economy.

By triangulation of all the data collected, we may conclude that the existing conformity assessment and the menu of the modules contained in Decision No 768/2008/EC is still relevant. Nonetheless, the possible future impact assessment on the NLF may reconsider an update in terms of a new module, specifically serving the objectives of circular economy, foreseen for products subject to substantial modification.

Remote conformity assessment

As documented in an EA communication, published on 23rd March 2020, the outbreak of the COVID-19 pandemic[102] and the related travel restrictions implemented by governments across the EU, conformity assessment and national accreditation bodies were forced, in the first instance, to "cancel or postpone most of their *in situ* activities such as on-site assessments, audits, witnessing visits and inspections"[103].

This situation forced all notified bodies to overcome any reluctance and implement remote assessment activities. As a peer evaluator at EA noted, the **workforces at CABs and NABs across the EU, as well as EA peer evaluators, were required to adapt extremely quickly** to ensure the competence and consistency of conformity assessment, accreditation and peer evaluation services was maintained when being conducted remotely.[104]

Views on the success of this shift to remote activities were sought through interviews with relevant stakeholders and an open-ended question in the targeted consultation. In this respect, the interviewed **notified bodies and NABs considered the experience to have been generally successful**. In the first instance, a respondent to the targeted consultation praised the speed with which EA responded to the emerging COVID situation in March 2020.

However, stakeholders highlighted a few caveats and disadvantages to remote assessments:

- Remote assessments will never fully replace face to face activities, particularly in certain areas where face to face conversations are perceived to be essential, such as audits.
- In relation to remote peer evaluations, an EA evaluator highlighted that contact and interaction between the personnel involved in the peer evaluation process can be more difficult, as can the process for defining and agreeing on non-conformities.[105]

With this in mind, the evolving situation of one NAB characterises the overall positive views across these stakeholder groups. The NAB noted that, in contrast to its pre-COVID scepticism about the appropriateness of remote assessments, it is now **actively exploring ways in which remote methods can improve the accreditation process**, highlighting ideas such as the use of smart glasses with an embedded camera and microphone for use in witnessing visits. However, as this is a recently emerging reality, the discussion on the merits and consensus on when remote conformity assessment services can be implemented and their appropriateness across different sectors is ongoing.

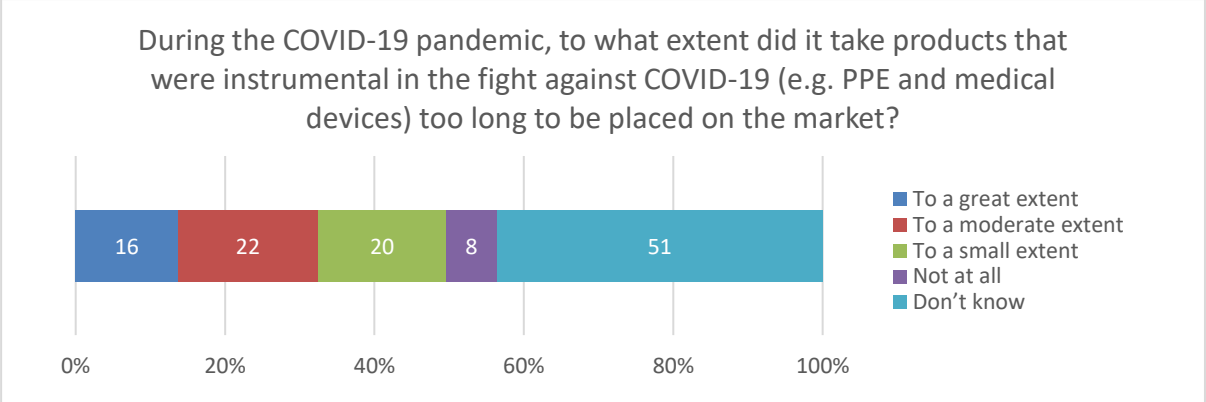
[102] From more details please see the Study, Section 4.2.5.2. Remote assessment of conformity assessment, accreditation and peer evaluation.
[103] https://european-accreditation.org/ea-communication-to-the-impact-of-the-covid-19-outbreak/
[104] https://european-accreditation.org/remote-peer-evaluation-feedback-from-mija-renko-sa-slovenia/
[105] https://european-accreditation.org/remote-peer-evaluation-feedback-from-mija-renko-sa-slovenia/

It was also suggested that the development of a normative harmonised procedure for conducting remote audits within the EN ISO/IEC 17000 series could be beneficial.

The remote conformity assessment procedure is not foreseen by the NLF. Nonetheless, the COVID-19 pandemic made us realise that even if it cannot replace the *in situ* procedure, it can often complement it. A possible future impact assessment may explore if the possibility to undertake remote conformity assessments should be included into the text of the NLF.

Relevance of the NLF in an emergency situation

Asked about the extent to which, during the pandemic, it took products that were instrumental in the fight against COVID-19 too long to be placed on the market, almost half of stakeholders (49.8%, 58 responses) in the targeted consultation agreed that it took too long (whether to a small, moderate, or great extent). However, 43.6% of the stakeholders (51/117) responded that they don't know. Only 6.8% of stakeholders (eight responses) answered 'not at all' i.e., that it had not taken too long for products such as PPE and medical devices to be placed on the market during the pandemic.



Question 57 was asked to: economic operators, industry associations, MSAs, national competent authorities, national accreditation bodies, national notifying authorities and notified bodies.

Figure 8 Targeted consultations: Extent to which it took products that were instrumental in the fight against COVID-19 too long to be placed on the market (Question 57, N=117)

There was some variation by stakeholder type: industry associations (31.3%, five responses) and national accreditation bodies (27.3%, three responses) were the most likely to agree to a great extent that it took too long for products to be placed on the market. Some stakeholders believe that the product conformity assessment system is too complex for crisis situations and that a special crisis-adapted procedure should be considered, perhaps centralised through an EU solidarity mechanism.

Others posited that the main problem in bringing products, such as PPE, to the market during the COVID crisis related primarily to supply and demand. It would have been more advantageous to address the shortage through increasing production capacity and conformity assessment capacity rather than by easing regulatory requirements. To reduce regulation would be to risk inadvertently allowing non-compliant and unsafe products to be marketed.

Another tool put forward by stakeholders to ensure an accelerated response to the market needs in case of emergency could be the more extended use of the remote conformity assessment, where it is appropriate.

Nonetheless, the Commission Working Programme 2022 – Making Europe stronger together, separately from this evaluation of the NLF, includes an initiative for a Single Market Emergency

Instrument[106]. Therefore, the Proposal for a Regulation on establishing the Single Market emergency instrument was adopted on 19 September 2022.

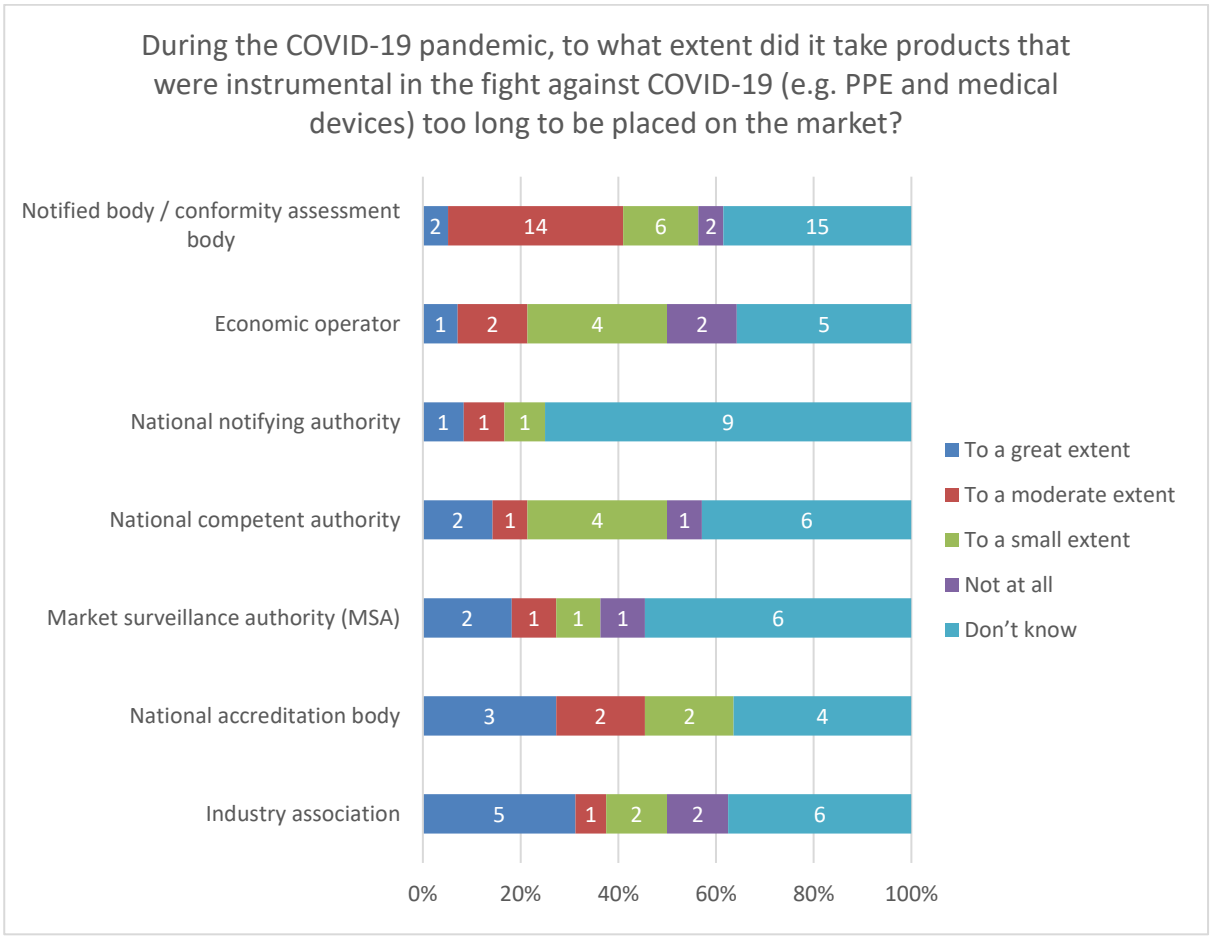


Figure 9 Targeted consultations: Extent to which it took products that were instrumental in the fight against COVID-19 too long to be placed on the market: responses by stakeholder type (Question 57, N=117)

Based on the triangulation of the evidence collected for this evaluation, **we conclude that the NLF by and large is still able to respond to current and emerging needs, nonetheless in the light of ongoing digitalisation and trends to better achieve the objectives of the circular economy, some of its provisions may soon lag behind the more modern solutions foreseen in newer proposals or legislations and therefore lose their future-proof coherence**. Digitalisation of the CE marking would be highly appreciated in some sectors, while it seems to be less relevant for others. Regarding the product information obligations, digitalisation has already been foreseen in certain legislative proposals, therefore in case of a possible future revision of the NLF it will be necessary to rely on the digital solutions already foreseen by then in certain product legislations.

[106] Single market – new EU instrument to guarantee functioning of single market during emergencies (europa.eu). The public consultations for the Call for evidence for an impact assessment were open between 13 April and 11 May 2022: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13181-Single-market-new-EU-instrument-to-guarantee-functioning-of-single-market-during-emergencies_en

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

1.8. 5.1. Conclusions

The above assessment, based on the triangulation of different data sources and expertise, shows that the NLF has **contributed strongly to the achievement of its general objectives**: it has provided a high level of protection of public interests, fostering the free movement of products within the single market and establishing a common harmonisation framework.

The conclusions are based on the triangulation of all the evidence collected with the methods listed in Section 1.1. (desk research, legal mapping, interviews and consultations, stakeholders' workshop, case studies), conducted by CSES. Nonetheless, in the absence of explicit data eligible for quantification, for certain aspects of the efficiency of the NLF, the interviews with the stakeholders, targeted consultations and the workshop were crucial for collecting evidence. Despite their usual limitations, the stakeholders' consultations are considered to be a credible and sufficiently deep base of evidence, given the diversity of participating stakeholders and their high interest in participating in the surveys and workshop.

The alignment with the NLF's reference legal provisions and use of the NLF's common implementation mechanisms has been ensured across 16 directives,7 regulations and a delegated act to date. Therefore, this assessment takes account of the earlier sector-specific evaluations, nonetheless, their relevance in the context of this evaluation is often limited. The fact that these assessments rather evaluate the performance of the specific pieces of EU product legislations, from the perspective of their specific policy objectives and without focussing on the performance of the NLF sets limitations to the suitability of conclusions drawn in the sector specific evaluations. The assessment of the effectiveness and efficiency is in most cases not explicitly attributable to the NLF. The estimation of the NLF-related costs and benefits and especially their quantification are therefore often limited. The **positive effects of the NLF, considering both monetary and non-monetary benefits, strongly outweigh the costs**. The NLF comprises very few direct costs, as most costs associated with the framework of EU product legislation stem directly from compliance with individual pieces of NLF-aligned legislation. However, **a wide range of cost savings** and other benefits have been highlighted by stakeholders. For economic operators, these benefits included reduced costs in familiarisation with legislative requirements by economic operators due to the implementation of common provisions; greater regulatory certainty; greater harmonisation of obligations; reduced market barriers; and, as a result, enhanced industrial competitiveness. Nonetheless, the lack of quantification elements impedes us to draw more precise conclusions on the costs and benefits of the NLF.

Positive progress has also been made across the NLF's specific objectives relevant to this evaluation as explained below, however, certain implementation challenges were highlighted in many cases.

Reinforcing the New Approach

The commitment to expressing essential requirements that avoid going into technical details has been clearly implemented across NLF-aligned legislation. The NLF managed to **reinforce the technology-neutral approach throughout the EU product legislation**.

Thanks to the technologically neutral regulatory framework based upon essential requirements, the NLF is perfectly suited to cope with the **higher speed of technical innovation.**

Nonetheless, **the success of the NLF depends heavily on having a quick and effective standardisation process**. The absence or delay in the adoption of harmonised standards leads to the

increase of the costs of conformity assessment and may have a negative impact on innovations: If the harmonised EU standards lag behind the newest international standards representing the state of the art, the NLF is not able to perform as expected.

Industry stakeholders are highlighting that there is a trend in the new legislative proposals of EU product legislation to incorporate more granular technical requirements. The impact of this tendency, according to these stakeholders, is reduced flexibility of the legal framework to deal with changes in the market, an **erosion of the principle of technological neutrality**, resulting in negative impacts on innovation and competitiveness.

To retain the NLF's technological neutrality, product legislation should limit itself to the expression of essential requirements. The drafters of new legislative initiatives should make sure not to include unnecessary technical details into the texts of future EU legislations to preserve the technological neutrality of the NLF-aligned legislations.

Supporting the consistency and coherence of EU harmonisation legislation

The process of aligning 23 pieces of EU legislation and a delegated act to the NLF has heavily strengthened the consistency and coherence of these acts. In support of these achievements, the internal coherence of the two NLF legal texts being examined was considered to be strong; no particular inconsistencies or overlaps have been identified.

In this respect, the **coherence of the NLF with wider EU legislation was considered to be strong in its first decade**, with only minor examples of divergence between the NLF / NLF-aligned legislation and non-NLF aligned legislation identified.

Mostly minor challenges and examples of divergence exist across the wide body of NLF-aligned legislation, but it remains important to consider the **cumulative impact of these minor challenges and divergences**.

Better implementation of the NLF in the revised or new product legislation could improve the coherence of the EU product legislation. To ensure consistency and avoid unnecessary divergences some stakeholders at the validation workshop suggested that **justifications for deviations in NLF-aligned legislations should be included in the recitals of the product legislation**, noting that such an exercise could also restrict the scale of deviations by ensuring that the legislator fully considers their necessity.

To further respond to the need of **future-proofing coherence of the NLF** as regards upcoming legislation developments to address the objective of the circular economy, some stakeholders and other experts in the field, including in the Commission services, suggest introducing additional definitions, such as 'refurbisher', 'remanufacturer', 'substantial modification'.

It seems that there is a potential need for updating and adding new definitions within the context of the NLF as a result of market trends and emerging Union legislative proposals, which could be further explored in a possible future impact assessment.

The Commission service responsible for trade stressed that to ensure coherence and consistency in the implementation of international trade agreements concerning the recognition of conformity assessment results, a possible future impact assessment could explore whether a set of reference provisions (e.g. on conformity assessment and notification of conformity assessment bodies under the mutual recognition agreements) to be used for the purpose of implementation of international trade agreements concerning the recognition of conformity assessment results could also be included in the NLF.

Strengthening the conformity assessment system

The adoption and practical implementation of the legal framework for accreditation was a very important achievement under this objective, as no European framework for accreditation existed previously. Similarly, the suite of conformity assessment modules detailed in Annex II to Decision No 768/2008/EC and the requirements for notification of conformity assessment bodies were considered to be important outputs by all relevant stakeholders. Due to the requirements set by the NLF, the notifying authorities also strengthened the supervision of the notified bodies.

However, the analysis done in the framework of the CSES study concludes that more needs to be done to ensure uniformity in conformity assessment services across the EU, as a range of application challenges currently persist, including the non-mandatory nature of accreditation. Therefore, the majority of stakeholders agreed that the NLF does not ensure that the procedures for monitoring non-accredited notified bodies are sufficiently reliable and appropriate for the purposes of notification.

The monitoring of subcontracted tasks of conformity assessment bodies seems to pose challenges to notifying authorities/accreditation bodies when these tasks are performed in another Member State or in a third country. Notifying authorities/accreditation bodies could most probably improve the current situation and eliminate those subcontractors that cannot be effectively monitored and the so called 'letter-box' notified bodies fully dependent on the services subcontracted from their non-EU based mother companies through a **more consistent implementation** of the existing rules on subcontracting. Nonetheless, stakeholders seem to agree that **the NLF does not provide enough clarity on the mandatory staff, on the extent of the activities that cannot be outsourced by the notified body and possible limitations of the tasks to be subcontracted.**

A future possible impact assessment may want to explore if more precise rules should be introduced in this regard to ensure the continuous high quality of services and level-playing field for the NBs, including when outsourcing certain substantial technical tasks.

The CSES study notes that, in the context of the changes brought by the digital and green transitions and more specifically the trend that products are modified, refurbished and being placed on the market as new products, there **may be room for an additional conformity assessment module**. Such an additional module applicable exclusively for remanufactured products, although not provided in the NLF, is not new in EU product legislation since it is foreseen in Directive 2013/53/EC on recreational craft and personal watercraft. A possible new module in the NLF could focus on validation and verification of products that were subject to substantial modification following their placing on the market or putting into service or the product's compliance for its entire lifecycle.

By triangulation of all the data collected, we may conclude that the existing conformity assessment and the menu of the modules contained in Decision No 768/2008/EC is still relevant. Nonetheless, the potential impact assessment on the NLF may reconsider an update in terms of a new module, specifically serving the objectives of the circular economy and add clarifications to rules on NBs.

Enhancing the clarity and credibility of the CE marking

Although the CE marking regime was well established prior to 2008, the NLF's rules contributed to the clarification of the CE marking. They increased the industry attention on CE marking requirements, strengthened its visibility and ironed out minor inconsistencies between the different pieces of legislation.

Consumer associations still share concerns with regard to understanding the purpose of the CE marking among consumers. Balanced against this, industry respondents made clear that CE marking was well-recognised among consumers and seen as a *de facto* quality mark which can allow them to export to some third countries without further product testing. Nonetheless, the reservations coming from consumer associations show that there still might be room for awareness raising and clarifying the meaning of the CE marking.

Industry stakeholders highlighted that the need to indelibly mark products costs to manufacturers and limits the flexibility of economic operators to respond to market developments globally, as certain 'marked' stock can only be sold in the specific regions or countries they are marked for.

None of the product legislations and legislative initiatives have departed from the NLF when it comes to CE marking, even if some EU product legislation explicitly foresee **software as a standalone product**. If such product is a downloadable software and being sold without any data carrier, **affixing the CE marking to an intangible product can be hardly imagined**.

Concerning other obligations, such as printing out product information to accompany the product (e.g. instruction manuals, guidance on reasonably foreseeable use etc.), more stakeholders consider burdensome providing hard-copy instructions to accompany the product, than CE marking.

In this respect, it can be concluded that **digitalisation offers a potential solution for simplification of administrative obligations** related to product information requirements and CE marking and could also serve the environmental protection. In addition to this, we should note that digitalisation of the CE marking and other obligations might be more appropriate in some product sectors (e.g. medical devices) that in others, where the characteristics of the products and the type of consumers require the CE marking affixed to the products (e.g. toys).

1.9. 5.2. Lessons learned

More and more legislative proposals include provisions on certain aspects of digitalisation of the product information obligations, while the NLF does not provide for any digitalisation of product information obligations. A lack of a digital solutions could render the NLF less relevant in the future and hamper its future-proofing coherence.

The Opinion of the Fit for Future Platform (F4F) suggested 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. The F4F recommended that **the Commission identifies where and when it could be encouraged that information is provided digitally.**

To respond to the suggestions of the Opinion, based on this evaluation, a possible future revision of the NLF may want to consider introducing the possibility of **the digital CE marking** and the **digital product passport**. The digital product passport could include an electronic declaration of conformity and the description of the conformity assessment procedure. The digitalisation of product information and CE marking could make more effective the work of market surveillance authorities and customs[107]. With regards to customs enforcement, digitalisation is an essential aspect not only in the framework of the digital product passport but also for the possible future revision of the NLF on these issues, and in the context of the Union Customs Code (UCC) revision and the reform of the customs governance which are ongoing. A coordination between market

[107] The Wise Persons Group reporting to Commissioner Gentiloni has identified that from customs union perspective there is a need for digitalization of certificates of conformity (see p. 23 at TAX-20-002-Future customs-REPORT_BIS_v5 (WEB).pdf (europa.eu).

surveillance authorities and customs is therefore necessary to allow proper enforcement at the EU external borders. **Instructions** that must accompany the product could also be alternatively provided in a digital format, but provided in a hard-copy upon request, while **safety information should always accompany the product in a paper-based format** (with the exception of intangible products, such as a software), to ensure that all consumers have the opportunity to read them immediately upon unpacking the product. The future possible impact assessment could assess how digitalisation can serve simplification and the red tape reduction, without presenting an additional obligation.

The lack of a general framework for a product passport may lead to a proliferation of versatile definitions (e.g. product passport, e-labelling) and different levels of digitalisation depending on the specific legislations. **The absence of such a general framework may risk the proliferation of versatile sectoral initiatives, leading to the fragmentation of the market and therefore increased burden for businesses. The NLF should be able to keep its position as the future-proof framework and alignment tool for product legislation. Without the necessary instruments for the alignment, including definitions and blueprints, this role of the NLF might be endangered**. Without a general framework for the digital solutions included in the NLF, the high level of coherence among product legislations could be jeopardized because the NLF does not contain a response to the current needs of the market.

Establishing the model for the product passport by the NLF in the future could be beneficial to retain its aligning function and ensure coherence among the different pieces of product legislations. The new legislative initiatives could tend to keep up with the digitalisation, while the existing legislation will also be revised to meet the modern market trends. **Without a general model offered by the NLF, product legislations could create their own models of the digital product passport.**

Regarding the digital passport model and concept, the possible future impact assessment on the NLF may want to explore the possibilities of **building on the currently proposed EU digital passport model** foreseen in the Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products.

To be able to respond to the current and upcoming needs of product legislation and preserve its relevance, the NLF should provide a general framework for dealing with the challenges of the complex value chains, accommodating the principles set out in the New Circular Economy Action Plan and therefore facilitating remanufacturing and high-quality recycling of products. The NLF will be able to retain its effectiveness and efficiency as an important general framework for product legislation if it manages to keep up with the UN Sustainable Development Goals and the objectives of the circular economy and digitalisation.

The NLF has been identified as a decisive cohesion tool in EU product legislation. Thanks to it, the highest possible level of coherence has been achieved in the EU's product legislation. Although Decision No 768/2008/EC only provides a template for specific legislation, it tremendously facilitates the drafting of EU product legislation and ensures the uniformity of the body of EU product legislation. If it does not contain framework provisions that are expected to be integrated in a modern EU legislative framework, the drafters of new legislative initiatives will necessarily look for inspiration anywhere else. Without the necessary updates of this general framework, the NLF may lose its actuality and become obsolete.

ANNEX I: PROCEDURAL INFORMATION

Lead DG, Decide reference and, if relevant, Work Programme reference.

DG for Internal Market, Industry, Entrepreneurship and SMEs

Agenda planning/ Work programme reference: PLAN/2020/9304

Organisation and timing.

Work started in November 2020, which the creation of the roadmap document. An Inter-Service Steering Group (ISSG) chaired by DG for Internal Market, Industry, Entrepreneurship and SMEs was established to this purpose. The ISSG met six (6) times (06/05/2021, 10/12/2021, 18/02/2022, 05/04/2022, 28/04/2022 and 27/06/2022).

Use of external expertise. Centre for Strategy & Evaluation Services (CSES), supported by the Centre for Industrial Studies (CSIL) produced a supporting study.

Fit for Future Platform

The following table summarises the Opinion of the Fit for Future Platform and the Commission's response as to how these issues are considered in its work.

Suggestions of the FFF Opinion	Follow-up
Maintain the European system for harmonized standards: 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.**	The evaluation will cover the aspects of harmonised standards relevant to the NLF, such as having technologically neutral essential requirements and relying on harmonised standards for presumption of conformity. The evaluation of the standardisation system should be a stand-alone process. It will take into account the evaluation of the NLF, which is already an extensive evaluation in itself covering a significant part of EU harmonised products. The recently adopted Standardisation Strategy provides for a separate evaluation of Regulation (EU) 1025/2012 to assess whether it is still fit for purpose.
Explain regulatory choices: 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.	The NLF was adopted in 2008 to improve the internal market and ensure a high level of protection of public interests (e.g. safety, protection of environment, protection of public health). However, industry, and society at large are fundamentally different today compared to the situation in 2008. As a result, the more recent proposals for product legislation have departed to some degree from the reference provisions of the NLF in that they try to tackle the legal consequences of modifications to products after they have been put into service (the proposal for a Regulation on a regulatory framework for Artificial Intelligence (COM(2021) 206 final) and the proposal

	for a Regulation on Machinery (COM(2021)202)) One of the main focuses of the evaluation of the NLF is therefore the relevance of NLF and whether it is fit enough to keep up with the ongoing digital and green transition.
Don't fix what isn't broken: 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.	Although the evaluation of the NLF has a forward-looking dimension, which is unmissable to assess the relevance of the NLF, **its focus is retrospective**. The evaluation findings include the effectiveness and efficiency of the uniform implementation and enforcement of harmonized product rules and ensuring a high level of protection of public interests. These aspects would also be duly considered in any possible revision of the NLF.
Updating NLF to the current and future business environment: 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 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.	In line with the Platform's suggestion, the evaluation of the NLF indeed assesses the relevance of the NLF, including its definitions. The evaluation takes into consideration that the NLF is based on assessing the safety and compliance of products at the time they are placed on the market and does not address changes that may occur to products after they are put into service. Today, within the circular economy objectives, the Commission encourages that products are reused, refurbished or even remanufactured rather than discarded after being in use for certain time. This is one of the important perspectives of this evaluation. Avoiding creating burdens and achieving increased efficiency while preserving the policy objectives are core principles that are considered when revising legislation. Findings of the evaluation on these aspects would inform any future potential revision of the NLF.
Evaluation of Member state's Notified Bodies: 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	Conformity assessment procedures need to ensure that products are compliant in a changing environment. The objectives of promoting the circular economy and ensuring product safety must be equally addressed in the conformity assessment procedure. The NLF evaluation assesses indeed if those procedures are efficient and effective to ensure the safety of products, as

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.**	well as whether or not they remain relevant. Furthermore, the evaluation also considers the rules and requirements for notified bodies to find out if they are robust enough to ensure the competence of those bodies performing third-party conformity assessment for the purpose of EU legislation, as per Platform's suggestion.
Supplementary market surveillance activities focused on compliance processes in companies: 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.	Regulation (EC) No 765/2008 relating to market surveillance has been recently amended by Regulation (EU) 2019/1020 following an evaluation (SWD (2017) 469), which was carried out in the REFIT programme context. Most of the Regulation's provisions started to apply 16 July 2021. The Commission issued its Guidance on Article 9 of Regulation (EU) 2019/1020 on joint activities to promote compliance. Market surveillance authorities might carry out "joint activities" under Article 9 of Regulation (EU) 2019/1020 on market surveillance and compliance of products with other authorities or organisations representing economic operators or end users, with a view to promoting compliance, identifying non-compliance, raising awareness and providing guidance on Union harmonisation legislation and with respect to specific categories of products, including those that are offered for sale online. If a market surveillance authority decides to carry out such a "joint activity", it must fulfil the obligations that are laid down in Article 9.
Digital information and documentation: 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**	The NLF evaluation takes into account that products are increasingly digital and continuously modified after they have been put into service**.** The NLF requires a CE marking that is visibly and indelibly affixed on the product, without the possibility of a digital CE marking. Additionally, certain paper-based documents are to be produced by the manufacturer and in some cases accompany the product. The evaluation looks into whether the NLF should still keep these requirements.

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.	The evaluation under the relevance aspects takes into consideration the increasing digitalisation and complexity of products, illustrated by the development of the Internet of Things (IoT). Among other issues, the integration of internet connectivity into many products raises considerations regarding how far the horizontal legal framework needs to be updated to integrate cybersecurity, and the linkages between product safety and security.
Fit for crisis situations: 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.	The COVID-19 crisis has put to test the resilience of Union product legislation based on the NLF and whether it can cope with an urgency situation. This evaluation assesses whether or not the lack of a crisis instrument renders the NLF less effective or efficient. Furthermore, the Commission Working Programme 2022 – Making Europe stronger together separately from this evaluation of the NLF, includes an initiative for a Single Market Emergency Instrument, which will consist of concrete elements in the short and medium term to respond to supply chain disruptions and possible future shortages.
One catalogue of obligations for economic operators: 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.**	The Commission's proposal for the General Product Safety Regulation takes into account the well-established product safety framework provided for by EU harmonisation legislation. Several obligations set out in the GPSR proposal related to economic operators and market surveillance will not apply therefore to harmonised products. The specific safety requirements provided for in the GPSR proposal will not apply insofar as the risks or categories of risks covered by Union harmonisation legislation are concerned. As concerns market surveillance, the GPSR proposal market surveillance rules align with the provisions of the Market Surveillance Regulation (EU) 2019/1020. The proposal stipulates that relevant articles of Regulation 2019/1020 apply to products covered by the GPSR. Regulation (EU) 2019/1020, which replaced the market surveillance part of Regulation (EU) 765/2008 introduced new definitions, such as 'fulfilment service provider', 'information society service provider', 'distance sales' and 'online interface', to capture the new roles associated with the emergence of online marketplaces. Stakeholders who participated to the consolations on the evaluation of the NLF welcome this recent revision and consider that these definitions could serve as a blueprint for refining the conformity assessment procedures applicable to these new types of economic operators in the distribution chain and contribute to the overall coherence of the NLF model.

Consultation of the Regulatory Scrutiny Board (RSB):

The draft evaluation was submitted to the RSB on 11 May 2022. The Board dealt with this evaluation in a written procedure and issued a positive opinion on 10/06/2022. The table below explains how the draft SWD was revised in order to take into account the recommendations contained in the Board's opinion:

RSB recommendations	Revisions introduced
(B) Main considerations	
The Board notes the additional information provided in advance and commitment to make changes to the report. The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects: (1) The report does not make the evidence base sufficiently clear.	Reference to the evaluation matrix is added in section 4.1. For more details on changes please see C1) below.
(2) The presentation of evaluation findings is not well structured.	The presentation of evaluation findings is restructured. Please see C2) below.
(3) The robustness of the conclusions is not sufficiently analysed and presented.	Please see C3) below.
(C) Further considerations and recommendations	
(1) The report should be clear on the use and soundness of the evidence base. It should refer more regularly and precisely to the evidence, including specific indicators outlined, that has been used to support the findings including making specific references to the relevant parts of the underlying study. It should refer to the earlier evaluation for the Internal Market Legislation on Industrial Products and the earlier sector specific evaluations, where relevant. The report should provide more details on the various methods used for collecting and analysing the evidence. It should also provide more details on the evidence used for the cost-benefit analysis and how it has been conducted.	Regular references to the evidence and methods of evaluation are added in section 4.1.1.. References to the underlying Study are also added throughout the SWD. References to the earlier evaluation for the Internal Market Legislation on Industrial Product are added in section 4.1.1.c) . Reference to the Evaluation of the Toys Safety Directive is added in section 4.1.2. c).
(2) The evaluation finding section should be	Sections 4.1.1.- 4.1.3. are restructured as

reorganised to make the analysis of the evaluation criteria, effectiveness, efficiency and coherence clearer. Currently this section is structured along the specific objectives of the original impact assessment. It should be restructured by reorganising it according to the respective evaluation criteria.	suggested.
(3) Taking into account the availability and soundness of the evidence (see above), the report should be clearer about the robustness of the conclusions. Against this background, a critical reflection on the quality of the conclusions needs to be incorporated. The report should be clear whether the conclusions are largely based on stakeholder views or on evidence triangulated from various sources by different methods. The report should clarify whether data limitations or potential issues with the robustness of the analysis have an impact on the conclusions and the lessons drawn from the evaluation. In this regard, also the limitations identified during the analysis related to the possible level of quantification, including of the costs and benefits, need to be clearly set out. The report should explain why no other data could be collected to assess the performance of the NLF and in what respect this may affect the conclusions reached.	We included short, more detailed conclusions at the end of every section and subsection in section 4.1. This ensures a more detailed overview of the arguments and limitations taken account for drawing the final conclusions. The conclusions are based on the triangulation of all the evidence collected by the methods listed in Section 1.1. of the SWD (desk research, legal mapping, interviews and consultations, stakeholders' workshop, case studies), since all of them separately have certain limitations. Nonetheless, in the absence of explicit data eligible for quantification, for certain aspects of the efficiency of the NLF the interviews with the stakeholders, targeted consultations and the workshop were crucial methods for collecting evidence. For example, reduced divergences, facilitated familiarisation with the rules, ease of compliance regulatory certainty are benefits that are stressed by all stakeholders. Although their quantification is not possible, these benefits are vital for the everyday smooth functioning of the internal market and its reliability. We also explained in more details that some of the costs and benefits cannot be directly attributed to the NLF as a framework. The Study takes account of the earlier sector specific evaluations, nonetheless, their relevance in the context of this evaluation is limited. The fact that these assessments rather evaluate the performance of the specific pieces of EU product legislations, from the perspective of their specific policy objectives and without focussing on the performance of the NLF to the sector specific objectives sets limitations to the suitability of conclusions drawn in the sector specific evaluations. The assessment of the effectiveness and efficiency is in most cases not explicitly

	attributable to the NLF. The estimation of the NLF-related costs and benefits and especially their quantification are therefore often limited. Although we often relied on the feedback from the stakeholders in our conclusions, we do not believe that this should weaken the trustworthiness of this assessment. The stakeholders' consultations are considered as a credible and sufficiently deep base of evidence, given the diversity of participating stakeholders and high interest of stakeholders to take part in the surveys and workshop.

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

The main sources of information used for this evaluation are the following:

Extensive desk research. It involved a review of a wide range of documents and a bibliography provided below in this Annex. The literature also included the previous evaluation for the Internal market legislation on Industrial products (SWD(2014)23), as well as the REFIT evaluation accompanying the 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 annexes (SWD(2017)469).

Data collection and mapping. In particular, the following were developed:

- Key research questions and issues for exploration;
- Set of tailored interview questionnaires, targeted to the different stakeholder groups (economic operators, industry associations, consumer associations, national authorities, and market surveillance authorities (MSAs), and notified bodies);
- Stakeholder mapping - To support the stakeholder consultations, an extensive stakeholder mapping exercise was conducted. Stakeholders across all relevant categories were identified and collated in an excel database to support the interview programme.
- Legislative mapping framework - A framework to map legislation that has been NLF-aligned was developed to support the assessment of the NLF's contribution to the alignment of product legislation. The legislative mapping compared the legal text of the 23 NLF-aligned legislation with the NLF reference provisions.

Interview programme. A pilot interview program testing the interview guides was launched by CSES before the exercise of the interviews. Thanks to the pilot interview program, the interview guides were refined an adjusted to better reflect the data relevant for the assessment. In total 110 interviews were conducted.

Online survey questionnaires

- The **targeted consultation** was supposed to be open for 8 weeks, however they were open for ten more days due to multiple requests from stakeholders.
- An **additional reach-out to important stakeholders** (notified bodies, notifying authorities, MSAs responsible for NLF-aligned legislation) were conducted to ensure a broad support of the consultation results. CSES circulated the survey directly to more than 2,500 relevant stakeholders by email.
- The Commission promoted the evaluation among SMEs and invited them for contribution via the Enterprise Europe Network.
- The targeted consultation received a total 190 complete responses, rising to 226 for certain questions. These responses cover all key stakeholder groups: economic operators (19); industry associations (32); MSAs (13); national accreditation bodies (19); national competent authorities (17); national notifying authorities (15); notified bodies (59); consumer associations (4); standardisation bodies (5) and others (7).
- The Commission conducted a **survey among notified bodies** to identify whether or not remote assessment techniques have been used, in the context of the COVID-19 pandemic and guidance provided by the European co-operation for Accreditation. Out of the 1536 NCABs reached, 142 responded to the survey (9%). Two thirds of the respondents (91 or 64%) have made use of remote assessment techniques, while one third (51 or 36%) have not.

Validation workshop with the stakeholders. CSES organized a workshop with the stakeholders to ensure the cross-checking of the evidence and information collected in the interviews and targeted consultations. 46 external stakeholders participated in the workshop, covering all key stakeholder groups.

The public consultation questionnaire was open for 12 weeks, from 13th December 2021 until 7th March 2022. The total number of responses is 125.

The data analysis methods included all the tools necessary to ensure counterfactual analysis, the triangulation of information and their well-structured presentation. The intervention logic analysis allowed us to carefully design outputs, results and impacts to ensure that the information and evidence collected during the evaluation is presented in a logical way.

The cost-benefit analysis is one of the challenges of this evaluation. The research covered both administrative and regulatory costs stemming from the NLF. The benefits were identified at minimum by estimating costs saved due to the NLF harmonisation, although other benefits were included wherever it was possible. The limitations of this analysis can be traced back to the often blurry separation of the effects and therefore costs and benefits that are directly attributable to the NLF from those that are related to specific product legislations is

Case studies. Case studies are related to specific product categories to provide practical examples of NLF-related issues. Case studies are used for the costs and benefits analysis, but also to demonstrate the fitness for purpose of the NLF.

Detailed analysis of each method is provided in the Study that was carried out for the European Commission – DG GROW by the Centre for Strategy & Evaluation Services (CSES), supported by the Centre for Industrial Studies (CSIL).

General literature on the NLF:

- Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, *OJ C 136, 4.6.1985, p. 1–9.*
- 2008-08-13 - Decision No 768-2008-EC on a Common Framework for the marketing of products (More)
- 2008-08-13 - Regulation (EC) 765-2008 on accreditation and market surveillance (More)
- 2017-12-19 - EC report on the implementation of Regulation (EC) No 765-2008 - COM/2017/0789 final (More)
- 2017-12-19 – EC Staff WD - Impact Assessment of the Alignment Package (More)
- 2017-12-19 - EC Staff WD - Refit Evaluation of the Alignment Package (More)
- 2017-06-20 - Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) No 765/2008 (More)
- 2014-01-22 - COM(2014)25 a vision for the internal market for industrial products (More)
- 2014-03-12 – CSES Evaluation of the internal market legislation for industrial products - Final report. Lot VI, Interim, final and ex-post evaluations of policies, programmes and other activities (More)
- 2018-05-07 - SWD(2018)160-F1 - Evaluation of the Machinery Directive (Download)
- 2019-02-19 - COM(2019)87/F1 - EC report on the implementation of the Lifts Directive (Download)
- 2019-02-22 - EC Staff WD on the evaluation of the Lifts Directive (More)
- 2017-04 - Study on introducing an electronic tag to supplement or replace the wheel mark in

marine equipment (More)

- 2018-04-19 - EC Implementing Regulation (EU) 2018-608 laying down technical criteria for electronic tags for marine equipment (More)
- 2017-02-16 - ECJ Case C-219-15 Elisabeth Schmitt vs TÜV Rheinland LGA Products GmbH (More)

NLF and the Single Market; trends towards the servitisation of manufacturing:

- 2020-11 – European Parliament – IMCO Study on **Legal obstacles in Member States to Single Market rules** (more)
- 2018-11 – Glinski & Rott - **Role and Liability of Certification Organisations in Transnational Value Chains** (More)
- 2018-07-12 – EC/EASME Study on the potential of **servitisation and other forms of product-service provision** for EU small and medium-sized enterprises (More)
- 2016-07-26 - **The 'Blue Guide' on the implementation of EU products rules** 2016 (More)
- 2014-10-30 – ECSIP Study for DG GROW on the **relation between industry and services in terms of productivity and value creation** – Final report (More)

Special reports of the European Court of Auditors:

- 2020-01 – ECA Special Report - EU action on **Ecodesign and Energy Labelling**: important contribution to greater energy efficiency reduced by significant delays and non-compliance (More)
- 2016- – ECA Special Report - Has the Commission ensured **effective implementation of the Services Directive**? (More)
- 2020 – ECA special report - **Digitising European Industry**: an ambitious initiative whose success depends on the continued commitment of the EU, governments and businesses (More)
- 2020 – ECA Special report on **EU added value** (various consideration on a **functional single market**) (More)
- 2019-03 – ECA Briefing paper on Challenges to effective **EU cybersecurity policy** (More)
- 2020 – ECA Risks, challenges and opportunities in the **EU's economic policy response to the COVID-19 crisis** (More)
- **Guide to application** of the **Machinery Directive** 2006/42/EC - Edition 2.2 (More)

NLF and the regulatory framework regarding robotics and AI in the EU:

- 2021 – 04 – new horizontal regulatory framework on AI
- 2020-10-11 EPRS_ATA(2020)659282_EN **An EU framework for artificial intelligence** (More)
- 2020-08-31 - VVA - Impact assessment study on the **revision of Directive 2006-42-EC on machinery** - Final Report - ET0319199ENN (More)
- 2020-07-01 IPOL_STU(2020)621926_EN **Artificial Intelligence and Civil Liability** (More)
- 2020-03-01 EPRS_STU(2020)634452_EN The ethics of **artificial intelligence- Issues and initiatives** (More)
- 2020-06-01 IPOL_STU(2020)652713_EN - **Opportunities of Artificial Intelligence** (More)

- 2019-09-26 - High-level expert group on **Artificial Intelligence** POLICY AND INVESTMENT RECOMMENDATIONS FOR TRUSTWORTHY AI (More)
- 2019-11-06 – Guide to the **application of the Directive 2006-42-EC on machinery** – Edition 2.2 (More)
- 2019-06-01 EPRS_STU(2019)631752_EN **Cost of non-Europe in robotics and artificial intelligence** (More)

NLF and the circular economy:

- Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020
- 2020-12-10 - Study on the **Competitiveness of the European Companies and Resource Efficiency** (More)
- 2020-03-11 – Communication on **A new Circular Economy Action Plan** for a cleaner and more competitive Europe - COM(2020) 98 final (More)
- 2018-03-13 - **EU competitiveness and the 2030 framework** (More)
- 2016-11-08 - Final report - **Regulatory barriers for the Circular Economy** (More)
- 2016-08-03 - **Identifying levers to unlock clean industry** (More: Summary; Background report)

Regulatory framework regarding civil product liability:

- 2018-05-07 – EC report on the Application of the Directive on **liability for defective products** (85/374/EEC) (More)
- 2018-01 – VVA - Evaluation of Directive 85-374-EEC on **product liability** - Final report - ET0118507ENN.en (More)

Contributions to public consultations on issues related to the NLF review (EC Have Your Say web page)

- 2020-12 - **Cybersecurity** – new EU strategy (More). The strategy was published on 16 December 2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020JC0018&qid=1611670081894 2020-12-02 - **Industrial products - evaluation of the new legislative framework** (More)
- 2020-11-26 - **Health & Safety at Work** – EU Strategic Framework (2021-2027) (More)
- 2020-09-01 - **General Product Safety Directive** – review (More)
- 2020-08-19 - **Construction products** – review of EU rules (More)
- 2020-07-17 - **Union Customs Code** – mid-term evaluation (More)
- 2020-06-30 - **Digital Services Act** – deepening the internal market and clarifying responsibilities for digital services (More)
- 2020-06-14 - **Artificial intelligence** – ethical and legal requirements (More)
- 2020-06-08 - **Energy efficiency in buildings** – consultation on 'renovation wave' initiative (More)
- 2020-02-21 - **Electromagnetic compatibility** - evaluation of the EU rules (More)
- 2020-01-20 - Circular economy – new action plan to increase **recycling and reuse of products**

in the EU (More)

- 2019-08-30 - Revision of the **Machinery Directive** (More)
- 2019-03-04 - Upload of software on **radio equipment** (More)
- 2019-03-04 - **Internet-connected radio equipment** and wearable radio equipment (More)
- 2018-06-04 - Towards an EU Product Policy Framework contributing to the **Circular Economy** (More)
- 2017-11-27 - Evaluation of the **Low Voltage Directive** 2014/35/EU (More)
- 2017-11-17 – EC Public consultation on the rules on **liability of the producer for damage caused by a defective product** (More) + 2017-10-20 Product Liability Conference (More)

Evaluations and impact assessments of individual pieces of product legislation:

- Evaluation of the Electromagnetic Compatibility Directive 2014/30/EU (still in progress, but nearing completion).
- Interim Evaluation of the Low Voltage Directive 2014/35/EU.
- The Evaluation of Directive 2006/42/EC on Machinery (September 2017).
- Impact assessment study on the revision of Directive 2006/42/EC on machinery (European Commission's DG GROW, 2020).
- Commission Staff Working Document - Evaluation of the Machinery Directive (SWD(2018) 161 final).
- Impact Assessment on Increased Protection of Internet-Connected Radio Equipment and Wearable Radio Equipment (European Commission's DG GROW, 2020).
- Commission Staff Working Document - Evaluation of the Lifts Directive 2014/33/EU
- Evaluation roadmap and impact assessment of the GPSD.

Position papers:

Position papers relating to the NLF and other product legislation where the NLF has been applied through the alignment process:

- BusinessEurope. (2020). The New Legislative Framework (NLF) evaluation: provisional comments.
- Orgalim. (2020). Orgalim comments on the 2020 draft 'Blue Guide'.
- Bitkom. (2019). Requirements for coherent cybersecurity regulation.
- BIN-DIN-DKE (2021) EU-wide Cybersecurity Requirements.
- Eurosmart. (2019). The Revision of the Machinery Directive, Answer to the European Commission Public Consultation.
- Digital Europe. (2019). A strong and united Europe that reflects European values and thrives globally in an open economy.

Impact of new technologies (including AI) and digitalisation:

- AI High-Level Expert Group (HLEG). (2019). Ethics guidelines for a trustworthy AI.
- AI High-Level Expert Group (HLEG). (2019). Policy and investment recommendations for trustworthy AI.

- BEUC. (2020). Product Liability 2.0 – How to make EU rules fit for consumers in the digital age.
- Check Point. (2020). Cybersecurity Report.
- Cowls, J, and Floridi, L. (2018). Prolegomena to a White Paper on an Ethical Framework for a Good AI Society.
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- CSES (2020). Study on the Competitiveness of the EU Engineering Industries and the Impact of Digitalisation (EASME Executive Agency/ DG GROW, 2020).
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- European Commission. (2020). Communication on A European strategy for data, Brussels, 19.2.2020, COM(2020) 66 final.
- European Commission. (2020). White Paper On Artificial Intelligence – A European approach to excellence and trust, Brussels, 19.2.2020, COM(2020) 65 final.
- European Court of Auditors. (2019). Briefing paper: challenges to effective cybersecurity policy, March 2019.

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ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

This below table presents the evaluation matrix for the study. For each key evaluation question, it presents sub-questions, judgement criteria, and indicators, as well as relevant data and information sources and assessment methods.

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
Effectiveness: How effective has the NLF been in achieving its general and specific objectives?				
• To what extent have the general and specific objectives of the NLF been achieved? *Sub-question:* 1. Are there any objectives that have not yet been achieved and what are the explanatory factors?	• Degree of progress in achievement of the global and specific objectives of the NLF: • Existence of objectives that have not been achieved and reasons why • Existence of obstacles to achieving the objectives	• Perceptions on perceived obstacles • Perceptions as to which objectives have been achieved, not yet achieved and any explanatory factors • Perceptions on factors that influenced achievement of objectives • Type of relevant technological developments and type of relevant environmental developments	• Desk research • Survey (targeted) • Survey (public) • Interview programme	• Qualitative assessment of 'effectiveness' criterion • Case studies • Contextual multi-stakeholder analysis of perceptions • Descriptive statistics analysis
General objectives: • How effectively has the NLF contributed towards the **achievement** of providing a **high level of protection of public interests**, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security (Regulation (EC) No 765/2008)? • How effectively has the NLF contributed towards the achievement of **ensuring that the free movement of products is not restricted** thereby guaranteeing an efficient and effective internal	• Effective protection of public interest (health and safety, including at the workplace, consumer and environmental protection) • Level of confidence in products in the European market • Improvements in the effectiveness of the internal market for goods through the removal of outstanding barriers; • Union harmonisation legislation more consistent and	Qualitative indicators • Extent to which public interests have been protected. • Extent to which products are circulating freely on the internal market. Quantitative indicators • Number and % of Union harmonisation legislation (directives, regulations) aligned with the NLF • Number of CABs accredited to perform services under different pieces of legislation (using NLF as the common framework) • Context indicator – evolution in market size and structure across product legislation aligned with the	• Desk research • Survey (targeted) • Survey (public) • Interview programme	• Qualitative assessment of 'effectiveness' criterion • Case studies

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
market for economic operators? (Regulation (EC) 765/2008) • How effectively has the NLF contributed towards the achievement of **establishing a common framework** of general principles and reference provisions for drawing up EU legislation **harmonising conditions** for the marketing of products (Decision No 768/2008/EC)?	easier to implement; • Existence of the free movement of products without restrictions contributing to an effective internal market for economic operators? • Extent to which the EU product legislation is well-aligned to the NLF	NLF.		
Specific objectives: • How effective has the NLF been in terms of providing a **coherent basis** for revision or recasts of specific product legislation that avoids going into technical detail but limit itself to the expression of essential requirements? • How effective has the NLF been in terms of **harmonising common administrative requirements** for economic operators (e.g. producing a Declaration of Conformity, technical file, affixing of the CE marking)? • How effective has the NLF been in terms of fostering an efficient and effective internal market for economic operators by expressing essential requirements without going into technical details while having recourse to **harmonised standards** for expressing	• Extent to which specific product legislation has been revised in line with NLF provisions • Extent to which the NLF has led to harmonising common administrative requirements • Extent to which rules for accreditation of CABs are clear and transparent • Degree to which quality and trust in conformity assessment processes has been improved • Extent to which CE marking has been clarified and increased in credibility • Clearer administrative requirements and information obligations for economic operators; • More harmonised approach to marketing products on the	Qualitative indicators • More harmonised approach to marketing products on the European internal market; • More harmonised administrative requirements for economic operators; • Clearer administrative requirements and information obligations for economic operators Quantitative indicators • Number and % of specific product legislation revised in line with NLF provisions • Availability and number of harmonised standards • Number of notified bodies accredited to perform services under each piece of legislation aligned with the NLF	• Desk research • Survey (targeted) • Interview programme	• Qualitative assessment of 'effectiveness' criterion • Case studies

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
technical specifications? • How effective has the NLF been in terms of improving your confidence in products placed on the market thanks to the system of **presumption of conformity** through the use of harmonised standards? • How effective has the NLF been in terms of improving the **transparency, quality of third-party conformity assessment** by setting clear and transparent rules for the accreditation of conformity assessment bodies (Regulation (EC) No 765/2008)? • How effective has the NLF been in terms of strengthening **traceability within value chains**? • How far has the NLF been effective in fostering **administrative simplification**? • How far is the role of harmonised standards fit for purpose in **accommodating state-of-the-art** effectively? • How effective has the development of accreditation procedures for notified bodies and third-country conformity assessment bodies been in strengthening the **quality of conformity assessment services**?	European internal market; and • Increased quality of the conformity assessment services			

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
• Has the NLF had unintended positive or negative consequences or collateral effects?	• List and nature of unintended consequence or collateral effects, both positive and negative • Extent to which these unintended consequences or collateral effects have contributed, or acted as a barrier, to the achievement of the objectives of the NLF	• Number and type of positive unintended consequences or collateral effects • Number and type of negative unintended consequences or collateral effects • Perceptions of the scale of any positive or negative unintended consequences or collateral effects • Perceptions on their impact on the achievement of the objectives of the NLF	• Survey (targeted) and interviews with economic operators and industry associations • Desk research	• Case studies • Contextual multi-stakeholder analysis of perceptions
• To what extent does the NLF ensure the safety and compliance of products during its lifetime?	• List and nature of challenges related to modification of products during their lifetime • List and nature of challenges related to reuse and remanufacturing of products • Level of product safety and compliance throughout the lifetime of products, including variation by product type • Level of variation of intended product lifetimes across different product categories	• Number and type of products becoming unsafe or non-compliant during their lifetime • Intended product lifetimes across different product categories • Number and type of products being modified during their lifetime (e.g. software updates, AI & ML) • Prevalence of re-use, remanufactured products • Perceptions on the safety and compliance of modified and reused / remanufactured products • Roles and types of economic operators involved in remanufacturing and product modifications	• Survey (targeted) and interviews with economic operators and industry associations • RAPEX-SAFETY GATE • Desk research	• Case studies • Contextual multi-stakeholder analysis of perceptions
• To what extent has the NLF ensured robust conformity assessment procedures and made sure that Notified Bodies are accessible to economic operators when needed?	• Extent to which rules for accreditation of CABs and NBs are clear and transparent • Quality and trust in conformity assessment process have been improved, including issues of accessibility • CABs / NBs can be used by economic operators, across all	• Number of CABs/NBs notified for each piece of harmonisation legislation • Number of CABs/NBs formally accredited for each piece of harmonisation legislation • Perceptions on the impacts of the NLF on CAB accreditation • Perceptions on the impacts of the NLF on the conformity assessment procedures, including issues of	• Survey (targeted) and interviews with economic operators and industry associations • Desk research	• Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
	product legislation	accessibility • % of economic operators using CABs / NBs, per product legislation		
• Does the accreditation guarantee the competence of conformity assessment bodies in the EU?	• Rules for accreditation of CABs and NBs are clear and transparent • Quality and trust in conformity assessment process have been improved, including issues of accessibility • CABs / NBs are used by economic operators, across all product legislation	• Number of CABs approved by regulation and directive across Union harmonisation legislation aligned with the NLF and perceptions on the impacts of the NLF on CAB accreditation • Perceptions on the impacts of the NLF on the conformity assessment procedures, including issues of accessibility • % of economic operators using CABs / NBs, per product legislation	• Survey (targeted) and interviews with economic operators and industry associations • Desk research •	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions
Efficiency: To what extent were the effects achieved at a reasonable cost?				
• How far has the NLF increased the efficiency of EU product legislation overall?	• EU product legislation has been successfully aligned with the NLF • Market surveillance rules have been improved, for products that could damage the environment or human health.[108] • Greater reliability in the quality of the conformity assessment services provided by notified bodies • Rules on requirements for the	• Perception of stakeholders and of market surveillance authorities. • Number of non-compliant products withdrawn from the market, by reason for non-compliance e.g. related to CE marking, declaration of conformity, technical documentation • Number of complaints regarding non-compliance of products with EU legislation (users) • Number of complaints regarding non-compliance of products with EU legislation (by economic operators) • Number of complaints regarding problems with	• Survey (targeted) and interviews with economic operators and industry associations • RAPEX-SAFETY GATE • EU - European Injury Data Base (IDB) • Desk research • Eurostat data on cross- border trade in	• Qualitative assessment of 'efficiency' criterion • Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

[108] The study will not reinvent the wheel and make use of existing data e.g. REFIT evaluation (SWD(2017) 469 final) (c.f. first page of the ToR)

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
	notification of conformity assessment bodies have been made clearer • The meaning and use of CE marking added value vs cost • Cross-border trade of products in the Internal Market has been enhanced? • Toolbox measures are being used to inform the development of future legislation.	accreditation rules • Number of complaints regarding problems with requirements for the notification of conformity of assessment • Reported court cases, litigation or accidents, by Member State • Volume of cross-border trade in goods in the internal market over time, with focus on SMEs • Number of reported deaths and injuries involving certain regulated categories of products (electrical goods, home and leisure goods, machines used at work etc.)	goods • Imports data • Cross-comparison with EU27 population growth • Growth in volume and scope of legislation fully or partially aligned with the NLF • Number of harmonised standards developed under NLF-type legislation • Data on deaths and injuries at work, home and during leisure activities	
• To what extent has the NLF led to **administrative simplifications** and a **reduction in costs and burdens**? *Sub-questions:* 1. What are the main **human and financial resources** required to implement the NLF? 2. What have been the main **types of administrative costs** associated with the NLF's	• Cost of NLF implementation in terms of human and financial resources • Regulatory costs and benefits for economic operators • Regulatory and administrative costs and benefits for notified bodies and market surveillance authorities • Actions required for inspections and their costs for national authorities and economic operators	• Preparing the documentation and information requested by MSAs in NLF legislation • Benefits Costs Ratio and Net Present Value for economic operators • Benefits Costs Ratio and Net Present Value for all stakeholders • Average time and cost for manufacturers to ensure conformity of equipment • % of the market/product segments broadly using harmonised standards vs. non harmonised/ other standards	• Desk research • Survey (targeted) and interviews with economic operators and industry associations • Budget spent on market surveillance vs. size of the population • Survey of European/ national standardisation	• Triangulation with the number of reported accidents or injuries for certain NLF regulated products. • Sectoral CBA and Societal CBA

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
implementation from an industry perspective? How does this compare with the situation before the NLF existed? 3. What difference have the **common provisions** in the NLF (especially in Decision No 768/2008/EC) made in terms of **cost savings** (e.g. through having more consistent and coherent legislation)? 4. How far has the putting in place of the NLF **stimulated innovation and risk-taking** by industry? 5. What are the **overall benefits of the NLF**? What are the specific benefits for industry, NGOs? To what extent can these be quantified? 6. Is the overall cost-benefit ratio favourable seen from i) an economic operator and industry ii) a national competent authority and MSA perspective? 7. How far has the NLF reduced compliance costs by eliminating inconsistencies in admin requirements?	• Amount of cost savings through common provisions • Costs to follow/participate in the standardisation process • Costs to use harmonised standards in product design (average in key categories of products: e.g. electrical, radio, mechanical, etc…)		bodies	
• How far do current conformity assessment procedures and the role	• Proportionate cost of conformity assessments	• Average time and cost for producers to ensure conformity of equipment	• Survey and interviews with	• Descriptive statistics analysis

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
of NBs guarantee product compliance, without creating any disproportionate costs?	• Extent of product compliance • Availability of relevant and updated information on applicable legislation, procedures and standards	• Number of products being rejected by notified bodies due to failing conformity assessments • Number of non-compliant products withdrawn from the market that claim to have been certified by a notified body • % of fraudulent use of a NB's mark or certificate for certain product categories (domestic or imported) • Availability of accredited NBs	economic operators and industry associations • Desk research RAPEX-SAFETY GATE reports • ICSMS database • Survey of Notified Bodies (e.g., incl. product blacklists on their own web sites	• Case studies • Contextual multi-stakeholder analysis of perceptions
• To what degree do existing horizontal requirements e.g. affixing CE marking or other information required by the NLF remain necessary and does not create unnecessary burdens?	• CE marking or other information required by the NLF is being applied correctly. • Strengthened awareness of the rules concerning the affixing of CE marking and other product information to the product itself (e.g., among manufacturers, end-users)	• Number of non-compliant products withdrawn from the market, by reason for non-compliance e.g., related to CE marking, declaration of conformity, technical documentation. • % of formal non-compliance vs. substantial non-compliance as case study of certain product categories	• Survey (targeted) and interviews with economic operators and industry associations • Desk research • ICSMS and other MSA data wherever available	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions
• How far does the voluntary participation of notified bodies in the new accreditation framework introduced through the NLF ensure 1) the quality of their services and 2) ensure their professional competence? • How does the quality of conformity assessment services compare between notified bodies that are accredited and those that are not?	• Extent to which there has been a discernible improvement in the quality of conformity assessment services. • Reduction of the need for central and local government to employ specialist assessment personnel. • Competence of NBs approved by accreditation organisations	• % of NBs that are accredited / total. • Average time and cost needed to ensure the accreditation of NBs • Number of NBs failing their regular verification • Qualitative - assessment of the quality of conformity assessment services (i) accredited NBs and ii) non-accredited NBs • Average time and cost needed to monitor and control the accreditation of NBs, including for those that mostly	• Survey and interviews with economic operators and industry associations • Desk research •	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
		operate from outside of the EU		
• To what extent has the NLF led to enhanced MS cooperation, market surveillance and border controls?	• Strong cooperation between MSAs and border controls	• Type and level of sanctions at MS level • Perception of stakeholders of market surveillance and border controls to protect consumers and ensure non-compliant products are removed from the market	• National market surveillance reports • Evaluation reports of sectoral legislation • Primary research	• Descriptive statistics • Contextual multi-stakeholder analysis of perceptions
Future-oriented questions: • How far would it be possible to further simplify **administrative requirements** through the horizontal framework of the NLF in respect of the preparation of i) a DoC and ii) technical files? • To what extent could the NLF's **common horizontal requirements** be simplified or improved in other specific areas, e.g. modernisation of the rules on packaging? • Which challenges linked with **new technologies** can be addressed through other legislation? (e.g. the Product Liability Directive? the Services Directive? an ad hoc horizontal legislation?) • To what extent could **digitalisation** of the affixing of the CE marking play a role in enhancing the traceability of products to the responsible economic operator (including	• Additional administrative simplification • More simplified **common horizontal requirements** • More digitisation of the affixing of the CE marking • Improved communication of product information	• Perceived room for additional administrative simplification • Perceived need for additional simplification of common horizontal requirements • % of tracked products with digitised CE marking • Perceived clarity and effectiveness of product information communication	• Desk research Survey (public and target) and interviews with economic operators and industry associations	• Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
regulatory compliance aspects) along industry value chains? How far could it lead to efficiency savings? Would this also have benefits for MSAs or industry? • How far could the efficiency of the communication of **product information** to end-users be improved (e.g. through use of e-documentation)? Would this also have benefits for MSAs? • Are there any ways in which the NLF could be updated and/ or improved in a way that could help to strengthen its efficiency and effectiveness? If yes, what **specific changes** need to be made?				
Relevance and fitness for purpose: To what extent do the objectives of the NLF still correspond to the needs?				
• To what extent are the NLF's objectives still appropriate?	• Identified needs and objectives are aligned ▪ The role of economic operators vs risk assessment and responsibility ▪ Understanding and credibility of CE marking ▪ Conformity assessment and accreditation of CABs ▪ Understanding and credibility of CE marking ▪ Regulatory fitness	• Degree of alignment between the objectives of the NLF and identified needs, by stakeholder group • Sector-specific cases and practices that are not fully covered by the features in the NLF • Current and emerging problems regarding health, safety and other public interest related to marketing of non-food products • Stakeholders' perception on the need to update the NLF in light of emerging issues in the internal market and public interest	• Desk research • Primary research from all stakeholder consultation methods (public consultation, online survey, interview programme)	• Qualitative assessment of 'Relevance' criterion • Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
	• The current temporal scope limit of "placing on the market" or "putting into service" continues to be appropriate • Product harmonisation legislation has been brought in line with the NLF			
• To what extent has the NLF allowed for technological, scientific, environmental and social developments? <u>*Sub-questions:*</u> • Is the NLF fit for purpose in addressing the potential for substantial modifications to be made to products after the placing on the market (e.g. through software and firmware updates, the integration of third-party apps?)	• Conformity assessment procedures and CE marking facilitate technological, scientific, environmental and social developments • Obstacles to technological, scientific, environmental and social developments resulting from the NLF • Coverage of and challenges related to substantial modifications made to products after the placing on the market	• Type of technological developments that may impact the NLF features • Type of obstacles to technological, scientific, environmental and social developments resulting from the NLF features • Type of challenges related to substantial modifications made to products after placing on the market	• Desk research • Primary research from online survey and interview programme	• Qualitative assessment of 'Relevance' criterion • Case studies • Contextual multi-stakeholder analysis of perceptions
• Are the provisions of the NLF clear enough in respect of the roles and responsibilities of the different economic operators? • How far does the 'Blue Guide' provide sufficient support to manufacturers in understanding the requirements of Union harmonisation legislation at a more horizontal level?	• Roles and responsibilities of the different economic operators are clearer	• Quality of non-binding application guidelines of NLF-aligned legislation	• Survey (targeted) with economic operators and industry associations • Interviews with economic operators, industry associations and MSAs	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions
• How far are the NLF provisions	• The features of the NLF are	• Perception of stakeholders as to	• Desk research	• Descriptive statistics

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
still relevant in terms of new modes of production (i.e. remanufacturing and reuse, 3D printing)? Sub-question: • The NLF (and aligned individual pieces of product legislation) is designed to be technology-neutral. How far are the NLF features fit for purpose in accommodating **new technologies** in products and the changeable nature of products post market-placement? • To what extent does the NLF need to be updated to reflect the **increased complexity of supply chains** (e.g. the close interactions between manufacturers, service providers and software and apps developers both in product development and post-market placement)?	considered appropriate to apply to e.g.: ○ evolutive products during their lifetime ○ products resulting from distributed design software	whether the NLF is fit for purpose in accommodating: • New modes of production (i.e. remanufacturing and reuse, 3D printing)? • Changes to the concept of placing a product on the European market (e.g. due to software updates and upgrades, AI and machine learning) • Number/type of safety or security issues. • Number and type of manufacturing practices that may impact the NLF features.	• Survey (targeted) and interviews with economic operators and industry associations	analysis • Case studies • Contextual multi-stakeholder analysis of perceptions
• To what extent is the current suite of conformity assessment modules well-adapted to the latest manufacturing and distribution practices? (e.g. division of roles across different economic operators in value chain in the design phase and in manufacturing)? Sub-question: • Should there be a specific	• Coverage of, and challenges related to new types of business models (e.g. distributed servitisation) and new types of economic operators (e.g. digital platforms, fulfilment centres) • Impact on product safety by products already on the market undergoing substantial modifications	• Number and type of manufacturing and business/ distribution practices that may impact the NLF features.	• Desk research • Survey and interviews with economic operators and industry associations	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
regulatory regime in terms of obligations of economic operators and administrative requirements for (re)placing products on the market that do not involve **substantial modifications** to products that have already been placed on the market? If yes, in which way? • To what extent does the NLF continue to be relevant to addressing [MSA; industry; NGO] needs (e.g. for regulatory certainty and predictability, for common, consistent and coherent rules on placing products on the European market) and consumer needs (e.g. considering new tech, circular economy)?				
• How far does the lack of a specific crisis instrument make the NLF less effective or efficient? Sub-questions: • How far has the NLF helped or hindered in mitigating the adverse economic effects of the **COVID-19 pandemic**? • Are there **legal gaps** in the NLF that need to be addressed? How far could they alternatively be addressed through individual pieces of product legislation, or through new horizontal legal frameworks (e.g. on AI, possibly	• Balance between economic operators taking responsibility and mandatory pre-marketing controls (third-party) • Availability of alternative CA or fast-track approval procedures • Existence of legal gaps within the NLF	• Number and type of mandatory administrative steps before placing a product on the market under the NLF • Levels of awareness among new market entrants about the requirements in the legislation on PPE • Speed of development of harmonised standards and availability for use after citation in the OJEU	• Survey (targeted) and interviews with economic operators and industry associations, especially in the medical device and personal protective equipment sectors • Survey of European/ national standardisation bodies	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
on cybersecurity)?				
Coherence: To what extent are there issues of coherence with other interventions and wider EU policy or legislation?				
• Are there any inconsistencies, overlaps or gaps within the different provisions of Decision No 768/2008/EC and Regulation (EC) No 765/2008)?	• Extent to which discrepancies and inconsistencies have emerged within the different provisions of Decision No 768/2008/EC and Regulation (EC) No 765/2008)? • Elimination of inconsistencies, overlaps and gaps in Union harmonisation legislation compared with previous situation	• Number of discrepancies, gaps or inconsistencies between Decision No 768/2008/EC and Regulation (EC) No 765/2008)	• Desk research • Survey and interviews with economic operators and industry associations	• SCM analysis • Content/categorical analysis based on survey and interview data • Contextual multi-stakeholder analysis of how the discrepancies influence market behaviour
• To what extent is the NLF still consistent with Union harmonised legislation applicable to products? • How far is the NLF coherent with other types of new legislation (e.g. the non-mandatory Cybersecurity Act) and in terms of the application of Directive 2001/95/EC to harmonised products not already covered by sectoral legislation? Sub-questions: • Are there any missing definitions? • How far are the **definitions in the NLF** appropriate? Does this take into adequate consideration the evolution of business models where products are placed on the market	• Extent to which the NLF has brought coherence across the current pieces of EU product legislation • Consistency of NLF with future/other EU legislation addressing other aspects of the product than its placing on the market. • Clarity of definitions within the NLF • Degree of regulatory certainty for economic operators	• Number of discrepancies with the NLF by product legislation • Types of inconsistencies between NLF and different legal provisions in EU legislation (e.g. GPSD, occupational health and safety legislation, cybersecurity, etc…) • Perceived clarity by stakeholders of definitions within the NLF • Perceived regulatory certainty by economic operators	• Desk research • Survey (targeted) and interviews with economic operators and industry associations	• SCM analysis • Content/categorical analysis based on survey and interview data • Contextual multi-stakeholder analysis of how the discrepancies influence market behaviour

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
as part of services, and the evolution in the complexity of value chains prior to putting those serviced products onto the market? • Are the common **obligations and administrative requirements** set out in individual pieces of sectoral legislation (NLF-aligned) sufficiently clear to provide for economic operators with regulatory certainty? • To what extent is the NLF sufficiently clear in terms of how risks relating to the integration of **new technologies** into products should be assessed, managed and mitigated by manufacturers and other EO in the value chain? Does the new AI proposal provide regulatory clarity for the NLF? • Are there any comments on the **interaction between the NLF and other EU legislation**, in particular individual pieces of product safety and sectoral legislation? Horizontal legislation, e.g. the Product Liability Directive, the General Product Safety Directive (GPSD)? Other types of relevant legislation and policies e.g. the Services Directive, Occupational Health & Safety Directives?				
EU added value: To what extent does the NLF add value compared to what could be achieved at the national level?				
• What is the NLF's added value	• Stakeholder perceptions on	• Estimated costs saved by complying with a harmonised	• Survey (targeted) of	• Qualitative assessment

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
compared to what could have been achieved at merely national level? • How far has the NLF framework added value through the provision of a **common EU legal framework** to ensure a **high level of protection of public interests**, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security? • How far has the NLF framework added value to establish general principles and reference provisions **for drawing up EU legislation** for regulators? • What are the main differences between the situation before the NLF was adopted and the recasting of the 23 Directives and Regulations thus far aligned with the NLF?	counterfactual considerations relating to added value. • Assessment of the extent of European value added for manufacturers following regulatory requirements at EU rather than national level. • Assessment of the extent of European value added for consumers.	regime over several national regimes. • Estimated benefit of the harmonisation in case of national divergent regulations for the same product • Number and cost of eliminated inspections (as conducted in other MS) • Estimated reputational benefits	economic operators and industry associations	of EU value added • Quantitative assessment of estimated cost savings
• Do the needs and challenges addressed by the NLF continue to require (harmonisation) action at EU level?	• Extent to which identified needs and objectives are aligned. • Extent to which the features of the NLF are considered appropriate • Whether provisions are needed to ensure the product remains compliant during its lifetime.	• Proxy indicators - % non-compliance of particular products (identified in joint market surveillance campaigns under particular directives and regulations e.g. through the ADCOs) • Number of enforcement measures taken against non-compliant products by MSAs • Degree of alignment between the NLF objectives, the	• Survey (targeted) and interviews with economic operators and industry associations	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
		essential requirements and identified needs		
• What would be the most likely consequences of repealing the NLF?	• Extent to which stakeholders and national administrations would be affected by a repeal of the NLF	• Budget allocated to market surveillance (including costs of the enforcement activities) • Difference in the enforcement costs by MS • Trends of internal market trade and exports	• Survey (targeted) and interviews with economic operators and industry associations	• Contextual multi-stakeholder analysis of perceptions

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS

The following Tables offer an overview of costs and benefit identified, assessed compared to the situation that preceded the 2008 legislative package, and of the potential for burden reduction.

Overview of costs and benefits identified in the evaluation of the NLF

Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Enforcement costs									
Resources spent by bodies at European level to ensure NLF implementation	Recurrent	N/A	N/A	N/A	N/A	**0**	Resources spent by the Commission's relevant units in relation to NLF implementation are considered to be business-as-usual costs.	**270,000-360,000 Euro**	Incremental cost of EA
Resources spent by national authorities to ensure NLF implementation	Recurrent	N/A	N/A	N/A	N/A	**Not quantifiable**	Resources spent by notifying authorities in relation to NLF implementation.	**Not quantifiable**	Resources spent by accreditation bodies in relation to NLF implementation (importantly, this cost is however borne largely by conformity assessment bodies through the purchase of accreditation services).
Resources spent by economic operators during conformity assessment procedures	Recurrent	N/A	N/A	**0**	Since the principles of conformity assessment have not changed with the 2008 introduction of the NLF, no additional costs are identified compared to the previous conditions.	N/A	N/A	N/A	N/A
Resources spent by economic operators for development of standards	Recurrent	N/A	N/A	**0**	The cost of the development of standards within the ESOs was approximately 3,000 million Euro in 2009. The approximate	**0**	The approximate cost of creating one standard was estimated at approximately 1 million Euro. This	N/A	N/A

Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
					cost of creating one standard was estimated at approximately 1 million Euro. This cost is financed primarily by industry (93-95%). Since no changes related to standards were introduced with the 2008 NLF, no additional costs are identified compared to the previous conditions.		cost is financed by national governments for around 3-5% and the Commission/EFTA for around 2%. Since no changes related to standards were introduced with the 2008 NLF, no additional costs are identified compared to the previous conditions.		
Cost of CE marking	Recurrent	N/A	N/A	**0**	Since no changes related to CE marking were introduced with the 2008 NLF, no additional costs are identified compared to the previous conditions.	N/A	N/A	N/A	N/A
Costs related to the accreditation framework: examination fee to an accreditation body	One-off (every time an accreditation expires)	N/A	N/A	N/A	N/A	N/A	N/A	**4,000-20,000 Euro per accreditation** (cumulative cost borne by CABs on the European scale in relation to accreditation in the order of magnitude of hundreds million Euro)	In addition to country-specific differences in fees, variations in costs borne by conformity assessment bodies also depend on the extent of the scope being sought, the number of locations, the experience and involvement of the conformity assessment body, the maturity of the quality management system and its processes, the availability of staff resources.
Costs related to the accreditation framework: annual fee to accreditation body	Recurrent	N/A	N/A	N/A	N/A	N/A	N/A	**Different practices by country (see comment).**	Concerning this cost, differences between accreditation bodies emerged. Among those bodies who foresee a maintenance fee, there are

Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
(continuous monitoring costs, maintenance fee)									the Italian body (maintenance fee calculated as a share of turnover) and the Latvian body (annual fee of 425 Euro). In Slovenia, a maintenance fee is charged at each surveillance visit (either on 12 or 15 months).
Costs related to the accreditation framework: cost of developing a quality management system	Recurrent	N/A	N/A	N/A	N/A	N/A	N/A	**0**	Established CABs typically already have a quality management system with established procedures in place, and already had a quality manager dealing with it. Considering this cost as being 100% borne even in the absence of the 2008 NLF, no additional costs can be identified compared to the previous scenario.
Costs related to the accreditation framework: insurance fee	Recurrent	N/A	N/A	N/A	N/A	N/A	N/A	**Not quantifiable**	Sector-specific and country-specific variations.
Direct benefits									
Reduced costs in familiarisation with legislation thanks to the introduction of common definitions	Recurrent	N/A	N/A	**Not quantifiable**	Savings thanks to absence of divergent requirements (e.g. common suite conformity assessment modules)	**Not quantifiable**	N/A	N/A	N/A
Cost savings in conformity assessment activities	Recurrent	N/A	N/A	**Not quantifiable**	Savings thanks to greater coherence between directives	N/A	N/A	N/A	N/A
Enhanced legal certainty	Recurrent	N/A	N/A	**Not quantifiable**	N/A	N/A	N/A	N/A	N/A

Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Indirect benefits									
Increased safety, health, and reduced environmental damages	Recurrent	**Not quantifiable**	Benefits deriving from the reduction of differences in the activities carried out by the notified bodies (thanks to the NLF).	N/A	N/A	N/A	N/A	N/A	N/A
Single market benefits	Recurrent	N/A	N/A	**Order of magnitude: tens of billions of Euro.**	N/A	N/A	N/A	N/A	N/A
Enhanced global relevance of EU regulations	Recurrent	**Not quantifiable**	Benefit deriving from the ability of EU legislation to elevate its model worldwide and shape international practices (so-called 'Brussels effect'). This in turn supports the global standing of the EU in global commerce.	N/A	N/A	N/A	N/A	N/A	N/A
Enhancement of Europe's industrial competitiveness	Recurrent	N/A	N/A	**Not quantifiable**	Comparative competitiveness between European manufacturers and third country counterparts.	N/A	N/A	N/A	N/A

Overview of simplification and burden reduction in the NLF

Simplification and burden reduction (savings already achieved)									
		Citizens / Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Indirect compliance cost savings									
Reduced costs in familiarisation with legislation thanks to the introduction of common definitions	Recurrent	N/A	N/A	**Not quantifiable**	Savings thanks to absence of divergent requirements (e.g. common suite conformity assessment modules)	**Not quantifiable**	N/A	N/A	N/A
Cost savings in conformity assessment activities	Recurrent	N/A	N/A	**Not quantifiable**	Savings thanks to greater coherence between directives	N/A	N/A	N/A	N/A

Potential simplification and burden reduction (savings) *Further potential simplification and savings that could be achieved with a view to make the initiative more effective and efficient without prejudice to its policy objectives.*								
	Citizens/Consumers		Businesses		Administrations		[Other]	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Possibility to increase efficiency through the introduction of an e-labelling scheme								
Recurrent	N/A	N/A	**490 million Euro per year**	A general consensus was found among interviewees on the possibility to increase efficiency through the introduction of an e-labelling.	N/A	N/A	N/A	Recurrent
Possibility of accreditation with accreditation body of a different MS								
Recurrent	N/A	N/A	N/A	N/A	N/A	N/A	**Not quantifiable**	Opening the chance of being accredited to the accreditation body of a different Member State could increase efficiency (e.g. since a national body can be slower and more costly than other ones)
Remote assessment								

<u>Potential</u> simplification and burden reduction (savings) ***Further potential simplification and savings that could be achieved with a view to make the initiative more effective and efficient without prejudice to its policy objectives.***								
	Citizens/Consumers		**Businesses**		**Administrations**		**[Other]**	
	Quantitative	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**	**Quantitative**	**Comment**
Recurrent	N/A	N/A	**Not quantifiable**	Strong indications that CABs could achieve cost savings and other positive impacts through the use of remote assessment techniques. Potential additional costs related to developing / familiarisation with new standards on remote techniques.	**Not quantifiable**	Strong indications that NABs could achieve cost savings and positive environmental and efficiency impacts through the use of remote assessment techniques. However, given the nature of NABs, the cost savings should be passed on to CABs. Potential additional costs related to developing / familiarisation with new guidance / standards on remote techniques.	**Not quantifiable**	Strong indications that EA could achieve cost savings and other positive impacts through the use of remote techniques in the peer evaluation process. However, there will be additional costs (borne by EA and ESOs) associated with developing guidance and standards related to remote assessment techniques.

ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

Objectives of the consultation

The Commission wanted to assess the effectiveness, efficiency, relevance, coherence, and EU added-value of certain aspects of the NLF. Although the study scope is further detailed below, it is important to note that the study will exclude the provisions of Regulation (EC) No 765/2008 relating to market surveillance. The market surveillance provisions were subject to an ex-post evaluation study in 2017 and have since been amended by Regulation 2019/1020. However, the evaluation will include the provisions within Regulation (EC) No 765/2008 pertaining to conformity assessment, accreditation, and CE marking.

The focus of the evaluation was retrospective, providing an informed assessment of the NLF's current performance and an evidence-based assessment of the above-mentioned evaluation criteria. However, there was also a forward-looking dimension to the evaluation, which formed an important part of the assessment of the NLF's relevance.

Consultation methods and tools

The main consultation activities contained an interview programme, a targeted online consultation survey and a public online consultation survey. A total of 92 stakeholders were interviewed; the targeted consultation received a total of 361 responses with 190 complete responses; and the public consultation received 125 responses, with 95 complete responses.

Furthermore, a stakeholder validation workshop was held on 9th March 2022, where the Commission presented the background and context to the evaluation of the NLF, clarifying the scope and the objectives of both the NLF and the evaluation. The evaluation team then presented an overview of the study's methodological approach, the conceptual challenges related to the evaluation and the findings and conclusions from the research.

The workshop participants were then separated into three break-out groups, where they had the opportunity to provide general feedback on the evaluation study's findings and conclusions, as well as specific feedback on one of the following specific topics: i) Weaknesses in the accreditation and notification systems; ii) COVID-19 & the NLF; and iii) Ongoing fitness for purpose of the NLF.

Results of the consultation activities

Interviews

The piloting of the interview guides was initiated in July 2021. At first, a small number of key stakeholders was targeted, spanning the wide variety of stakeholder groups. The aim of the piloting exercise was to test and ensure the suitability of the interview guide. Through this exercise, it was identified that, for the most part, the questions posed in the different interview guides worked as intended. Following this exercise and the refinement of the interview guides, the full interview programme was initiated.

In total, 117 stakeholders were contacted and interviews were conducted with 92 stakeholders. These engagements span the following key stakeholder groups: economic operators; industry associations; conformity assessment stakeholders (including notified bodies); consumer associations; EU and national authorities; standardisation bodies; and legal

experts. The below table provides the full breakdown of interview status per stakeholder group.

Targeted consultation

The targeted consultation was launched on 16th November 2021 and was originally intended to be open for 8 weeks, closing on 11th January 2022. However, following multiple requests for an extension from key stakeholders, the deadline was extended to 21st January 2022. To support the reach of the targeted consultation, an additional stakeholder mapping process was conducted to develop a comprehensive list of relevant national authorities. Through this process, contact details for all national accreditation bodies, national notifying authorities and MSAs responsible for each NLF-aligned legislation across all Member States were collected, as well as all notified bodies covering all NLF-aligned legislations. As many of the publicly available contact details, particularly for notifying authorities were generic, this stakeholder mapping was enhanced by liaising with the Commission to get explicit permission from specific contacts within national notifying authorities. In total, the survey was circulated directly to more than 2,500 relevant stakeholders by email.

The targeted consultation received a total 190 complete responses, rising to 226 for certain questions.

A total of 361 organisations covering all 27 EU Member States and seven non-EU countries took part in the consultation. The most common country of origin for respondents was Germany, which accounted for 14.4% of responses (52 respondents), followed by Belgium and Czechia, each accounting for 12.2% of responses (44 respondents). However, 29 of the Belgium-based respondents identified as EU-level and/or international organisations. Together, respondents from the EU made up just over 94% of the total (340 respondents). Among the non-EU countries (21 respondents), the most represented country was Switzerland (1.9%, seven respondents).

In terms of achieving its objectives, stakeholders responded positively across all key NLF objectives. Respondents were most likely to consider the NLF to have been either very or somewhat effective at reinforcing the free movement of products within the single market (80.5%, 182 respondents). Considering the other objectives, 75.7% (171 respondents) considered that the NLF was either very or somewhat effective in reinforcing a high level of protection of public interests; similarly, respondents perceived the NLF to have been effective in: strengthening the visibility and use of the CE marking system (70%, 158 respondents); and reinforcing the technology-neutral approach to setting essential requirements (66%, 149 respondents).

Among the NLF's most beneficial aspects, stakeholders frequently mentioned the harmonised conformity assessment and accreditation system, which enables the free movement of goods within the EU. Others suggested that the NLF's main advantage is that it determines the requirements for bodies assessing the conformity of products, which increases trust in their competence and the quality of their work. In relation to conformity assessment, industry representatives clearly stated that they perceive module 'A' (Internal Production Control involving a self-declaration of conformity), in combination with effective market surveillance, as providing a flexible and fair level playing field for manufacturers. The fact that the NLF provides a flexible suite of conformity assessment modules, sets out rules on accreditation for conformity assessment bodies, and makes provisions for effective market surveillance (including for strengthening cooperation and coordination between MSAs and customs authorities) was said to build stakeholder confidence in the overall regulatory

framework and the efficacy of its implementation, as well as ensuring the safety of products within the single market.

Respondents praised the NLF for creating a situation in which actors in the supply chain are responsible for placing their product on the market, for risk assessment and must be aware of its properties. This was seen as leading to a well-defined supply chain with differentiated responsibilities, depending on the role of the specific economic operator (EO) concerned. Stakeholders pointed out that this was a paradigm shift, as manufacturers (or importers or distributors) assume full legal responsibility to ensure compliance for the product they are placing on the market according to the specified obligations for different types of EOs.

Nonetheless, the NLF was said to have been broadly effective in protecting the integrity of the single market and in supporting effective enforcement and surveillance. The overall NLF approach of setting high-level essential requirements but with technical details being set in harmonised standards to provide a presumption of conformity is also appreciated by stakeholders. The option for manufacturers of choosing Module A, which relies on internal production control was seen as allowing for greater flexibility, speed, and lower cost, and gives a predictable timeline to obtain market access for new products. However, the timeliness of the availability of published harmonised standards was a concern identified by industry stakeholders.

Industry associations and economic operators were convinced that the New Approach and the continuation of its principles through the implementation of the New Legislative Framework are the best tools to support the free movement of goods and the proper functioning of the Single Market for goods. The introduction of the NLF was also said to have been beneficial for SMEs in that it has reinforced access to the EU's single market for smaller firms, in particular through the availability of harmonised standards and the ability to reduce costs by following Module A should SMEs so wish. Having a stronger Single Market was said to have further benefitted the global competitiveness of European industry and economic operators as it has improved the speed of adoption of state-of-the-art technologies, as compared to the old approach. Strengthened coherence across sectoral legislation was reported to have improved legal certainty, the ease of compliance, and led to higher compliance levels, resulting in an improved level-playing field for economic operators.

The NLF was considered fit for purpose to deal with upcoming challenges through technological developments. Reducing the technical details in the EU product legislation and placing the focus on essential health and safety requirements through a technology-neutral approach was seen by industry respondents to the consultation as allowing manufacturers space to innovate. Leaving the technical details to harmonised EU standards was said to allow the legislation to follow state of the art. Yet, delays in the process for developing harmonised standards and in their citation in the Official Journal were also identified as a problem.

Industry associations urged that any changes to the NLF should be made only in response to clear needs, within the existing framework. Some respondents maintained that, although the NLF has contributed to achieving all the strategic objectives, environmental protection was the area where progress had been the least obvious. Furthermore, according to some respondents, there remain a considerable number of unsafe products, as illustrated by reports on RAPEX/Safety Gate. Stakeholders argued that all EU harmonised product legislation should be founded on NLF-principles, including CPR, eco-design, and batteries.

In turn, 41.2% of respondents (93 responses) considered that there are negative impacts, challenges or unintended consequences resulting from the NLF.

Stakeholders reporting negative impacts suggested that the implementation of the NLF has not always been as effective as it could be, depending on the understanding of economic operators and the practical application of the rules at national level. Economic operators, industry associations, and some national notifying authorities suggested that there are diverging requirements in NLF-aligned legislation when it comes to the type of accreditation granted to notified bodies, and depending on the Member States, since competences required for notification under a particular NLF-aligned directive or regulation can vary.

Furthermore, economic operators and industry associations were asked to indicate the scale of the costs stemming from the conformity assessment procedure established by the NLF, excluding the costs of compliance with individual sectoral / product legislation. The most important costs reported related to the involvement of notified bodies (rated by 60.7% - 34 responses - as high or very high) and performing laboratory tests (rated by 53.6% - 30 responses - as high or very high).

Looking to efficiency in terms of possible simplification, 79.2% of the respondents (54.2% to a great extent and 25% to some extent) considers that digitalisation of the declaration of conformity / technical product information / technical file would improve the efficiency of the conformity assessment procedure, without hindering market surveillance activities.

Economic operators, industry associations, and national competent authorities were asked whether the common requirements for economic operators in the NLF could be further simplified or improved. Two thirds (66.7%, 48 responses) agreed that they could. Areas identified for improvement by respondents included: documentation (and its digitisation), languages, circular economy requirements, harmonisation (greater consistency of definitions and terminology between different legal acts), material compliance, and transition periods.

National accreditation bodies, national competent authorities, national notifying authorities, and notified bodies / conformity assessment bodies were also asked to assess the burden they experienced resulting from the introduction of the accreditation framework. 42.3% of respondents (47 responses) reported the burden to be high or very high, while a further 27% (30 responses) considered it to be moderate.

Considering internal coherence, a majority of respondents (35.8%, 69 responses) reported that they did not know to what extent inconsistencies, overlaps or gaps exist between the different provisions of the NLF. 28% (54 responses) considered that such inconsistencies, overlaps, or gaps exist to a small extent, while 10.7% and 3.6% consider they exist to a moderate or great extent (20 and seven responses respectively).

Similarly, on external coherence, significant numbers of respondents did not know whether the NLF is coherent with other EU legislation that may apply simultaneously or in complementarity with NLF-aligned legislation. Among those respondents expressing an opinion, the majority believe the NLF is partially (rather than fully) coherent with horizontal policy and legislation, environmental legislation, and other types of relevant legislation.

81.5% of stakeholders (123 respondents) perceive that the suite of conformity assessment modules remains fit for purpose to at least a moderate extent to ensure that products placed on the Union market comply with relevant EU legislation, including 50.3% (76 respondents) who considered this to be the case to a great extent. When it comes to the question of personnel and real activity that the NB has to perform by itself without outsourcing, only 22% (34/135 responses) agreed in the targeted consultations to a great extent that the NLF is sufficiently clear on that issue.

Some industry associations expressed their concern at the interplay and the lack of coherence among some of the main pieces of EU legislation that are currently being revised, reviewed, or newly proposed and the NLF. When it comes to proposals on general product safety, AI, and cybersecurity, respondents stressed the importance of consistency. The NLF should be the "leading legislation" for horizontal definitions.

Over half of the stakeholders (57.9%, 110 responses) considered that the common legal framework provided by the NLF delivered high added value compared to what could have been achieved through the development of product legislation in its absence. A further 25.3% (48 responses) considered that the framework had delivered some added value.

Furthermore, 27.4% of stakeholders (52 responses) considered that the needs and challenges addressed by the NLF's common legal framework still require (harmonisation) action at the EU level to a great extent, while a further 45.3% (86 responses) thought this was the case to a moderate extent. Only three respondents perceive that EU level action is no longer required.

Stakeholders found it difficult to imagine that a more robust or progressive framework could replace the NLF. It was said that other regions around the world, that deploy more "regressive" approaches (i.e. jurisdictions with greater reliance on third party certification, less sophisticated approaches to the presumption of conformity and self-declaration, and less mature standardisation frameworks), do not show greater levels of safety and compliance. At the same time, market access in such countries can be more difficult and expensive for economic operators and, ultimately, for end users. A national competent authority suggested that an important consequence of repealing the NLF would be damage to the confidence in the safety of products among consumers and other users, which has been built up for decades.

Regarding the relevance of the NLF, the proportion of stakeholders who judged that the needs and problems that the NLF was originally designed to address remain relevant, at least to a moderate extent, ranged between 68% (136 responses, in relation to the need to strengthen the visibility and use of the CE marking system) and 78% (156 responses, in relation to the need to address inconsistencies between different pieces of product / sectoral legislation). The need to ensure the free movement of goods within the single market was most often seen by stakeholders as remaining relevant to a great extent (57.5%, 115 responses).

2/3 of the stakeholders (74/96 respondents) perceive that the suite of conformity assessment modules remains fit for purpose to at least a moderate extent to ensure that products placed on the Union market comply with relevant EU legislation.

Significant numbers of stakeholders considered that the scale of the burden deriving from the NLF's communication obligations were 'not all appropriate': 35.7% took this view regarding the obligation to print out technical product information and the technical file (30 responses) and 34.5% for printing out the EU declaration of conformity (29 responses). As mentioned above, digitalisation is seen as a possible simplification in this regard.

Stakeholders were consistent in their answers regarding the extent to which the NLF is able to accommodate important trends related to the circular economy examined: between 41.4% and 45.5% (82 and 90 responses) agreed to at least a moderate extent that the NLF was able to accommodate the key trends in question. On the other hand, between 27.3% and 41.4% (54 and 82 responses) thought this was only the case to a small extent or not at all. Only 21.5% of stakeholders (43 responses) perceive that the requirements for economic operators related to (re)placing substantially modified products on the market remain fully clear, while 33.5% (67 responses) perceive that the definitions of different economic operators, in light of new models of production and increasing value chain complexity, remain fully clear. Finally,

regarding the impact of the COVID-19 pandemic, asked about the extent to which it took products that were instrumental in the fight against COVID-19 too long to be placed on the market, almost half of stakeholders (49.7%, 89 responses) agreed that it took too long (whether to a small, moderate, or great extent). However, most stakeholders (43.6%, 78 responses) responded that they don't know. Only 6.7% of stakeholders (12 responses) answered 'not at all' i.e., that it had not taken too long for products such as PPE and medical devices to be placed on the market during the pandemic.

There was some variation by stakeholder type: national accreditation bodies (21.1%, four responses), industry associations and MSAs (each with 20%, seven and three responses respectively) were the most likely to agree to a great extent that it took too long for products to be placed on the market.

Public consultation

The public consultation questionnaire was finalised and sent for translation on 9th November 2021. It was launched on 13th December 2021 and ran until 7th March 2022. A total of 125 responses were received, with 95 complete responses covering all relevant stakeholder groups.

A total 125 respondents spread across 22 EU Member States and five non-EU countries took part in the consultation. The largest group were based in Belgium, representing 30% of all respondents (37 responses), over 75% of which were EU-level organisations or multi-national companies. The second largest group of respondents were based in Germany (26%, 32 responses), far ahead of the third largest group, Austria (6%, seven responses). 94% of all respondents were based in the EU (117 responses). Among the eight responses from third countries (6%), half were from the United Kingdom. The largest group of respondents by type were industry associations. This group represented 30% of all consultation responses (37 responses). The next largest groups were citizens (EU or non-EU) (24%, 30 responses) and economic operators (14%, 18 responses).

All respondents, except citizens, were asked for their views on the effectiveness of the NLF in its contributions to achieving the objectives of EU product legislation, through providing a common regulatory toolbox to be applied across all different product legislations, establishing a framework for the accreditation of notified bodies, and reinforcing the rules on CE marking. The majority agreed that the NLF has been very effective in reinforcing the free movement of products within the single market (55%, 52 responses) and in reinforcing a high level of protection of public interests (e.g., health and safety, consumer and environmental protection) (49%, 47 responses).

Respondents who took a positive view of its effectiveness said that the NLF enables the free movement of goods in the EU Internal Market and provides for a high level of protection of public interests. SMEs were said to benefit from effective market access. The NLF allows for recent technological developments to be quickly used and to implement the state-of-the art. Through the combination of manufacturer self-declaration (Module A) for conformity assessment, which provides for an acceptable time to market, combined with a strong market surveillance control system for possible intervention, the system provides for a level playing field. This makes a very effective regime in comparison to third countries, where certification is predominantly used, said some respondents. Moreover, the NLF provides an excellent a concept that allows for coherence across different pieces of sectoral legislation that apply to a specific product at the same time.

All respondents, except citizens, were asked for their views on the extent to which the NLF has performed well or faced challenges in relation to four important issues. Improving the regulatory alignment of EU product legislation was the issue for which most respondents considered the NLF has delivered a strong performance (47%, 45 responses); at the other end of the scale, only 34% (32 responses) considered the NLF to have delivered a strong performance in relation to introducing clear and transparent rules for the accreditation of conformity assessment bodies.

For three of the issues, the proportion of respondents who considered the NLF to be performing well though with some challenges was slightly smaller than the proportion who considered the NLF to be delivering a strong performance. The exception was the issue of introducing clear and transparent rules for the accreditation of conformity assessment bodies: here, the proportion of respondents who considered there were some challenges (38%, 36 responses) were in the majority. Strengthening the clarity and credibility of the CE marking system was the issue with the highest proportion of respondents indicating that strong challenges existed in relation to the NLF's performance (15%, 14 responses).

Respondents were asked for their views on the extent to which the NLF had a positive or negative impact in specific areas. The responses showed significant variation: while 83% of respondents (78 responses) thought the NLF had a positive or very positive impact on compliance levels and product safety, and on regulatory certainty and ease of compliance with EU product legislation, only 48% took this view regarding the NLF's impact on product innovation.

Most stakeholders agreed that the meaning of the CE marking is clear to a great extent (50%, 62 responses) or to a moderate extent (34%, 42 responses). Slightly fewer took the same view regarding the trustworthiness of the CE marking as an indicator that a product will function safely and as intended: 46% agreed this was the case to a great extent (57 responses) and 31% to a moderate extent (39 responses).

Economic operators and industry associations were asked to indicate the scale of the most important costs stemming from the conformity assessment procedure established by the NLF. Costs related to the involvement of notified bodies were most likely to be described as very high (47%, 26 responses). High or very high costs were also identified as pertaining to laboratory tests, with 77% of respondents reporting this to be high or very high (42 responses). 59% described the overall costs of the conformity assessment procedure as high or very high (32 responses).

Most respondents were positive about the benefits that have been achieved as a result of the NLF. Regarding cost savings due to facilitated familiarisation with different EU legislation (e.g., due to common definitions, reduced market fragmentation etc.), 47% agreed that strong benefits had been achieved (45 responses), while a further 30% thought there were at least some benefits (28 responses). Respondents were only slightly less positive regarding cost savings in the process of demonstration of conformity across different EU product legislation: 41% agreed that strong benefits had been achieved (39 responses), while a further 28% thought there were some benefits (27 responses).

Looking to efficiency in terms of possible simplification Regarding the provision of information in digital form, most stakeholders agreed that providing product information in a digital format (e.g. instruction manuals) would be positive (26%, 33 responses) or even very positive (46%, 57 responses) in its impact on consumers. Over half of stakeholders (63%, 79 responses) agreed that providing other traceability information (e.g., the postal address of the manufacturer/importer) digitally would be positive or very positive. Respondents were less

sure about providing the CE marking in a digital form: 44% thought this would have a positive or very positive impact on consumers (54 responses), while 24% thought it would have a negative or very negative impact (30 responses).

Stakeholders were asked to consider to what extent the provisions of the NLF are coherent with one another, in particular whether Decision 768/2008/EC containing a model to be used in preparing and revising Union harmonisation legislation is coherent with Regulation 765/2008/EC applicable to accreditation and CE marking. Stakeholders were broadly positive about the coherence of the NLF's provisions with one another. 36% agreed that the provisions were fully coherent (34 responses), while a further 26% consider that they are partially coherent (25 responses). 37% of stakeholders said that they did not know (35 responses).

Most stakeholders agreed that the NLF has delivered high added value compared to what could have been achieved through the development of product legislation without the NLF (60%, 56 responses). A further 23% consider the NLF to have delivered some added value (21 responses).

Reflecting their positive views of the NLF's added value, many respondents reiterated their view that the NLF had proven its ability to add value in multiple aspects. The NLF is of great importance for the placing of products on the market and underpins the competitiveness of European industry. The added value of the NLF lies in its consistent application, said respondents. Businesses have built their entire compliance system around this regulatory framework. The very idea of significantly changing the structure of the NLF would have very negative consequences for businesses, weaken the internal market and the competitiveness of European industry, and have a negative impact on the European quality infrastructure.

Stakeholders agreed that the objectives of the EU legal framework for products remain relevant, although there was some variation between the objectives. While 77% of respondents agreed that improving the regulatory alignment of product legislation remains a relevant objective to a great extent (73 responses), only 57% took the same view regarding the continuing relevance of the objective to ensure clear and transparent rules for the accreditation of conformity assessment bodies (54 responses).

Stakeholders were asked for their views regarding the extent to which the NLF, through its technology-neutral approach, is able to accommodate important trends related to the digital and circular economy. The answers showed significant variation depending on the trend in question: while 33% of stakeholders (31 responses) consider the NLF is able to accommodate trends relating to cyber security and the increasing complexity and interconnectedness of products (e.g., the Internet of Things), only 12% (11 responses) agreed that this was the case in relation to the emergence of new types of economic operators due to new models of production and increasing value chain complexity. Increasing product refurbishment and remanufacturing was the trend that the highest proportion of stakeholders (18%, 17 responses) thought the NLF is not at all able to accommodate.

Stakeholder validation workshop

First and foremost, many participants across all stakeholder groups noted their general agreement with the conclusions presented by the contractor, highlighting the positive impact of the NLF overall, the strong performance of the suite of conformity assessment modules and the generally positive role played by the accreditation framework. However, participants noted the following challenges and areas for improvement across the NLF, such as divergence between NLF-aligned legislation and the conformity assessment system.

The more general challenge of updating the NLF and ensuring it remains fit for purpose divided stakeholders. Some participants referred to this as a "chicken and egg" situation whereby the NLF and its general principles remain broadly relevant and coherent in many areas, but the wide array of new legal developments in recent years means that the NLF needs to be reviewed and possibly modernised and updated. A key challenge in this regard relates to circular economy developments. New types of economic operators (such as repairers, refurbishers, and remanufacturers) have become more prominent in the market since the NLF's adoption; currently, such economic operators are not defined in the NLF and their obligations with regard to conformity assessment and compliance are not clear.

Mixed views were presented regarding whether the NLF itself should be amended or whether some of these developments could be better addressed by building on existing work ongoing within the Commission and other stakeholder fora. For instance, work is being done to update the Blue Guide and to provide an appropriate place within it (instead of within the NLF) to support the implementation of the legal framework to accommodate the need for common definitions (such as "remanufacturing, refurbishing and reprocessing"). Furthermore, other stakeholders noted the positive experience with CE marking of software under the MDR. However, there was no consensus on which approach was most appropriate.

Work by the Commission to extend the ecodesign requirements through the Sustainable Products Initiative (SPI) to adopt more of a product lifecycle approach was also mentioned. It was questioned whether the NLF itself should be reformed or could simply build on and cross-reference to other legislative developments, including standardisation-related initiatives with horizontal relevance. The updating of the Blue Guide, for instance, expected to be published in May 2022 was mentioned as a suitable place to provide a broader set of common definitions.

Looking forward, there was no consensus amongst participants on how the weaknesses and challenges identified should be tackled, whether through a revision and updating of the NLF or by using the NLF as the basic building block and relying on other mechanisms. For instance, some participants pointed to the upcoming revision of the Blue Guide as a key opportunity to tackle many of these challenges without needing to make legislative changes. However, the Blue Guide is not legally binding and other participants stated that tackling many of these challenges would require a revision of the NLF. DG GROW confirmed that the revised Blue Guide does aim to tackle some of the definitional issues and questions relating to the circular economy (e.g. substantial modifications) and should be adopted by May 2022.

Feedback to stakeholders

The consultation processes revealed that the NLF has contributed strongly to the achievement of its general objectives; namely providing a high level of protection of public interests, fostering the free movement of products within the single market, and establishing a common harmonisation framework.

Concerning the efficiency of the NLF, the positive effects of the NLF, considering both monetary and non-monetary benefits, strongly outweigh the costs identified. The NLF comprises very few direct regulatory and administrative costs, as most costs associated with the framework of EU product legislation either stem directly from compliance with individual pieces of NLF-aligned legislation or did not change significantly with the introduction of the NLF. However, a wide range of cost savings and other benefits have been highlighted by stakeholders. For economic operators, these benefits included reduced costs in familiarisation with legislative requirements by economic operators due to the implementation of common provisions; greater regulatory certainty; greater harmonisation of obligations; reduced market

barriers; and, as a result, enhanced industrial competitiveness. A further strategic benefit was the enhanced global recognition of the CE marking stemming from its prominence within the NLF.

The NLF legal framework, as set out in Regulation (EC) No 765/2008 and Decision No 768/2008/EC, was relevant in addressing the problems identified in the 2007 impact assessment, prior to the adoption of the NLF. In particular, the reference provisions and common implementation mechanisms have been appropriate to improve legislative harmonisation, maintain the technology-neutral approach to setting essential requirements, and improve the rules and systems for conformity assessment and CE marking. Although significant progress has been made towards addressing these needs, stakeholders clearly feel that these needs, the related objectives, and the overarching framework implemented by the NLF remain relevant moving forward.

Finally, there is a need to ensure that the NLF retains its core principles, as there is a broad consensus that these are appropriate in terms of their effectiveness, relevance and efficiency. However, given changes to the EU legal framework and trends in product markets towards digitalisation and the circular economy, there is a clear need for the NLF to be reviewed with active consideration given to its possible revision to ensure that it remains fit for purpose.

ANNEX VI. CONFORMITY ASSESSMENT – STATE OF PLAY

The system of notified conformity assessment bodies

Notifying authorities. The model provision R14 of the Annex of Decision No 768/2008/EC sets out that Member States should designate a notifying authority responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies.

Across the body of NLF-aligned legislation, 160 notifying authorities are in operation,[109] with 139 based across the EU-27, 12 in the EEA-EFTA countries[110] and nine spanning seven third countries[111]. These notifying authorities may have responsibility for one or multiple NLF-aligned legislation.

In terms of territorial coverage in the Member States, 25 Member States have established notifying authorities for each of the NLF-aligned legislation (at least 17 out of 21) for which notification of CABs is relevant.[112][113] In some instances, Member States have multiple notifying authorities with responsibility for one NLF-aligned legislation.[114]

Only two directives have notifying authorities in all 27 Member States: the Toys Safety Directive and the Construction Products Regulation[115].

Notified conformity assessment bodies. Chapter R4 of the Annex of Decision No 768/2008/EC details extensive reference provisions related to the notification of conformity assessment bodies, including, amongst other provisions, the procedure for notification, and the requirements relating to, and obligations on, both notifying authorities and notified bodies.

There are 1649 notified bodies across the 21 NLF legislation.[116]

The following map illustrates the prevalence of notified bodies by Member State. As can be seen, the number of notifications per Member State varies significantly from 2 in Malta or 9 in Luxembourg to 348 in Italy and 309 in Germany, with a median of 59 notifications.

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[109] *NB*: Analysis conducted on data extracted from the European Commission's online NANDO database in November 2021. Since, a small number of changes to the roles of national notifying authorities have been implemented; for instance, in Germany, the authority responsible for Directives 2014/31/EU and 2014/32/EU is now the Bundesministerium für Wirtschaft und Klimaschutz (BMWK); it was formerly the Bundesministerium für Wirtschaft und Energie (BMWi).

[110] Comprising 5 notifying authorities in Iceland, 1 in Liechtenstein, and 6 in Norway.

[111] Comprising 1 in Australia, 2 in Canada, 1 in Switzerland, 1 in Japan, 1 in New Zealand, 1 in Turkey and 2 in the US.

[112] The RoHS Directive 2011/65/EU and the Low Voltage Directive 2014/35/EU only use module A (internal product control) and therefore do not require the notification of conformity assessment bodies.

[113] The exceptions are Cyprus, which covers 13 of the 21 relevant NLF-aligned laws, and Malta, which only covers eight.

[114] For example, in Poland, both the Ministry of Economic, Development, Labour and Technology and the Ministry of Infrastructure have responsibility for the Transportable Pressure Equipment Directive.

[115] Most NLF-aligned legislation are covered in most Member States (between 24-27 countries); the remaining legislation is the Marine Equipment Directive (23 Member States), the Radio Equipment Directive (22), the Civil Explosives Directive (21) and the Cableway Installations Regulation (18).

[116] The vast majority (1,489) of CABs are notified by Member State authorities: these NBs account for 90.7% of the total notifications (2,198 of 2,424).
The remaining NBs have been notified by EEA-EFTA countries (29) or third countries which may notify their conformity assessment bodies based on Mutual Recognition Agreements with the EU116 (131). These NBs account for 1.7% (40) and 7.7% (186) of the total notifications, respectively.

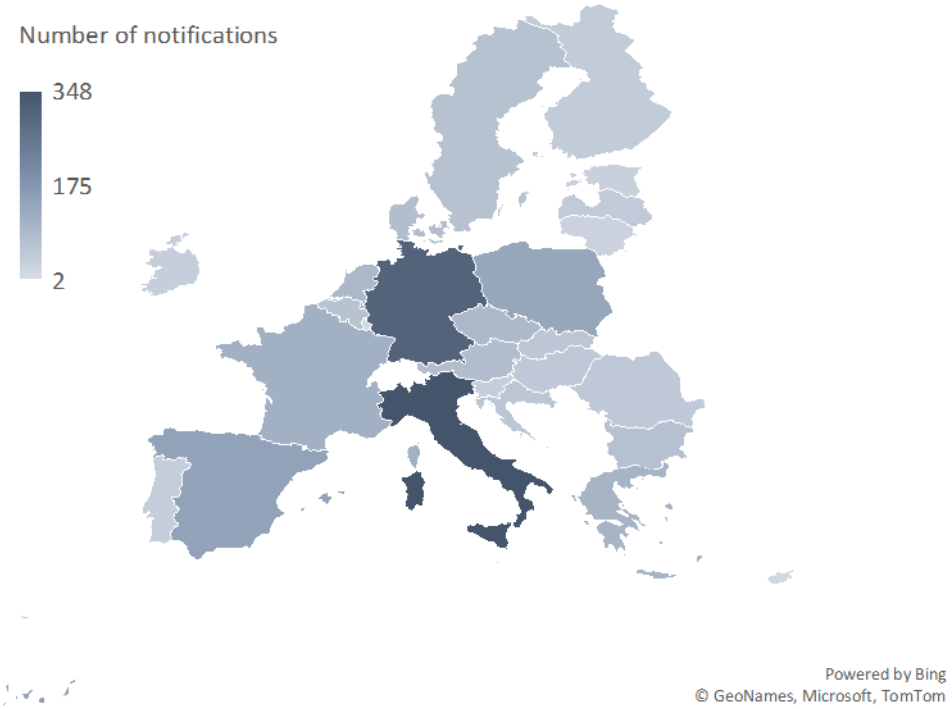

Figure 10 Number of notifications of conformity assessment bodies per Member State

Considering notifications across the different NLF-aligned legislation by EU Member States, 54% of these notifications are related to three pieces of legislation: the Construction Products Regulation with 30.6% (673 notifications), the Pressure Equipment Directive with 12.5% (275 notifications, and the Lifts Directive with 10.8% (238 notifications)[117].

Data from the Commission's NANDO database has been extracted to investigate the evolution of the number of notified bodies under NLF-aligned pieces of legislation. Trends are not consistent across different directives and regulations. In some cases (Toy Safety Directive, Recreational Craft Directive, Lifts Directive, Electromagnetic Compatibility Directive and Simple Pressure Vessels Directive) a reduction in the number of notified bodies has been observed in the 2008-2020 period, broadly coinciding with the introduction of the new NLF-aligned directives. In other cases (Marine Equipment Directive, Pressure Equipment Directive), however, the number of notified bodies has increased.

Statistics from NANDO

EU Member States, EFTA countries (EEA members) and other countries with which the EU has concluded Mutual Recognition Agreements (MRAs) and Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) designate Notified Bodies, established per individual piece of legislation. Notified Bodies can be searched on the website of the **NANDO** (New Approach to Notified and Designated Organisations) **Information System** [118].

[117] Beyond these, the highest number of notifications for a single legislation is 175 (8% – Transportable Pressure Equipment Directive). The legislation with the fewest notifications at the time of analysis are the EU Fertilising Products Regulation (3 notification) and the *In vitro* Diagnostic Medical Devices Regulation (6 notifications).
[118] https://ec.europa.eu/growth/tools-databases/nando/

This Annex offers an overview of the evolution over time of Notified Bodies by piece of legislation and country. It is based on a database provided to the evaluation team in the form of an Excel spreadsheet by the European Commission (DG GROW). The evaluation team performed consistency checks and cleaned the data before performing elaborations and reporting the results.

In addition to NLF-aligned directives and regulations and their predecessors, the received database extracted from NANDO includes data on other legislation as well. The list of all 56 pieces of legislation covered by the received database is provided in the following table. In what follows, the analysis is however focused only on NLF-aligned directives and regulations and their predecessors.

Legislation	Name of legislation	In force
NLF-aligned		
2014/34/EU	ATEX Directive	Yes
Regulation (EU) 2016/424	Cableway Installations Regulation	Yes
2014/28/EU	Civil Explosives Directive	Yes
Regulation (EU) 305/2011	Construction Products Regulation	Yes
2014/30/EU	Electromagnetic Compatibility Directive	Yes
Regulation (EU) 2019/1009	Fertilising Products Regulation	Yes
Regulation (EU) 2016/426	Gas Appliances Regulation	Yes
Regulation (EU) 2017/746	In Vitro Diagnostic Medical Devices Regulation	Yes
2014/33/EU	Lifts Directive	Yes
2014/90/EU	Marine Equipment Directive	Yes
2014/32/EU	Measuring Instruments Directive	Yes
Regulation (EU) 2017/745	Medical Devices Regulation	Yes
2014/31/EU	Non-automatic Weighing Instrument Directive	Yes
Regulation (EU) 2016/425	Personal Protective Equipment Regulation	Yes
2014/68/EU	Pressure Equipment Directive	Yes
2013/29/EU	Pyrotechnic Articles Directive	Yes
2014/53/EU	Radio Equipment Directive	Yes
2013/53/EU	Recreation Craft and Personal Watercraft Directive	Yes
2014/29/EU	Simple Pressure Vessels Directive	Yes
2009/48/EC	Toy Safety Directive	Yes
2010/35/EU	Transportable Pressure Equipment Directive	Yes
Regulation (EU) 2019/945	Unmanned Aircraft Systems Regulation	Yes

Legislation	Name of legislation	In force
Not NLF-aligned		
Regulation (EC) 552/2004	Air Interoperability Regulation	Yes
92/42/EEC	Boiler Efficiency Directive	Yes
Decision 2009/750/EC	European Electronic Toll Service Decision	No
2006/42/EC	Machinery Directive	Yes
2000/14/EC	Outdoor Noise Directive	Yes
2016/797	Rail Interoperability Directive	Yes
90/385/EEC	Old Active Implantable Medical Devices Directive	No
94/9/EC	Old ATEX Directive	No
2000/9/EC	Old Cableway Installations Directive	No
93/15/EEC	Old Civil Explosives Directive	No
89/106/EEC	Old Construction Products Directive	No
89/336/EEC	Old Electromagnetic Compatibility Directive_1989	No
2004/108/EC	Old Electromagnetic Compatibility Directive_2004	No
2009/142/EC	Old Gas Appliances Directive	No
98/79/EC	Old In Vitro Diagnostic Medical Devices Directive	No
95/16/EC	Old Lifts Directive	No
2006/95/EC	Old Low Voltage Directive	No
98/37/EC	Old Machinery Directive	No
96/98/EC	Old Marine Equipment Directive	No
2004/22/EC	Old Measuring Instruments Directive	No
93/42/EEC	Old Medical Devices Directive	No
2009/23/EC (ex-90/384/EEC)	Old Non-automatic Weighing Instruments Directive	No
89/686/EEC	Old Personal Protective Equipment Directive	No
97/23/EC	Old Pressure Equipment Directive	No
2007/23/EC	Old Pyrotechnic Articles Directive	No
99/5/EC	Old Radio Equipment Directive	No
2008/57/EC	Old Rail Interoperability Directive	No
94/25/EC	Old Recreational Craft Directive	No
2009/105/EC	Old Simple Pressure Vessels Directive	No
98/13/EEC	Old Telecommunications Terminal Equipment Directive	No

Legislation	Name of legislation	In force
88/378/EEC	Old Toy Safety Directive	No
2001/16/EC	Old Trans-European Conventional Rail Interoperability Directive	No
96/48/EC	Old Trans-European High-Speed Rail Interoperability Directive	No
99/36/EC	Old Transportable Pressure Equipment Directive	No

Table 2 Pieces of legislation covered by NANDO

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
ATEX Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**57**	**63**	**68**	**71**	**75**
Old ATEX Directive	53	53	54	54	56	59	61	64	66	0	0	0	0	0
Cableway Installations Regulation	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**17**	**18**	**19**
Old Cableway Installations Directive	23	23	24	23	24	23	24	24	23	24	23	0	0	0
Civil Explosives Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**11**	**10**	**10**	**10**
Old Civil Explosives Directive	13	13	13	12	12	12	13	13	12	0	0	0	0	0
Construction Products Regulation[119]	**0**	**0**	**0**	**0**	**0**	**0**	**459**	**587**	**620**	**632**	**648**	**653**	**653**	**669**
Old Construction Products Directive[120]	554	612	651	669	697	732	0	0	0	0	0	0	0	0
Electromagnetic Compatibility Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**81**	**89**	**92**	**95**	**96**
Old Electromagnetic Compatibility Directive_1989	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Old Electromagnetic Compatibility Directive_2004	119	160	163	165	170	153	153	145	143	0	0	0	0	0
Fertilising Products Regulation[121]	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Gas Appliances Regulation	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**37**	**47**	**45**
Old Gas Appliances Directive	46	46	45	47	48	49	47	49	50	50	55	0	0	0
In Vitro Diagnostic Medical Devices Regulation	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**4**
Old In Vitro Diagnostic Medical Devices Directive	21	19	19	20	21	22	22	21	20	18	17	18	18	18
Lifts Directive	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**14**	**224**	**235**	**231**	**229**	**234**
Old Lifts Directive	234	251	256	253	241	230	238	239	235	0	0	0	0	0
Marine Equipment Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**22**	**37**	**37**	**40**	**44**
Old Marine Equipment Directive	30	30	30	30	29	30	31	33	34	1	1	1	1	1
Measuring Instruments Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**86**	**97**	**98**	**96**	**93**
Old Measuring Instruments Directive	53	76	92	94	103	104	104	104	104	0	0	0	0	0
Medical Devices Regulation	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**8**	**17**
Old Active Implantable Medical Devices Directive	19	19	19	18	18	19	17	16	15	13	12	11	11	10
Old Medical Devices Directive	69	68	68	69	75	75	70	66	58	53	52	54	54	53
Non-automatic Weighing Instrument Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**65**	**71**	**71**	**71**	**74**
Old Non-automatic Weighing Instruments Directive	205	204	206	182	186	188	188	184	175	1	1	1	1	1

[119] Data include also Technical Assessment Bodies under the current Construction Products Regulation. See legislation-specific section for further details.
[120] Data include also Approved Bodies under the old Construction Products Directive. See legislation-specific section for further details.
[121] Three NBs under the Fertilising Products Regulation started their activities in late 2021. As the figures for each year relate to the 1st of January, these three NBs are not considered in the table.

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Personal Protective Equipment Regulation	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**36**	**89**	**101**	**106**
Old Personal Protective Equipment Directive	98	102	105	104	104	105	109	106	106	104	104	92	1	1
Pressure Equipment Directive[122]	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**7**	**266**	**298**	**321**	**336**	**336**
Old Pressure Equipment Directive[123]	249	254	263	259	254	255	261	270	280	4	4	4	4	4
Pyrotechnic Articles Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**11**	**13**	**13**	**14**	**13**	**12**
Old Pyrotechnic Articles Directive	0	1	3	10	13	13	17	17	0	0	0	0	0	0
Radio Equipment Directive	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**1**	**41**	**54**	**66**	**68**	**71**
Old Radio Equipment Directive	49	52	52	50	50	50	51	55	55	58	1	1	1	1
Old Telecommunications Terminal Equipment Directive	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Recreation Craft and Personal Watercraft Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**21**	**26**	**28**	**32**	**31**
Old Recreational Craft Directive	29	30	28	31	29	31	34	35	35	27	6	5	5	1
Simple Pressure Vessels Directive	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**3**	**56**	**69**	**72**	**72**	**73**
Old Simple Pressure Vessels Directive[124]	94	100	103	104	102	103	100	102	98	8	7	6	5	4
Toy Safety Directive	**0**	**0**	**0**	**1**	**37**	**45**	**46**	**46**	**43**	**42**	**42**	**40**	**41**	**42**
Old Toy Safety Directive	59	59	60	57	1	1	1	1	1	1	1	1	1	1
Transportable Pressure Equipment Directive	**0**	**0**	**0**	**0**	**79**	**96**	**107**	**122**	**126**	**131**	**138**	**145**	**144**	**144**
Old Transportable Pressure Equipment Directive[125]	147	151	152	144	0	0	0	0	0	0	0	0	0	0
Old Low Voltage Directive[126]	*139*	*139*	*146*	*143*	*144*	*145*	*143*	*143*	*141*	*1*	*1*	*1*	*1*	*1*

Table 3 Evolution of number of notified bodies over time, by piece of legislation (2008-2020)

***Source**: CSES report based on NANDO database.*

Notification procedure. The approach/procedure of the notified bodies is not based on the same set of rules everywhere. Some industry stakeholders report that national level notification procedures for the notification of NBs diverge across the Member States.

Many stakeholders that responded to the questions of the targeted consultation have stressed the weakness of the NLF in ensuring the harmonisation of notification requirements among the Member States. This is conducive to reliability and appropriateness issues (see Chapter 4.1.3.).

Subcontracting of substantial technical tasks. The Blue Guide provides a number of clarifications on the scope and conditions of such contracts in its Section 5.2.5. A notified body can subcontract strictly limited technical tasks (such as tests and examinations), as long as these can be defined as substantial and coherent parts of the technical operation. A notified body can only subcontract a task for which it has the competence itself, if the subcontractor also has and maintains that necessary competence. The notified body must be able to demonstrate the compliance of its subcontractors with the requirements laid down in the relevant Union harmonisation legislation. A subcontracting notified body remains responsible

[122] Data include also User inspectorates as well as Recognised third-party organisations (as recognised in current PED). See legislation-specific section for further details.
[123] Data include also Article 14 user inspectorates as well as Third-party organisations. See legislation-specific section for further details.
[124] Data include also Third-party organisations. See legislation-specific section for further details.
[125] Data include also Approved Bodies under Article 9 of the old TPED. See legislation-specific section for further details.
[126] In the received database, no NB is related to the Low Voltage Directive currently in force.

for all the activities covered by the notification. Subcontracting does not entail the delegation of powers or responsibilities.

The notified body must inform the notifying authority of its intention to subcontract certain work. The extent to which the notified body intends to rely on subcontractors must be appropriately assessed by the notifying authority. The notifying authority may decide that it cannot take the overall responsibility for such an arrangement, and withdraw or limit the scope of the notification. The notified body must keep a register of all its subcontracting activities, and update it systematically. The notifying authority must be capable of ensuring effective monitoring of the competence of the body subcontracted by the notified body.

If accreditation is the chosen path for notification, it must cover the subsidiary companies of notified bodies to which they have recourse. If notification is not based on accreditation, the contents of the information to be provided to the notifying authority should be further specified by aligning it to the relevant practices in accreditation.

During the interviews conducted by CSES, conformity assessment bodies confirmed that the subcontracting of conformity assessment activities is a well-established and necessary instrument.

The conformity assessment bodies explained that outsourcing by an accredited CAB to non-accredited CABs is not possible. Besides, the CAB must verify that the test reports on which they rely are trustworthy. For instance, the standard EN ISO/IEC 17065:2012 Conformity assessment - Requirements for bodies certifying products, processes and services allows EU CABs to rely on test reports from labs established in the USA, China and Australia; however, in the standard EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories, systematic outsourcing is not allowed.

The European system for accreditation of conformity assessment bodies

The adoption and practical implementation of the legal framework for accreditation is a very important achievement under the objective of strengthening the conformity assessment system in Europe.

The NLF created the European system for accreditation of conformity assessment bodies. Regulation (EC) No 765/2008 recognised **the European Cooperation for Accreditation (EA)** as a single organisation at European level and introduced a mandatory membership of the national accreditation bodies in the EA. The EA is responsible for the peer evaluation for its members (national accreditation bodies). The Commission may request the EA to contribute to the development and implementation of the accreditation in the EU and to lay down evaluation criteria and procedures for peer evaluation and to develop sectoral accreditation schemes, including the development of sectoral accreditation schemes. In this context, the *General Guidelines for Cooperation between the European cooperation for Accreditation and the European Commission, the European Free Trade Association and the Competent National Authorities* was signed on 1 April 2009.[127] This agreement aimed to strengthen cooperation on accreditation and "stabilise the position of accreditation [and] accreditation bodies in EU and EFTA Member States"[128]. Since its inception, EA has also

[127] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009XC0521%2804%29

[128] European Accreditation (EA). (2019). EA MLA Report 2019. Building on this agreement, EA and the Commission signed the first Framework Partnership Agreement (FPA) covering the four-year period 2010-2013. The second FPA ran from 2014-2017 and the third and current iteration of the FPA was signed in 2018 for the period 2019-2022.

published a wide range of mandatory, guidance and informative documents to support its members.[129]

EA currently has 49 NAB members covering the EU-27, EEA-EFTA countries and third countries.

Based on the NLF, national accreditation bodies have been appointed in all Member States. Although in many cases these bodies were already operating prior to the NLF, all 27 EU Member States and Norway, as well as Switzerland, Canada, and Turkey, have appointed NABs in line with Regulation (EC) No 765/2008.

The European accreditation system ensures the mutual recognition of test reports issued by accredited notified bodies. According to Article 11 of Regulation (EC) No 765/2008, national authorities in the Member States should recognise the equivalence of the services delivered by the accreditation bodies in the different Member States. Therefore, the principle of mutual recognition of certificates and test reports issued by the accredited conformity assessment bodies in the area of their competence is applicable throughout the EU.

Accreditation is the favoured instrument for the verification of competence of conformity assessment bodies, although not mandatory for the notification. Nevertheless, it provides an authoritative statement of the competence, professional integrity and impartiality of the bodies to be notified to the Commission and the other Member States.

The harmonised standards of the EN ISO/IEC 17000 series that can be used to demonstrate the competence of the candidate notified body may vary depending on the specific conformity assessment tasks (modules) and the different products in Union harmonisation legislation. First of all national accreditation bodies have to meet the requirements of the harmonised standard EN ISO/IEC 17011 "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies". To demonstrate that they are capable and competent to carry out accreditation in the different fields of conformity assessment serviced by them, the following standards are, for example, available: EN ISO/IEC 17025 for testing and calibration laboratories; EN ISO/IEC 17020 for inspection bodies or EN ISO/IEC 17065 for bodies certifying products, services and processes.

In order to ensure harmonisation of the assessment of competence of candidate notified bodies, the European Cooperation for Accreditation (EA) has developed a recommendation on standards for accreditation for each relevant Union harmonisation legislation and for each conformity assessment module[130]. For a notification to be considered as accompanied by an accreditation certificate, the accreditation certificate must indicate the competence of the candidate notified body in relation to the specific Union harmonisation legislation for which notification is being sought.

According to EA, there are sufficient common criteria for the notification of CABs in Decision No 768/2008/EC.

The conformity assessment procedures

The conformity assessment system detailed in the NLF underpins the entire internal market, as it represents the means by which economic operators demonstrate the compliance and

[129] Recent examples from 2020 include: the guidance document on Consultancy, and the Independence of CABs129; the document listing the risks of accreditation processes and operation of NABs129; and the document on Accreditation for Notification Purposes, https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-17-m.pdf

[130] EA-2/17 - EA Document on Accreditation for Notification Purposes

conformity of their products with the essential requirements laid down in specific product legislation.

Annex II of Decision 768/2008/EC sets out in details 8 different overarching modules from module A, which does not include a third-party assessment, to module H, which is based on a full quality assurance. All the modules are based on the same phases or steps, although the more complex modules contain more of those phases. These modules represent a menu, from which the legislator may choose the most appropriate for a specific legislation, depending on the risk related to the product within its scope.

For example, under the Low Voltage Directive or Toys Safety Directive the involvement of notified bodies is not mandatory, since they foresee only module A. On the other hand, the involvement of notified bodies is mandatory for example under the Pressure Equipment Directive for categories II, III and IV of pressure equipment.

ANNEX VII. MAIN COSTS AND BENEFITS IDENTIFIED BY EVALUATIONS OF CERTAIN NLF-ALIGNED EU PRODUCT LEGISLATION

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
Directives			
Toy Safety Directive 2009/48/EU **2020 Evaluation**	***For manufacturers:*** • One-off costs to adapt to manufacturing, testing and documentation requirements: 2% of annual turnover, and recovered over 3 years on average. • Recurring costs due to new safety requirements. • Time spent to comply with the Directive's requirements when developing a toy: 485 man-hours on average (corresponding to €10,900 per toy), of which 43% for testing and documentation (€4,700); 33% for safety aspects (€3,600); 12% packaging (€1,400); 12% other. • Preparing and updating technical documentation (safety assessment, conformity assessment documents and supply chain information). • Purchasing standards. • Testing of raw materials. • Testing of toys. • Translation of product documentation. ***For importers:*** • Time spent to comply with Directive's requirements: 110 man-hours per toy type (€2,500). ***For distributors:*** • Time spent to comply with Directive's requirements: 86 man-hours per toy type (€1,953). ***For public authorities:*** • Enforcement costs.	• Ensuring safety. • Ensuring legal certainty. • Ensuring a level playing field in the internal market.	• No quantification possible. • Stakeholders consider that **benefits outweigh costs**.
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU	***For manufacturers:*** • Compliance costs of the RoHS Directive for businesses include collecting and reviewing information, gathering supply chain information, costs related to a dedicated IT system to manage all required pieces of information, and costs related to the exemption system. • Technical costs include complying with	• Reduced exposure to restricted substances, leading to environmental and health benefits. • **Economic**	• Benefits driven by the environmental and health **benefits outweigh the compliance and enforcement**

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
2021 Evaluation	the hazardous substance restrictions in their product (i.e. product development). The highest costs are related to the exemption system and product development. ***For public authorities:*** • In Member States, resources allocated to enforcement and implementation range from 0.3 to 4.75 full-time equivalent employees (FTE) per country and per year. Their annual budget ranges from €10,000 to over €400,000.	**benefits**: levelling the playing field for businesses in the internal market regarding the use of hazardous substances, creating legal certainty, and sometimes spurring innovation through substitutions. • The main **indirect benefit** of the Directive is that it influences creation of similar legislation in many countries outside the EU.	**costs**. • Stakeholders also generally agree that costs of the Directive are justified.
Electromagnetic Compatibility Directive 2014/30/EU **2021 Evaluation**	Almost all costs generated by the EMCD are borne by manufacturers. The largest type of costs are the costs of development and the costs of laboratory tests (part of conformity assessment costs to produce the technical file). However, most of the costs borne by manufacturers can be considered as business-as-usual costs. Generally, the cost of complying with the EMCD corresponds to 5-15% of total costs of production. Administrative and reporting costs therefore represent only a minority share of the total production costs borne by manufacturers. The self-certification approach made possible by the EMCD, in particular, contributes to keeping costs relatively low and grants a certain level of flexibility to economic operators. ***For manufacturers:*** • Costs during product development (engineering costs; purchasing standards; pre-testing). • Conformity assessment costs (preparing technical documentation; laboratory tests; involvement of notified body). • Costs during production process (e.g.	• **Technical benefits:** reduced incidence of electromagnetic disturbance leading to the incorrect functioning of electrical equipment and increased electromagnetic immunity. • **Strategic benefits**: fostering of the free movement of products in the internal market and increase in industrial competitiveness.	• Stakeholders consider that **benefits outweigh costs**.

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
	EMC-relevant measures). • Familiarisation with legislative requirements. ***For public authorities:*** • Enforcement costs.		
Low Voltage Directive 2014/35/EU **2019 Evaluation**	***For manufacturers, distributors and importers:*** • Resources to deal with LVD compliance (Internal resources for regulatory follow up and participation in standardisation activities; external legal advice). • Technical compliance cost during production process (internal resources to ensure compliant manufacturing. • Purchase of standards. • Procedural compliance cost during conformity assessment (internal resources for verification of compliance, drawing of DoC and other documents, labelling; third party labs and certifiers). • Administrative cost (internal resources for updates of products and documentation and archiving of documentation; third party services). ***For national authorities:*** • Transposition costs. • Implementation costs (e.g. day-to-day operations of national implementation bodies). • Enforcement costs (market surveillance). ***For taxpayers:*** • Taxes for public health and social security.	***For manufacturers, distributors and importers:*** • Access to markets thanks to harmonised rules and procedures. • Access to innovation: voluntary use of standards allows to tap into innovation opportunities and set the scene for updated safety requirements. • Compliance savings. • Reputational benefits. ***For national authorities:*** • Regulatory cost savings. • Savings on market surveillance and coordination. • Synergies in topical expertise. ***For taxpayers:*** • Wider choice of low voltage products. • Increased safety of products throughout the	• Stakeholders consider that **benefits outweigh costs**.

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
		EU.	
Regulations			
Construction Products Regulation 305/2011 **2018 Evaluation**	***For manufacturers:*** • Increased regulatory and administrative costs (0.6-1.1% of the sector's turnover, corresponding to €2.62-3.4 billion), linked to the supply of the Declaration of Performance (DoP) and the CE marking. It is also noted that the information required in the DoP and the CE marking overlap, generating unnecessary burden. • Testing costs and quality control mechanisms would also have incurred without the CPR. Efficiency for individual manufacturers (in terms of cost-effectiveness) depends to a large extent on the size of the company. For larger companies and those that have a history of compliance (e.g. they have installed Factory Production Control systems), costs are relatively low.	• Better access to other EU markets. • Common technical language and common rules. • Uniformity in information for end users. • Improvement in production processes due to CPR requirements.	• **Costs are commensurate to benefits**. However, this is an assessment based on average costs. The main factor influencing the proportionality of costs is the size of the company, and the largest burdens (in relative terms) are borne by the smallest companies. The burden of costs also depends on the type of product and the complexity of requirements of the relevant standard, as well as the number of different products each company produces.

ANNEX VIII. CASE STUDIES

This Annex presents a selection of four case studies developed to support the evaluation of the NLF:

- **Case study 1:** Coherence of non-aligned EU product legislation with NLF-aligned legislation.
- **Case study 2:** Accreditation process
- **Case study 3:** Assessment of NLF-related costs and benefits under the Electromagnetic Compatibility Directive (EMCD).
- **Case study 4:** Assessment of NLF-related costs and benefits under the Toy Safety Directive (TSD).

Case study 1: Coherence of non-aligned Union harmonisation legislation with NLF-aligned legislation

Case Study: Coherence of non-aligned Union legislation with NLF-aligned legislation

Purpose: This short case study aims to illustrate the complexity for manufacturers to comply with Union legislation through examples of industrial products falling under both EU product legislation (for placing product on the market and non-aligned legislation that covers other aspects such as the **putting into service**, **installation or use** of these products.

Background and context: Legislation aligned with the NLF aims to harmonise the condition of placing products on the Union market. Union harmonisation legislation covers a wide range of products, hazards and impacts (e.g. energy consumption), which both overlap and complement each other. Due to product complexity, several pieces of EU product legislation may apply to the same product, besides other pieces of Union legislation that regulate other energy, chemical, environmental, recycling, privacy, or cybersecurity aspects.

For example, as illustrated in the below table, a manufacturer of household appliances should pay attention to between 2 and 4 pieces of NLF-aligned legislation and 5 to 7 other pieces of EU legislation. These can require different conformity assessment procedures, some of them involving a notified body.

EU legislation applicable to household appliances in 2021

Type of products	EU product legislation-NLF	Other Union legislation
All household appliances	RoHS Directive (2011/65/EU)	
		Directive 2009/125/EC on the Ecodesign of energy related products (with all product specific Regulations)
		Regulation (EC) No 1907/2006 (REACH)
All electrical appliances	Low Voltage Directive (LVD) 2014/35/EU	
	Electromagnetic Compatibility (EMC) Directive 2014/30/EU	
		WEEE Directive 2012/19/EU
Consumer and industrial laundry washing or drying machines and dishwashers	Machinery Directive 2006/42/EC	
Kitchen robots		Regulation (EC) No 1935/2004 on Food

Type of products	EU product legislation-NLF	Other Union legislation
		Contact Materials
Appliances for cooking, heating, hot water production, refrigeration, lighting and washing	Regulation (EU) 2016/426 on appliances burning gaseous fuels	
All wireless appliances	Radio Equipment directive RED (2014/53/EU)	
Refrigerating appliances		F-gas Regulation (EU) No 517/2014
Large household appliances		Energy Label Framework Regulation (2017/1369) with all product specific delegated Regulations (supplementing Directive 2010/30/EU)
All Internet connected appliances		General Data Protection Regulation (EU) 2016/679)
Household appliance with medical applications	Medical Devices Regulation (EU) 2017/745	

***Source**: CSES Study and APPLiA*

Besides, additional national provisions may apply regarding the putting into service, installation or use of these products (in compliance with the Treaty, in particular Articles 34 and 36 TFEU), which renders even more complex the range of legal and administrative information obligations for manufacturers. The following paragraphs provide concrete examples of cases where overlaps, gaps and divergence between NLF-aligned legislation and other types of legal requirements impacts on economic operators.

Stakeholder feedback on the Machinery Directive vs. other Union legislation

A good illustration of divergence in the simultaneous application of the NLF and non-harmonised Union legislation occurs for products covered by Directive 2006/42/EC on Machinery (MD) which is almost – but not fully– aligned with the NLF yet, although a new Proposal for the Machinery Regulation to replace the Directive has been put forward (cf. below figure).

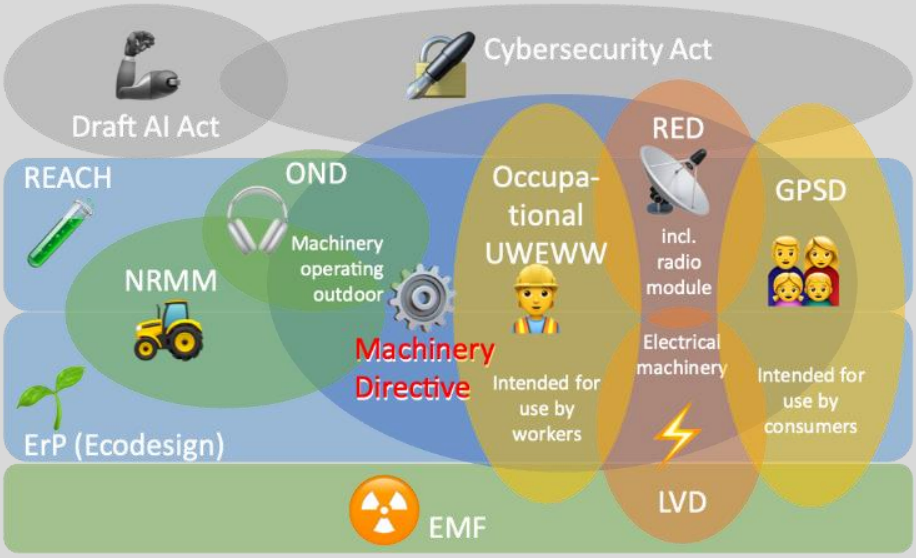

Figure 11 Divergence in the simultaneous application of NLF and non-harmonised Union legislation

Machinery Directive vs. Outdoor Noise Directive (OND): The OND is not harmonised with the NLF. According to a large Italian machinery manufacturer, this results in **duplication of work, inconsistencies, differences in conformity assessment procedures, legal uncertainty regarding terminology and definitions**, etc. According to a European trade association of garden machinery,

there is a mismatch between the concept of risks to users and the environment in the simultaneous application of the OND and the MD; for instance, a circular saw is not regarded as a high-risk machinery and conformity with the essential requirements could be self-declared by the manufacturer (under module A), while the measurement of the noise limits for all types of machines requires the involvement of a notified body. It is expected that new legislation under development will take coherence as the guiding principle.

Machinery Directive vs. Non-Road Mobile Machinery (NRMM): Mobile machinery is indispensable for the proper functioning of the agricultural, construction, municipal equipment, lifting/handling, gardening and forestry sectors. It is subject to the Machinery Directive 2006/42/EC, but also to diverging national safety requirements for the design and manufacturing of such machinery in various Member States. These requirements are particularly demanding in the main manufacturing Member States of mobile machinery (Germany, Italy and France). According to the Industrial Task Force on Non-Road Mobile Machinery (ITF NRMM)[131], companies can spend between 25 % and 50 % of their staff time to produce and maintain the technical files for national homologation purposes, in addition to the costs of additional product markings required for this type of machinery. The assessment of vehicle performance and control, its dimensions and braking requirements, in particular, generate difficulties for the industry that are way beyond the administrative burden and costs required for compliance with the MD. The Commission has however commissioned various studies and a cost-benefit analysis to support a possible future impact assessment to examine ways forward to harmonise the NRMM[132].

Machinery Directive vs. workers' protection: In the Guide to the application of the Machinery Directive (MD)[133], it is explained that Directive 2009/104/EC on the use of work equipment by workers at work (UWEWW) can be considered as a measure complementary to the Machinery Directive: On the one hand, the MD, which is almost aligned with the NLF but not fully requires the manufacturer to design machinery to be inherently safe for their placing on the market, on the other hand, non-harmonised Directive 2009/104 requires the employer to ensure that the same machinery is safe during its lifetime. As reported in the Impact Assessment on the revision of Directive 2006/42/EC on machinery (2020)[134], "if a machine that is compliant is modified later (e.g. by software changes) to now work within different boundaries, then a new risk assessment would be needed". However, when the machine is in use, maintained or possibly upgraded via software updates, there is no consensus to date, including among industry stakeholders, as to whether it is the responsibility of the manufacturer to conduct the risk assessment under the Machinery Directive or up to the employer-user to do it according to Directive 2009/104/EC. This legal uncertainty generates diverging interpretations and costs (See also Chapter 6.3.2 "Impact of the circular economy").

Other stakeholder feedback on NLF external coherence:

NLF vs. environmental legislation: According to a large German trade association "*the obligations for Economic operators under the **Energy-related Products (ErP)** Directive 2009/125/EC (Formerly EuP) are not fully consistent with NLF. The definition of placing on the market in **REACH** is also not consistent with the NLF framework*".

NLF vs. General Product Safety Directive: A consumer association backed by a Competent Authority in Ireland stress that the NLF is not applied coherently with the GPSD, because of diverging definitions "*The proposal for a GPSR, which aligns with Regulation 1020/1019 is an improvement, but not for all aspects*." (See Chapter 5.3.2 on definitions for more details)

Machinery Directive/ NLF vs. Cybersecurity legislation: the Radio Equipment Directive Delegated Act on Article 3.3 (d, e and f), the AI Act, the Cybersecurity Act, the proposal for a NIS 2 Directive and the proposed GPSR provide diverging definitions of cybersecurity features which according to an Italian federation of mechanical products will adversely impact the coherence of the NLF regulatory

[131] https://www.cema-agri.org/index.php?option=com_content&view=article&id=710&catid=21&Itemid=212
[132] European Commission, (2019), Cost-benefit analysis study for impact assessment on road circulation of non-road mobile machinery.
[133] Guide to application of the Machinery Directive 2006/42/EC, Edition 2.2 – 2019 (Update of 2nd Edition)
[134] European Commission, (2020), Impact Assessment report on the revision of Directive 2006/42/EC on machinery (08/2020)

framework and "*cause unnecessary costs and burdens*" to manufacturers.

Radio Equipment Directive (RED) vs. Automotive directives and other legislation: According to the German authority for radio equipment, there is a tendency to apply equal rules for the protection of the radio spectrum to all sectors; "*whereas this might be acceptable for formal requirements, uniformity may adversely impact the technical content of products and equipment for medical, cybersecurity or automotive applications".* For instance, in the latter case, this could cause conflicts of assessments between notified bodies involved, whether notified under the RED or the non-NLF aligned Automotive Directives.

LVD, RED and Medical Devices Directives vs. electromagnetic fields: as stressed by a large manufacturer of medical devices, the protection of users from electromagnetic fields (EMF) is referred to in several pieces of NLF-aligned legislation, especially in the Low Voltage Directive, the Radio Equipment Directive and the Medical Devices Directives. Besides, either Directive 2013/35/EU on the minimum health and safety requirements regarding the exposure of workers to the risks arising from EMF or the Council recommendation on the limitation of exposure of the general public to EMF apply. The alignment with the NLF was suggested alongside EURATOM/EU Basic Safety Standards on Radiation protection.

All these examples show how whilst core pieces of EU product legislation have been NLF-aligned, there is a lack of external coherence between the NLF and other types of legislation in some cases. This increases compliance and enforcement costs for economic operators, notified bodies and market surveillance authorities. In addition, differences in the combined implementation of EU legislation between Member States could prevent the full potential of a well-functioning internal market from being achieved.

Case study 2: Accreditation process

Case study: Accreditation process

Purpose: Illustrate the weaknesses in the accreditation framework and their impacts through an examination of the accreditation process and its complexity.

Background and context: Regulation (EC) No 765/2008 established a European accreditation system and ensured the mutual recognition of test reports and certificates issued by accredited notified bodies. In summary, the Regulation establishes *inter alia*:

- Principles of the accreditation framework (Art. 4), including that Member States shall appoint a single national accreditation body (NAB) and the principle of non-competition (Art. 6).
- Rules for the operation of accreditation activities (Art. 5), including rules on evaluating, certifying, and monitoring conformity assessment bodies (CABs), and on cross-border accreditation (Art. 7).
- Requirements for NABs (Art. 8), covering, amongst others, independence, impartiality, confidentiality, and the identification of areas of competence, as well as the need for sufficient competent persons and internal controls.
- Rules for the peer evaluation of NABs (Art. 10).

The accreditation framework is a key part of the European conformity assessment system alongside the suite of conformity assessment modules, the rules on notification of conformity assessment bodies relying on the system of harmonised standards cited in the *Official Journal of the EU* (OJEU).

As stipulated in Article 11 of Regulation (EC) No 765/2008, NABs are presumed to fulfil the relevant requirements summarised above if they have undergone peer evaluation and demonstrated conformity with the criteria laid down in the relevant harmonised standard

published in the OJEU. In this respect, EN ISO/IEC 17011:2017 is the relevant harmonised standard against which national accreditation bodies are assessed.

Similarly, as per Article R18 of Annex I to Decision No 768/2008/EC, NBs can use the relevant harmonised standards referenced in the OJEU to obtain presumption of conformity with the requirements for NBs provided for in NLF-aligned legislation (based on Article R17).

Accreditation cycle: In line with Regulation (EC) No 765/2008, EN ISO/IEC 17011:2017 details requirements for the "accreditation process but also the structure of the NAB, the impartiality and competence of a NAB, the management and internal controls, procedures, subcontracting, appeals and complaints"[135]. An outline of the overarching accreditation cycle is illustrated in the below figure. The main steps of the process, described based on EN ISO/IEC 17011 and detail from the Italian accreditation body (Accredia), include:

- **Application for accreditation**: CABs must submit an application for accreditation that: i) clearly specifies the activities required by the CAB; and ii) provides key pre-defined documentation, including a copy of management systems.
- **Resource review and assessment preparation**: The NAB will conduct an initial review of the application to check for adequacy. In this context, the NAB will examine its own ability to carry out the assessment to a sufficient level of quality and in a timely manner, considering its own policies, competence and availability of suitable personnel. If the outcome of this initial review is positive, a cost estimate for the accreditation services will be provided to the CAB.[136]

  Subsequently, the NAB will start preparations for the assessment of the CAB. This includes: i) the appointment of an assessment team comprising a lead assessor, assessors and/or experts; ii) establishing procedure for sampling where the scope of the assessment covers multiple conformity assessment services. A preliminary visit to the CAB may also be conducted at this stage.
- **Initial assessment**: Within the context of the initial assessment, the NAB will conduct a thorough review and analysis of the documents provided with the aim of assessing the conformity of the CABs activities against the applicable requirements. Upon completion of this review, an on-site assessment is performed, aiming to determine whether the applicant's modalities are in line with the requirements, technical regulations, standards, and procedures defined by the CAB in its formalised management system documentation. A report is written summarising the findings of the on-site assessment. If critical challenges or non-conformities have been identified, the NAB may conduct further assessments or stop the accreditation process.

  When accrediting CABs for certain conformity assessment activities (i.e. certification, inspection and verification), a witness visit takes place after a successful on-site visit. Witness visits take place at a public or private client of the CAB. As for the on-site visit, a follow-up report will be developed and further actions taken based on the findings.

  On the basis of these initial activities, a first decision for accreditation will be taken by

[135] European Commission, (2022), Guidance Document: The Accreditation and Verification Regulation – Relation between the AVR and EN ISO/IEC 17011.
[136] Accredia, (2022), The path to accreditation, accessed via the website of ACCREDIA (the Italian accreditation body) on 16 March 2022.

the NAB. In the case of Accredia, an internal Sector Accreditation Committee with expertise and responsibility for the relevant conformity assessment sector will evaluate the evidence from the assessment activities and take a decision. If positive, an agreement between Accredia and the CAB is signed and the accreditation certificate is issued. In addition, the name of the CAB is then published in Accredia's online databanks.

The key output of the initial assessment is an accredited CAB with a clear scope, and comprehensive records of the CAB and the accreditation assessment.

In Italy, accreditation has a validity period of four years. However, setting the length of the validity period is the responsibility of the Member States and therefore differs across the EU. EA notes that the accreditation cycle can cover 2-5 years.[137]

- **Surveillance**: Over the accreditation cycle, the NAB will undertake period surveillance assessments of the activities of accredited CABs. The purpose of these assessments is to check the maintenance of compliance requirements, including CAB competence, independence, impartiality, and conformity with standards. Concerning the frequency of surveillance assessments, the Polish NAB noted that for a typical accreditation in the field of the Construction Products Regulation, three surveillance visits would be conducted over the four-year cycle.
- **Reassessment**: Before the expiration of each accreditation cycle, the accredited CAB can initiate the accreditation renewal process, which will follow the same process as the initial accreditation. In addition, accredited CABs can apply for an extension of accreditation to new activities and locations within the context of an existing accreditation or the renewal process.

However, there are a range of application challenges within this process that stem from the NLF legal texts and their implementation. These challenges are examined below.

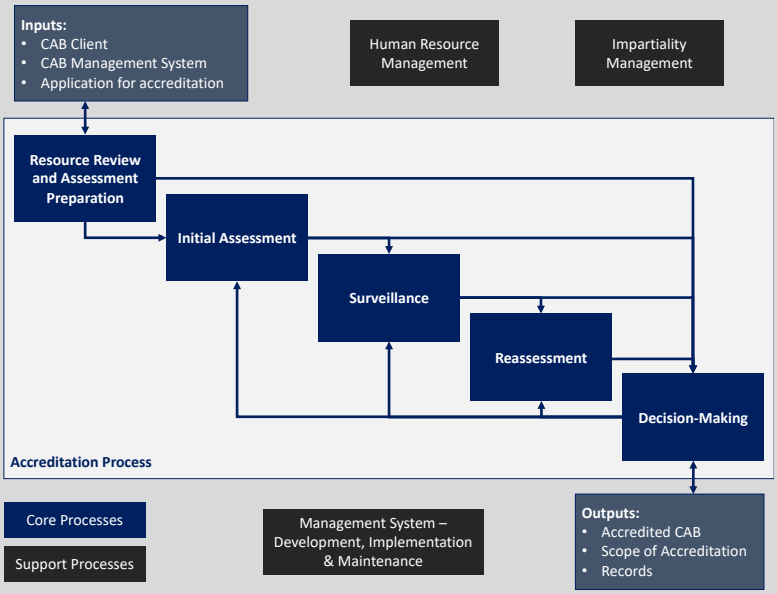

Figure 12 Illustration of a typical accreditation process

Source: CSES, adapted from IAQG, (2015), Presentation on Oversight Assessment of Accreditation Bodies – Overview from ISO/IEC 17011.

[137] European Accreditation (EA), (2018), Accreditation: A tool to support regulators.

Analysis and stakeholder feedback: Although the approach to the process of accreditation is well understood and established through Regulation (EC) No 768/2008 and EN ISO/IEC 17011, stakeholders have highlighted related challenges that can impact the effectiveness and efficiency of the accreditation framework and the wider conformity assessment system.

The first **challenge relates to the practice of accreditation for the purposes of notification** and results from the interplay between the following elements:

i) Definition of accreditation in Regulation (EC) No 765/2008, which includes a general reference to "harmonised standards and where applicable additional requirements".

In Regulation (EC) No 765/2008 accreditation is defined as follows: *an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity*".

The definition refers to harmonised standards without specifying them. EA has issued a policy document EA-2/17 M: 2020" with a focus on accreditation "as a tool to support notification of CABs in the framework of Union harmonisation legislation elaborated according to the provisions of Decision No 768/2008/EC". However, certification bodies are of the opinion, that accreditation of CABs cannot be reduced to notification purposes only, as provided in the harmonised standard EN ISO/IEC 17065:2012 on "*Conformity assessment — Requirements for bodies certifying products, processes and services*". For example, the German Federal Maritime and Hydrographic Agency (BSH), as a notifying authority, provides the example of the Marine Equipment Directive (MED) 2014/90/EU. According to its ANNEX III, which prescribes the requirements for notified bodies, the condition to comply with EN ISO/IEC 17065:2012 is one of the 19 requirements for notified bodies defined in that legislation. Stakeholders consider that this can lead to a situation where member State have different interpretations of the different criteria for accreditation, as for example the objection period for notification[138].

Certification bodies have expressed concerns regarding varying interpretations of the definition of 'accreditation' across the Member States. The definition states that conformity assessment should be based on harmonised standards without specifying to what depth the applicable harmonised standards should be developed. This leaves room for ambiguity and, as experience shows, varying interpretations by both national accreditation bodies and notifying authorities that set different criteria and implementation procedures from one Member State to another.

According to CABs, this situation may distort the EU level playing field between conformity assessment bodies with consequences for economic operators. More specifically, certifiers and economic operators point at different levels of competence among notified bodies that allow rogue operators to 'forum shop' and have their products certified by less competent bodies. Most of the CABs are of the opinion that this situation can hamper the eventual level of safety of products on the market, especially for risks arising from connected or refurbished products, and thus contribute to reducing trust in certified products, which is damaging for the business of conformity assessment services.

ii) Descriptions of conformity assessment activities and procedures in the suite of conformity assessment modules and aligned EU product legislation, which often use general instructions for notified bodies such as 'carry out appropriate examinations and tests' in accordance with the relevant harmonised standards for the product being examined.

[138] Sometimes authorities do not agree that another authority assessed the conformity assessment body against EN 17025 instead of EN 17065. They consider that in such cases the notification should be submitted as the COB has not been accredited and an objection period of 2 months instead of 2 weeks should apply.

iii) Harmonised standards related to conformity assessment, which detail requirements for different types of conformity assessment bodies. As illustrated below, there are many different types of bodies, aligned to different activities, with specific harmonised standards.

Figure 13 Types of bodies with specific harmonised standards

Source: European Accreditation (EA), (2018), Accreditation: A tool to support regulators.

While recognising that Regulation (EC) No 765/2008 is clear that NABs shall use harmonised standards in assessments for accreditation, EA summarised the challenge stemming from these elements as follows: "the conformity assessment activities described in the modules defined in Decision (EC) 768/2008 or conformity assessment procedures defined in other EU product legislation are not described in a way which fits exactly with the description in the [harmonised standards] (i.e. testing, inspection and certification), and each module does not identify the [harmonised standards] to be used for its conformity assessment activities"[139].

As such, individual NABs across the single market are free to determine the harmonised standard(s) against which CABs will be assessed for accreditation for the purposes of notification under specific pieces of EU product legislation. Stakeholders across NABs and CABs noted that, in turn, this has resulted in **divergent accreditation requirements for the purposes of notification across the EU**.

EA has taken steps to address this challenge, most prominently through document EA-2/17. Through this document, EA presented a thorough mapping of the requirements across pieces of EU product legislation and the suite of conformity assessment modules with the different harmonised standards for conformity assessment. The main outputs were tables presenting:

- Preferred alignment of harmonised standards per module and per legislation for aligned Directives and Regulations.
- Preferred harmonised standards for non-aligned Directives and Regulations and conformity assessment activities (e.g. under the PED, the CPR and the IVDMD).

An extract of the first alignment table, for Modules A1, A2, B and C, is presented below. Although complexities still exist, as reflected by the 'Exceptions' column and the different 'Preferred Standard' for different pieces of legislation under module C, a preferred approach for harmonised accreditation is clearly stated.

[139] European Accreditation (EA), (2020), EA Document on Accreditation for Notification Purposes, EA-2/17 M:2020.

Module		Other references equivalent to this module	Preferred Standard	Exceptions
A1	Internal production control plus supervised product testing		ISO/IEC 17020	
A2	Internal production control plus supervised product checks at random intervals		ISO/IEC 17020	Measuring Instruments Directive No 2014/32/EU: ISO/IEC 17065
B	EU Type Examination	Machinery Directive No 2006/42 EC- Annex IX; In vitro diagnostic medical devices (IVDMD) Directive No 98/79/EC Annex V; Active implantable medical devices (AIMD) Directive No 90/385/EEC Annex III;	ISO/IEC 17065	
C	Conformity to EU-type based on internal production control		ISO/IEC 17020 (SPV) ISO/IEC 17065 (HWB)	Module C does not require a NB with the exception of: Simple Pressure Vessels Directive No. 2014/29/EU (SPV) Hot-Water Boilers Directive No. 92/42/EEC (HWB)

Source: EA, (2020), EA Document on Accreditation for Notification Purposes, EA-2/17 M: 2020.

However, NAB and CAB stakeholders have highlighted that, as this is not implemented in a uniform manner and divergence in this respect still exists across the EU.

Other challenges highlighted by NAB and CAB stakeholders include:

- Although the Blue Guide contains clarifications on 'multi-site accreditation' and subcontracting, the relevant harmonised standards for conformity assessment activities take different approaches to outsourcing. For instance, EN ISO/IEC 17065 allows test reports from US, Chinese and Australian laboratories, but EN ISO/IEC 17025 does not permit systematic outsourcing. In this complex landscape, **NABs are unable to directly assess any CAB subsidiaries or facilities when outside their country of operation**, making it difficult to ensure the competence of such subsidiaries. In this respect, some NABs have taken steps to address this challenge; in Spain, for instance, ENAC has developed and implemented their own requirements to ensure all the necessary skills for conducting the relevant conformity assessment services are permanently available in Spain.
- CABs have highlighted the introduction of **additional national level requirements** for accreditation beyond those detailed in the relevant Union harmonisation legislation or harmonised standards for conformity assessment. For example, it was highlighted that a German authority requires notified bodies providing conformity assessment services in the field of protective equipment against non-ionizing radiation to have a laboratory with appropriate own competency or an exclusive contract with a competent laboratory. As a result, a German notified body was not able to provide such a service because they could not agree on exclusivity with a competent laboratory.

These challenges, in combination, can lead to a range of **negative impacts** on individual businesses and on the functioning of the single market. More specifically, NAB and CAB stakeholders highlighted that the lack of harmonised requirements and practices across the single market can lead to certain CABs achieving accreditation at a reduced cost on the basis of less stringent or less costly accreditation processes in some countries compared with others.

Furthermore, when permitted by certain countries, the challenge related to the use of subsidiaries –for instance, when taken to the extreme of establishing a mere letterbox company in the EU and conducting all real activity outside the EU – raises questions related to the EU's strategic autonomy regarding compliance with the NLF. This can also exacerbate the challenge of unfair competition if such

subsidiaries can deliver the same conformity assessment services at a much lower cost.

In combination, these competitiveness impacts can undermine the trustworthiness of conformity assessment services and certificates, as well as trust in the compliance of products placed on the single market.

Costs related to the accreditation of conformity assessment bodies

Examination fee to an accreditation body: Examination fees vary significantly, depending on the number and types of legislation covered, the conformity assessment module(s) to be accredited against, the staff size[140] and number of locations of the organisation under assessment, and whether the examination has a quick positive outcome or requires multiple assessments because of initial failure to pass the examination. Country-specific differences emerge.[141] While daily fees are made publicly available by accreditation bodies, duration and frequency are generally kept confidential, contributing to a lack of harmonisation in examination practices across Europe. In addition to fees, it is also necessary to consider costs for travelling, for internal consultations as well as consultations with third parties, or for the involvement of other authorities, if necessary.

Anecdotal evidence of examination costs is provided:

- Evidence from Spain suggests that, for a small CAB (with a staff size of 2-3 employees) covering one module, the assessment will require around 4-5 days of work, with a cost of about 8,000 Euro.
- In the area of Personal Protective Equipment (PPE), in Italy, a notified body reported paying for an in site and on file examination fee of around 4,000-5,000 Euro for each Directive / Regulation.
- A Spanish certification body, mainly active in the area of RED and EMCD, reported a cost of around 7,000 Euro for a new scheme accreditation, including for CE marking.
- A German CAB estimated a typical cost of 15,000-20,000 Euro per accreditation corresponding to the average procedure and scope. However, cases of less complex accreditations (10,000 Euro), as well as more elaborate ones (50,000-100,000 Euro) were also mentioned, illustrating the potential differences in scale across accreditation exercises.

Annual fee to an accreditation body (continuous monitoring costs, or maintenance fee): The differences in cost of accreditation bodies (borne by accredited bodies) depend (as for examination fees) on the number and type of legislations covered and are also linked with the different living standards and price levels of EU countries. Not all accreditation bodies foresee an annual maintenance fee. Among those who do, there are the Italian body (maintenance fee calculated as a share of turnover) and the Latvian body (annual fee of 425 Euro). In Slovenia, a maintenance fee is charged at each surveillance visit (either on 12 or 15 months). However, the Hungarian NAB is an example of an accreditation body that does not foresee maintenance fees.

Cost of developing and maintaining a quality management system: Large organisations typically already have a quality management system with established procedures in place, and already have a quality manager dealing with it, irrespective of the accreditation needs.

[140] For example, according to the Lifts Directive evaluation, the average cost for accreditation increases with size: from 625 Euro for micro notified bodies (1% of annual turnover) to 3,800 Euro for medium and large notified bodies (0.01% of annual turnover).

[141] For example, the fee per hour of an assessor at the German accreditation body is 120 Euro, while the hourly fee of an assessor at the Italian accreditation body's Department of calibration Laboratories is 96.25 Euro.

As such, this cost is not necessarily borne by newly accredited bodies. The development of operative instructions for a quality management system is estimated to require at least 3 months.

Insurance fee (in most cases): For instance, some of the Spanish requirements foresee that conformity assessment bodies shall have a civil liability insurance of 300,000 Euro (RED) / 1,200,000 Euro (EMCD, CPR) or a bank guarantee for that amount. According to feedback from a Spanish notified body, this liability is very specific and usually not covered in general insurance contracts. Therefore, even if the company already has an insurance contract, certification liability must be additionally subscribed. No figures about the insurance fees could however be provided.

Should accreditation become mandatory and why?

Stakeholder views on the question of whether and how accreditation should become mandatory are presented and discussed in the following box.

Certification stakeholders highlighted that the notification system is not harmonised at EU level, and as such does not impose accreditation as a prerequisite, leaving room for varying implementation procedures.

Both consumer associations and industry associations interviewed have suggested that accreditation should become mandatory to create a true level playing field for notified bodies, based on competence. The primary goal of mandatory accreditation, according to these stakeholders, would be to ensure that all notified bodies are certified to the same minimum level of competence, thereby providing a consistent service of a known quality to economic operators across the EU. One NAB respondent noted that accreditation is essential for this purpose.

However, there are a range of challenges related with mandatory accreditation that stakeholders have highlighted. Some notification authorities, for instance, noted that when an organisation which is not notified wishes to become an accredited CAB, it can be difficult for it to achieve this accreditation. In some Member States only notified conformity assessment bodies may apply for accreditation. For instance, in Slovenia, the accreditation body does not accredit conformity assessment bodies without evaluating their product assessment process (as set out in relevant product legislation); however, the would-be-notified-body is not able to make such a demonstration since it is not notified. In such case, as some of the stakeholders highlight, notifying the conformity assessment bodies without accreditation makes sense, but only for a certain period of time.

Another national notifying authority responsible for the Marine Equipment Directive noted that it notifies CABs without accreditation due to the significant amount of time it takes to complete this process and the associated costs. This authority stated that, for the most recent instance of accreditation, the process took nearly five years. Compared with around 6 months for the quickest notification process, this represents a significant additional burden for CABs.

For notified bodies, it is less a problem of diverging rules, than a problem of absence of effectiveness in the harmonised application and uniform enforcement of those rules by national notifying authorities and accreditation bodies. Notified bodies interviewed believe that one solution to this challenge could be peer assessment among notified bodies. Mixed Assessment Teams, including a Technical Assessor from an active foreign notified body, accompanying the local Member State assessing / authorising body could help align and ensure the quality of the approaches across the EU, as well as support the effective exchange of information.

According to notified bodies, mandatory accreditation is not considered the optimal solution, but could help ensure the best possible alignment in the notification processes and competencies of the assessing body (accreditation body) to be somewhat aligned through peer assessment and with that, ensure a level playing field in terms of requirements put on the Notified Bodies. Some notifying authorities also have reservations about the need for mandatory accreditation for all CABs because of its cost, which many small entrants to the conformity assessment market cannot afford.

EA, however, suggests that the peer evaluation system could be rejuvenated either by appointing an agency within the Commission, or a service of the European Commission that would perform the peer evaluation of accreditation bodies in an independent and objective way. It seems reasonable to the EA that each accreditation body could detach one staff for two years to contribute with expertise to such task.

Case study 3: Assessment of NLF-related costs and benefits under certain NLF-aligned legislation (EMCD)

Case study: Assessment of NLF-related costs and benefits under the EMCD

Background and context: The European Commission has recently published an evaluation of the NLF-aligned Electromagnetic Compatibility Directive No 2014/30/EU (EMCD).[142] In this case study, the costs and benefits generated by the EMCD are mapped and assessed. The assessment of the EMCD was mainly based on a critical analysis of replies to online stakeholder consultations, enriched with anecdotal evidence and illustrative figures whenever available.

The below tables list the costs and benefits identified in the EMCD evaluation (structured based on the categories set out in the European Commission's Better Regulation Toolbox, which distinguishes between direct costs, enforcement costs and indirect costs, and between direct and indirect benefits) and for each of them, offers considerations on whether it can be attributed to the NLF.

Stakeholder feedback and other evidence: The results of the EMCD evaluation (although no monetisation of the costs and benefits was acknowledged to be possible) suggest that **the benefits generated by the EMCD are considerably higher than its costs**.

Within this overarching context, **EMC-relevant costs of product development** and **costs related to the conformity assessment to produce the technical file** were the types of costs most frequently identified as costly by consulted stakeholders. Although significant, the other costs were less frequently deemed to be high, according to the results of the evaluation's surveys.

According to the EMCD evaluation, EMCD-compliance costs are in a range between 5 and 15% of the total cost of production. Moreover, the impact of the EMCD in percentage terms does not significantly change depending on how much the cost of production of the selected product amounts to in absolute terms. Despite this relatively high share, according to the evaluation analysis, the **benefits generated by the Directive clearly outweigh its costs.**

Out of the EMCD costs, as noted above, those that were identified as most costly were i) **EMC-relevant costs of product development** and ii) **costs related to the conformity assessment to produce the technical file.** In the first case, the cost can be attributed to the NLF only to a very limited extent. For instance, one contributing aspect is that although the framework for and incentives to use harmonised standards to achieve a presumption of conformity are established in the NLF, the standards are highly specific to the area of EMC and are paid-for, rather than freely available (as is the case for the RED). In addition, costs such as EMC-related engineering costs and pre-testing costs are exclusively business as usual costs that are not related to the NLF. See the below tables for more detail.

In the second case (costs related to conformity assessment), the costs can be partially attributed to the

[142] CSES (2021). Study on the Evaluation of the Electromagnetic Compatibility Directive 2014/30/EU (EMCD).

NLF, as they stem from the integration of NLF rules in the EMCD. These costs include preparing technical documentation, performing laboratory tests and potentially using a notified body. However, in a hypothetical scenario without the NLF, the EMCD would probably still contain a conformity assessment procedure, with less similarities with the conformity assessment provided in other product legislation. Moreover, costs of familiarisation with the procedures would likely be higher in the absence of the NLF model of conformity assessment procedures, due to lack of harmonisation: in fact, although conformity assessment costs are NLF-related, the NLF actually brings about cost savings compared to a scenario without NLF.

Considering conformity assessment costs, and the other, less burdensome costs, the share of NLF-related costs generated by the EMCD can be estimated to be significantly **lower than 5-15% of total cost of production,** for products falling under the EMCD scope.

Similarly, many of the EMCD-specific **benefits** are primarily the result of EMCD provisions, such as the technical benefits of reduced incidence of electromagnetic disturbance resulting from the essential requirements. However, some benefits, such as increased market efficiency and improved industrial competitiveness can be attributed to some extent to the NLF.

Although the EMCD costs attributed to some extent to the NLF are more than its benefits, their scale, based on stakeholder feedback, is strongly pending towards benefits, which are more strategic and wide-ranging than punctual costs generated upfront.

Costs generated by the EMCD and relationship with NLF

Type of cost	Name of cost	Relationship with NLF
Direct costs	**Cost of product development (EMC relevant)**: a) Cost of purchasing the relevant standard b) Cost of engineering (i.e. the cost of addressing EMC-relevant aspects) c) Cost of pre-testing d) Cost of risk assessment	a) The cost of purchasing standards (which varies depending on the product, ranging from 1,000 to 15,000 EUR) can be **only partially attributed to the NLF**. Under the EMCD, harmonised standards are paid for, due to the active role of CEN-CENELEC and industry, whereas under the RED, standards are developed by ETSI, and are freely downloadable. CENELEC seeks to base EMC standards closely on the international standards of CISPR and the IEC, which can generate some cost savings in having EN standards as closely aligned with international EMC standards as possible. b) EMC-related engineering costs are **not related to the NLF** (business-as-usual cost). c) Pre-testing costs are **not related to the NLF** (business-as-usual cost). d) Risk assessment costs can be **partially attributed to the NLF**. However, the EMCD evaluation noted that risk assessments on EMC are conducted very rarely, if ever
	Cost of conformity assessment to produce the technical file: a) Documentation b) Cost of laboratory tests (internally / third party) c) Involvement of a notified body	a) The cost of preparing the technical documentation as part of the conformity assessment procedure can be **attributed to the NLF**. b) The cost of performing laboratory tests (either internally or through a third-party laboratory) as part of the conformity assessment procedure can be **partially attributed to the NLF**. c) The cost of involving a notified body as part of the conformity assessment procedure (when applicable) can be **attributed to the NLF**.

Type of cost	Name of cost	Relationship with NLF
	Compliance costs during the production process: a) EMC-relevant measures (e.g. shielding) b) Including information to the user c) Markings (traceability, identification, CE marking) d) Ensuring that the manufacturing process and its monitoring are compliant with the technical documentation	a) EMC-relevant measures are **not related to the NLF** (business-as-usual costs). b) Can be **attributed to the NLF**. c) Can be **attributed to the NLF**. d) Can be **partially attributed to the NLF**.
	Cost of familiarisation with the legal framework	Can be **partially attributed to the NLF**. Importantly, the NLF generates cost savings compared to a situation characterised by a lack of harmonisation.
	Cost of keeping technical documentation for 10 years	Can be **attributed to the NLF**.
	Cost of authorised representative	Can be **attributed to the NLF**.
Enforcement costs	**Enforcement costs**: a) Enforcement costs (for authorities) b) Enforcement costs (for manufacturers)	Can be **partially attributed to the NLF**.

Source: *CSES Study.*

Benefits generated by the EMCD and relationship with the NLF

Type of benefit	Name of benefit	Relationship with NLF
Direct benefits	**Technical benefits:** a) Reduction of the incidence of electromagnetic disturbance leading to incorrect functioning of electrical equipment b) Regulation of application of good engineering practices for fixed installations c) Improvement of harmonised standards relating to EMC d) Increased electromagnetic immunity	Can be **partially attributed to the NLF**.
Indirect benefits	Market efficiency	Can be **partially attributed to the NLF**.
	Industrial competitiveness (EU vs Third countries)	Can be **partially attributed to the NLF**.

Source: *CSES Study.*

Case study 4: Assessment of NLF-related costs and benefits under certain NLF-aligned legislation (Toy Safety Directive)

Case study: Assessment of NLF-related costs and benefits under the TSD

Background and context: The 2020 evaluation of the Toy Safety Directive (TSD)[143] aimed to assess the performance of the Directive since its entry into force in relation to its two objectives of (1) ensuring a high level of safety of toys with a view to ensuring the health and safety of children, and of (2) guaranteeing the functioning of the internal market for toys.

The below tables list the costs and benefits identified in the TSD evaluation and for each of them, offers considerations on whether it can be attributed to the NLF.

Stakeholder feedback and other evidence: The evaluation quantified costs generated by the TSD to a certain extent, while benefits could not be quantified. Stakeholder response however pointed to benefits outweighing costs.

According to the evaluation, complying with the TSD caused **one-off costs** to economic operators, in particular manufacturers, due to the many new requirements. These one-off costs were reported to be between 1% and 3% of turnover. The ongoing costs for producing toys were considered to be higher than under the previous Directive, due to the higher number of requirements to be met. In monetary terms the median value of this one-off cost amounted to an average of € 17 million per large firm and € 110,000 per SME. This meant an average of € 150,000 per toy type produced by a large firm and € 12,000 per toy type produced by a SME. This one-off cost was on average recovered over 2 years and 10 months (3 years in case of SMEs). Using Eurostat data on turnover and number of companies, the one-off cost for the whole toy manufacturing industry amounted to between € 140 million and € 200 million.

On the other hand, costs did not prevent several hundred companies from entering the market, increasing the total number of companies by some 10% between 2013 and 2017 and the TSD did not hinder the cost competitiveness of the toy industry. Furthermore, according to the evaluation, manufacturers are only exceptionally required to request the intervention of a third party (notified body), namely when producing novel toys that have hazardous features not covered by the existing toy safety standards, the references of which have been published in the Official Journal.

Costs generated by the TSD and relationship with NLF

Type of cost	Name of cost	Relationship with NLF
Direct costs	One-off costs for adapting to the TSD	One-off adaptation costs are **not related to the NLF**, as they stem from the increased number of detailed safety requirements for toys, in particular on chemicals.
	Recurring costs for manufacturers (production costs)	Recurring production costs increase are **not related to the NLF**, as they stem from new requirements of the TSD on chemicals, an increase in the cost of materials, fixed costs, salaries, energy and transport cost.
	Time spent by manufacturers, importers and distributors to comply with the Directive's requirements when developing a toy.	Time resources spent to ensure compliance with the TSD can be **partially attributed to the NLF** (e.g. as regards testing and documentation and safety aspects).
	Preparing and updating technical documentation (safety assessment, conformity assessment documents	As defined in the evaluation, the cost related to technical documentation can be **partially attributed to the NLF**.

[143] European Commission, SWD(2020) 287 final.

Type of cost	Name of cost	Relationship with NLF
	and supply chain information, translation of product documentation).	
	Other costs borne by manufacturers: a) Purchasing standards. b) Testing of raw materials and testing of toys.	a) The cost of standard can be only **partially attributed to the NLF**. b) Testing costs can be only **partially attributed to the NLF**.
Enforcement costs	Enforcement costs borne by public authorities	Can be **partially attributed to the NLF.**

Source: *CSES Study.*

Benefits generated by the TSD and relationship with the NLF

Type of benefit	Name of benefit	Relationship with NLF
Direct benefits	Safety	Can be **partially attributed to the NLF.**
Indirect benefits	Reduced legal uncertainty	Can be **attributed to the NLF**.
	Level playing field in the internal market	Can be **partially attributed to the NLF.**

Source: *CSES Study.*

ANNEX IX. RAPEX – SAFETY GATE DATABASE – ANALYSIS OF THE SAFETY GATE DATA

The RAPEX-Safety Gate system, is the EU's rapid alert system for sharing information between national authorities on dangerous non-food products. The system operates as follows:

- When a national authority in an EU Member State or EEA/EFTA country discovers a dangerous product on the market, it submits an alert to Safety Gate. Each alert contains a wide range of information, including the type of product, a description of the risk, the country of origin and the measures ordered by the authority or taken by the economic operator.
- All other authorities are required to follow up on each alert and share any information on the presence of the dangerous product on their own market.

This Annex provides an overview of the key methodological considerations before presenting an analysis of the data contained in the Safety Gate alerts covering the period 2005-2021.

Methodological considerations

This analysis aims to support the evaluation of certain aspects of the NLF by providing **contextual descriptive statistics on trends related to the detection of unsafe products that are subject to NLF-aligned legislation** across the internal market.

The Safety Gate data was provided to the evaluation team in the form of an Excel spreadsheet by the European Commission (DG GROW). The evaluation team prepared and cleaned the data before conducting an exploratory analysis and reporting the results. A key activity undertaken in the data preparation phase, in collaboration with DG GROW, was the development of a mechanism for linking the Safety Gate data to the NLF.

As Safety Gate contains a wide variety of different information (up to 28 data fields for more than 30,000 alerts across 17 years), it was important to consider the relevance and utility of the data to the evaluation and work to maximise these elements through the analysis. Most prominently, the utility of the analysis relied on the ability to link Safety Gate alerts to specific pieces of NLF-aligned legislation. The following two data points were useful in this regard, but came with challenges:

i) **Product categories**: Each year from 2005-2018, between 25 and 29 product categories were used in Safety Gate; this figure increased in 2019 (31), 2020 (37) and 2021 (41). Although some of these categories have strong links to specific pieces of NLF-aligned legislation (e.g. 'Toys' with the Toy Safety Directive and 'Protective equipment' with the PPE Regulation), many are not closely aligned to the legislation that sets the rules and requirements that ultimately define whether a product is safe. For instance, categories such as 'Gadgets' and 'Hobby/sports equipment' have no clear link to specific pieces of legislation.

ii) **Risk / Risk legal provision**: In many cases, reference to the specific piece of EU legislation with which a product is non-compliant is flagged within the 'Risk' (from 2005-2010) and 'Risk legal provision' (from 2011-2021) data fields. However, these fields are qualitative in nature, as they also contain a description of the risk identified. Given the lack of pre-determined options, it is therefore not clear whether the relevant legislation has been flagged in all alerts.

On this basis, the evaluation team identified all instances where non-compliance with one or more NLF-aligned legislation was specifically indicated in the 'Risk' or 'Risk legal provision' data fields. A new column was created to record these links and a total of 10,788 alerts (35% of all alerts) were positively identified as being linked to NLF-aligned legislation. Additional complexity is added by the fact that non-compliance with more than one legislation is referenced in some alerts.

As for the evaluation, the primary **scope** of the analysis is the period 2014-2021. However, contextual data from 2005-2013 will also be included where useful, in particular to examine the impact of NLF-related legislative changes prior to 2014. Throughout the examined period, different pieces of legislation were aligned to the NLF at different times; this has been factored into the analysis.

Beyond the above challenges, it is important to note the **impact of external factors** on the Safety Gate data. Over the period under examination, for instance:

- Product markets have experienced significant changes, including the growth of e-commerce and the increased presence of products from third countries (and China, in particular) on the internal market. As will be seen, more than 16,000 products originating in China have been reported through Safety Gate in the period 2005-2021; this is six times more than the second most common country of origin, which is the combined 'Unknown' category (2,757 alerts).
- Roles, responsibilities and practices of market surveillance authorities (MSAs) have changed over this period, and differences exist in the practices and resources of MSAs across EU Member States and EEA/EFTA countries, as clearly reported in the impact assessment study of the proposed Goods Package from 2013[144]. These factors strongly influence both the number of unsafe products identified and reported via Safety Gate, and their proportion by product category from one Member State to another.

These external factors, as well as others, **significantly restrict the ability of the analysis to attribute or link any product safety trends identified to the NLF**. As a result, this analysis will focus on providing contextual descriptive statistics, highlighting this caveat where relevant.

Analysis of all NLF-related alerts

In total, 30,532 product alerts have been reported via Safety Gate in the period 2005-2021, with 16,765 alerts in the period 2014-2021. A total of 10,788 of these alerts are directly linked to NLF-aligned or their predecessor legislation; 6,183 in the period 2014-2021 (37% of alerts in this period). As illustrated in the below figure, both the annual number of alerts and the annual number of NLF-related alerts have stayed relatively consistent in the period 2014-2021. The number of unsafe products reported via Safety Gate has increased significantly in the period 2005-2014, rising from 713 in 2005 to 2,268 in 2014; however, the number of NLF-related alerts did not change as significantly.

[144] SWD(2013) 33 final of 13.2.2013, Commission staff document on an impact assessment accompanying the document "Product Safety and Market Surveillance Package"

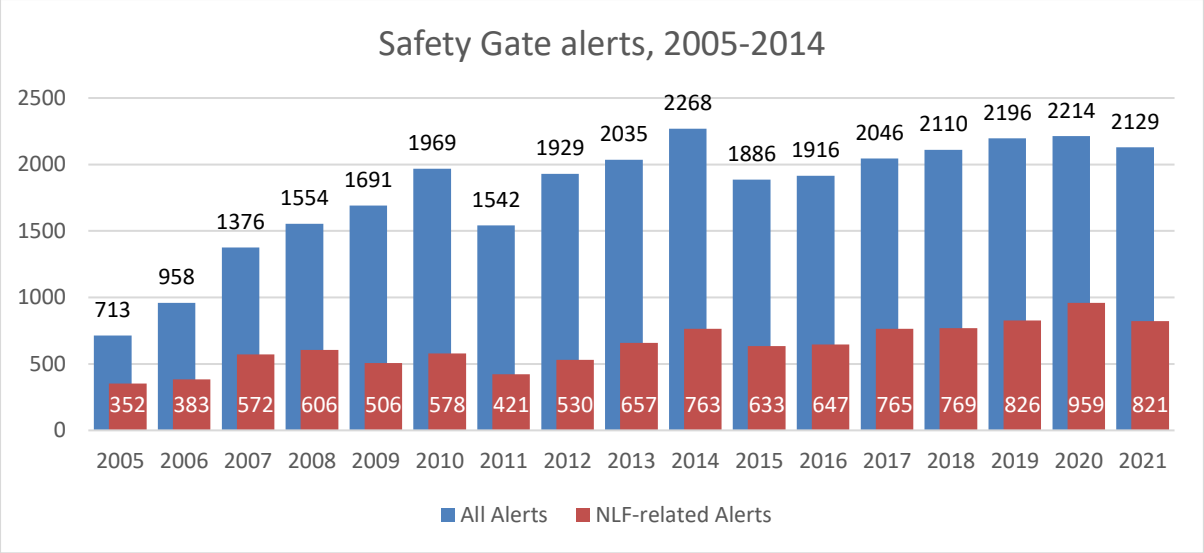

Figure 14 Total number of Safety Gate alerts and NLF-related alerts, 2005-2021

For each NLF-related alert, the **reporting national authority** and the product's **country of origin** are also recorded. As illustrated in the below map, the countries that most commonly report products with clear reference to NLF-aligned legislation or its predecessor legislations in the period 2005-2021 are Hungary (1,392, 12.9%), Spain (1,262, 11.7%), the UK (884, 8.2%) and France (875, 8.1%).

Considering differences between the 2005-2013 and 2014-2021 periods, changes in the reporting practices of certain countries are notable. For some countries, the number of alerts submitted has increased considerably over the time period; one reason for this could be the time taken for MSAs to adapt to the using RAPEX - Safety Gate. In the following countries, the number of alerts in the period 2014-2021 was more than 50% higher than the period 2005-2013: Belgium, Denmark, Italy, Latvia, Luxembourg, Poland and Sweden.

In other countries, however, the number of alerts submitted has decreased over this time period. In Bulgaria, Greece, and Portugal, for instance, the number of alerts in the period 2014-2021 was more than 130% lower than the period 2005-2013. Although in some cases this may reflect changes stemming from the NLF, these trends are more likely the result of a wide range of other external factors such as changes in MSA resourcing, changes in market surveillance priorities, and changes in import routes.

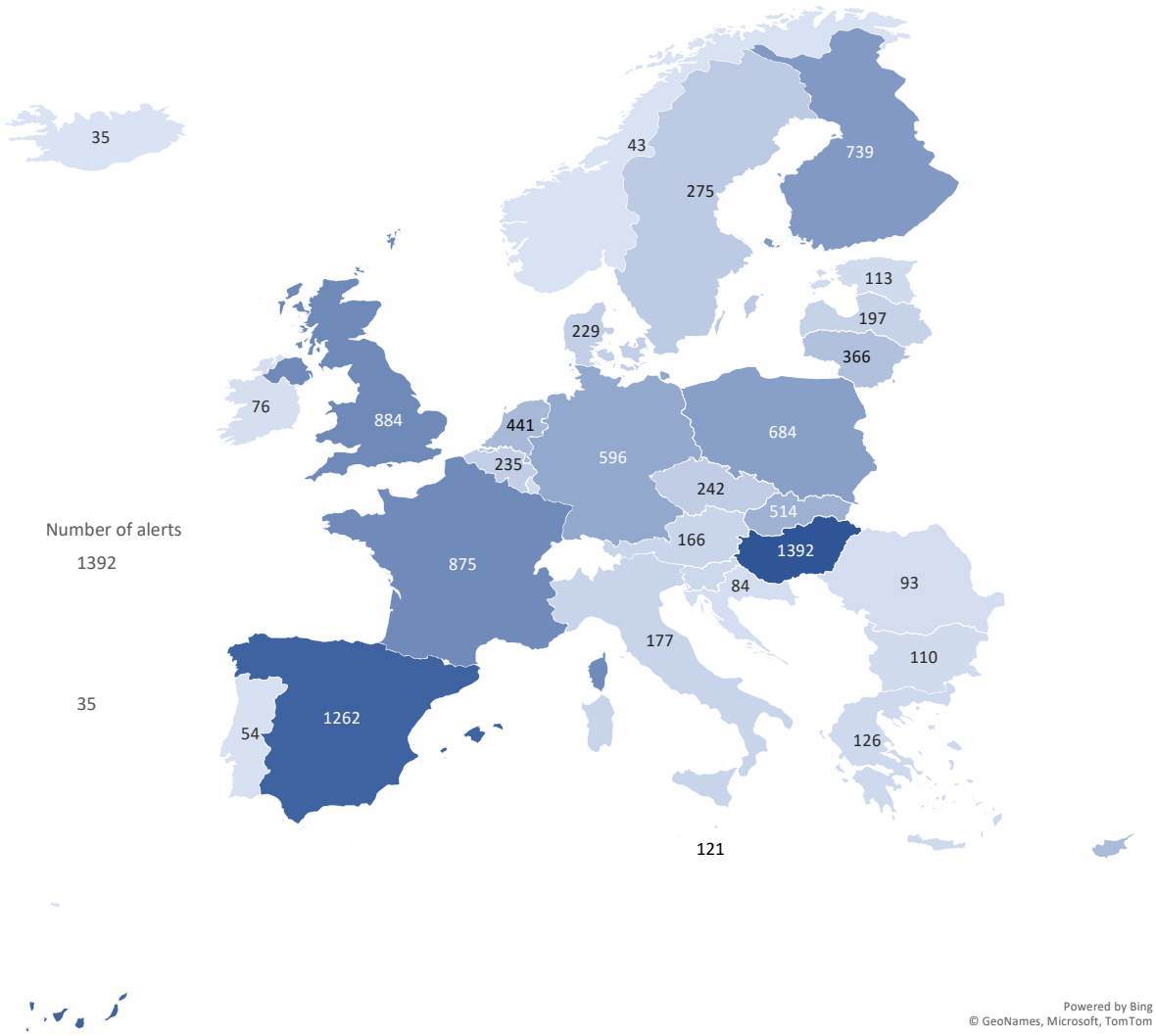

Figure 15 Number of NLF-related alerts submitted by country, 2005-2021

The below table illustrates the top ten **countries of origin** for alerts specifically related to NLF-aligned legislation. China is by far the most common country of origin for non-compliant products, totalling 8,456 alerts specifically referencing NLF-aligned legislation over 2005-2021. This equates to 78% of all such alerts. Furthermore, the number of such alerts related to Chinese-origin products has increased over this period; from 2005-2013, an average of 385 alerts per year related to products originating from China compared to 624 alerts per year in the period 2014-2021.

Products of 'Unknown' origin are the second most common (853 alerts over the period 2005-2021), followed by prominent EU markets (Germany, Poland, Italy, Spain, the Netherlands) and Asian countries with strong reputations in industrial manufacturing (Hong Kong, Taiwan). However, the number of alerts from these countries are minimal compared to those coming from China.

Together, the top 10 countries of origin account for 94% of all alerts that specifically reference NLF-aligned or predecessor legislation.

	2005-2013	2014-2021	Total
People's Republic of China	3,466	4,990	8,456
Unknown	432	421	853
Germany	97	102	199
Poland	51	61	112
Italy	54	52	106
Hong Kong	54	47	101
Taiwan	64	28	92
Spain	33	37	70
Turkey	32	35	67
The Netherlands	26	34	60
…			
Total (all NLF-related alerts)	**4,605**	**6,183**	**10,788**

Table 4 Top 10 countries of origin – NLF-related alerts, 2005-2021

Safety Gate also records the **risk type** associated with each alert, spanning from asphyxiation to chemical risks to electromagnetic disturbance. The below table shows the scale of different risk types in NLF-related alerts. As can be seen the most common risk type are electric shock (3,753 alerts), choking (3,226), injuries (1,474) and fire (1,278).

Risk type	Total
-	3
Allergy	0
Asphyxiation	45
Burns	890
Chemical	965
Choking	3,226
Cuts	127
Damage to hearing	364
Damage to sight	132
Drowning	33
Electric shock	3,753
Electromagnetic disturbance	8
Entrapment	24
Environment	194
Fire	1,278
Health risk / other	329
Injuries	1,474
Microbiological	125

Strangulation	237
Suffocation	335
Total	**13,543**

Table 5 Number of NLF-related alerts, by risk type

Disaggregated analysis by NLF-aligned legislation

Of the 23 NLF-aligned pieces of legislation, 16 are directly referenced in Safety Gate alerts. These include both current NLF-aligned legislations and their non-aligned predecessors(for instance, the Radio Equipment Directive and the Radio Equipment & Telecommunications Terminal Equipment Directive are both referenced).

The below table lists these legislations, alongside the total number of Safety Gate alerts related to each and the number of alerts pre-and post-alignment with the NLF. As can be seen, the most commonly referenced legislations are the Toy Safety Directive and its predecessor (total of 5,351 alerts over the period 2005-2021), the Low Voltage Directive and its predecessor (4,206 over this period) and the legislations on PPE (629 over this period). Other regularly referenced legislations include the Pyrotechnic Articles Directive and the RoHS Directive (both 196 alerts). The following sectoral trends are interesting to note:

- Although the absolute number of post-alignment alerts related to the Toy Safety Directive is much greater than the number of pre-alignment alerts, the average number of annual alerts per year is not as significant. Post-NLF-alignment, an average of 345 alerts have been submitted per year compared with 259 in the pre-alignment period. However, the number of alerts per year has remained relatively constant since 2007.
- The average number of alerts per year under the Low Voltage Directive (LVD) is very similar for the pre- and post-alignment periods; 243 across 11 pre-alignment years and 256 across six post-alignment years. In addition, LVD alerts spanned 18 Safety Gate categories, the widest range of any NLF-aligned legislation. These categories included ‘Electrical appliances and equipment’, ‘Lighting equipment’ and ‘Lighting chains’.
- For PPE, there is a clear escalation in 2020 (164 alerts) and 2021 (157) as a result of the COVID-19 pandemic, rising from an average of 22 over the preceding years.
- RoHS-related unsafe products experienced large increases in 2019 (89 alerts) and 2021 (56). Together, these years comprise 74% of all RoHS-related alerts.

However, as highlighted above, there are a range of caveats and external factors that could be impacting these data, including better labelling practices for the risks related to certain legislations.

NLF-aligned legislation	Pre-alignment	Post-alignment	Total
Toy Safety Directive 2009/48/EU	1,552	3,799	5,351
Low Voltage Directive 2014/35/EU	2,668	1,538	4,206
Personal Protective Equipment Regulation (EU) 2016/425	262	367	629
Pyrotechnic Articles Directive 2013/29/EU	79	117	196
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU		196	196

Gas Appliances Regulation (EU) 2016/426	68	9	77
Construction Products Regulation (EU) No 305/2011	22	23	45
Pressure Equipment Directive 2014/68/EU	12	25	37
Radio Equipment Directive 2014/53/EU	20	7	27
Recreational Craft and Personal Watercraft Directive 2013/53/EU	12	8	20
Electromagnetic Compatibility Directive 2014/30/EU	10		10
Transportable Pressure Equipment Directive 2010/35/EU	1	7	8
Medical Devices Regulation (EU) 2017/745	1	2	3
ATEX Directive 2014/35/EU		2	2
Marine Equipment Directive 2014/90/EU	2		2
Lifts Directive 2014/33/EU		1	1
Grand Total			**10,810**

Table 6 Number of alerts per NLF-aligned legislation, pre- and post-NLF-alignment

Considering the **national authorities** reporting the alerts, a few findings emerge from the data:

- Despite the relatively consistent spread of toy safety-related submissions across 30 countries, Spain is the most common contributor by a large margin, submitting around 16% of all toy safety alerts (839 alerts) over the 2005-2021 period. The contributions of France (489, 9%), Poland (463, 9%) and Hungary (413, 8%) are also notable.
- In the same manner, Hungary is by far the most active country considering alerts related to the Low Voltage Directive, submitting around 23% (967 alerts). Finland (435, 10%) and Spain (361, 9%) are the next highest contributors. Alerts related to the Low Voltage Directive have been submitted across 29 countries.
- Alerts related to PPE legislations are also relatively evenly spread across 30 countries. Germany is the most productive country, submitting 131 PPE-related alerts (21%), followed by Belgium (80, 13%).

When analysing the disaggregated data by a product's **country of origin**, the most notable trends all relate to products originating in China. More specifically, Chinese-origin products are the target of the majority of NLF-related alerts across the Low Voltage Directive (3,210, 76%), the Toy Safety Directive (4,382, 82%), PPE legislations (423, 67%), and the RoHS Directive (165, 84%).

The **risk types** that are prominent across NLF-relevant Safety Gate alerts are:

- Alerts related to the Low Voltage Directive and its predecessor are strongly aligned to the risk type category of electrical shocks, which was reported in around 66% of such alerts (3,733). In addition, fire-related risks were highlighted in 1,157 (21%) alerts that specifically referenced the LVD.
- Half of the alerts that reference the Toy Safety Directive or its predecessor (3,211) highlight choking as a risk type, while injuries (998, 16%) and chemical risks (829, 13%) are also key for this piece of legislation.
- In line with its purpose, RoHS-related alerts have a strong alignment with environmental risks. In fact, around 81% of all RoHS-related alerts (193) highlight environmental risks.

ANNEX X. MAPPING OF NLF-ALIGNED LEGISLATION

The mapping of NLF-aligned legislation focuses on: i) mapping the conformity assessment modules used within each directive and regulation; and ii) examining the extent to which substantive differences exist between the reference provisions detailed in Annex I to Decision No 768/2008/EC and the provisions stipulated in each of the NLF-aligned legislations. The first table below covers the first point above, as well as Chapters R1 and R2 of the reference provisions; namely the definitions and obligations for economic operators.

The second table covers Chapters R3 and R4 of the reference provisions, which present template legal text on issues related to the conformity of the product (e.g. presumption of conformity, EC/EU declaration of conformity, CE marking) and the notification of conformity assessment bodies. Moreover, in the examination of the provisions from Chapter R3, divergence from the declaration of conformity template (Annex III to Decision No 768/2008/EC) and the CE marking provisions from Regulation (EC) No 765/2008 were also considered.

Legislation	Conformity assessment modules used	Differences in the definitions used (Chapter R1, Decision No 768/2008/EC)	Differences in the obligations of economic operators (Chapter R2, Decision No 768/2008/EC)
Toy Safety Directive	Article 19 & 20: Module A (if OJEU cited harmonised standards applied by manufacturer) Module B + C (under four circumstances)	No	No
Transportable Pressure Equipment Directive	Not explicitly stated in the Directive External link suggests a range of modules possible, including: A1, C1, F & G. To be validated with relevant Commission desk officer	Minor differences: e.g. Economic Operators	Minor differences: less developed in the Directive than in the NLF re manufacturers (e.g. no mention of instructions and safety information). Additional mention of owners and operators. Reassessment of conformity linked to the Pi marking
Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive	Article 7(b) - Module A	No	Minor differences: e.g. Art.7(f) refers only to a register etc. whereas Art.R2(4) includes also sample testing and investigation; and Art.7 (c) or (h) RoHS contain an additional sentence compared to Art.R2 (2) or (6).
Pyrotechnic Articles Directive	Article 17 - either module B+C2/D/E or module G or module H, depending on the type of product	Minor differences: e.g. Economic Operators	No
Recreational Craft and Personal Watercraft	Article 20-22 - significant variation in required modules based on product type	No difference in definitions of traditional	Major in relation to novel Article 12 'obligations of private importers', e.g. stating that "If the required technical documentation is not available from the

Legislation	Conformity assessment modules used	Differences in the definitions used (Chapter R1, Decision No 768/2008/EC)	Differences in the obligations of economic operators (Chapter R2, Decision No 768/2008/EC)
Directive	and other aspects Article 23 – Additional novel module for post-construction assessment (Module PCA)	economic operators Novel definition of "private importer"	manufacturer, the private importer shall have it drawn up using appropriate expertise" (art. 12.2). Private Importer can carry responsibility for compliance (art. 12.1). Economic operators or private importers are required to affix watercraft identification (Annex I.A.2.2.1) and watercraft builder's plate (Annex I.A.2.2.2). DoC in Directive may in some cases include additional information e.g. statement of the propulsion engine manufacturer and that of the person adapting an engine in accordance.
Civil Explosives Directive	Article 20 - Module B + C2/D/E/F or Module G	Minor differences: e.g. dealer & economic operators	No
Simple Pressure Vessels Directive	Article 13 - Module B + C1, C2 or C depending on the product	No	No
Electromagnetic Compatibility Directive	Article 14 (for apparatus) - Module A or Module B + C	Minor differences: e.g. "components" or "mobile installations" considered as apparatus	Minor differences, no mention of the responsibility of manufacturers/importers to "carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of such monitoring" (Decision No 768/2008/EC R2 Art.4)
Non-automatic Weighing Instruments Directive	Article 13 - Module B + D/F (or Module D1 or F1 in certain circumstances) or Module G	No	No
Measuring Instruments	Article 17 – manufacturers can use any modules detailed in Annex II, which presents Modules A, A2, B + C/C2/D/E/F, D1, E1, F1, G, H, H1 (i.e. all except A1 and C1)	Minor differences, apart from additional definitions: e.g. putting into use	No
Lifts Directive	Article 16 – Annexes detail different modules for different products. i.e. Annex IV (Module B), Annex VI (Module E), Annex VII (Module H), Annex VIII (Module G), Annex IX (Module C2), Annex X (Module E), Annex XI (Module H1), Annex XII (Module D)	Minor differences: e.g. "placing on the market" of lifts (see recital 4) or "installer"	No – additional role of installers (in practice, 'installer' is equivalent to a 'manufacturer', however, the choice was made to call a manufacturer of a lift an 'installer')
ATEX Directive	Article 13 - for certain products, Module B (detailed in Annex III) + D (Annex IV) /	Minor differences: e.g. "intended use"; Manufacturer is a person who either markets	Minor differences: e.g. Art.6.1 – Obligation of manufacturer refers to products, which are supposed to be placed on the market or products which are supposed

Legislation	Conformity assessment modules used	Differences in the definitions used (Chapter R1, Decision No 768/2008/EC)	Differences in the obligations of economic operators (Chapter R2, Decision No 768/2008/EC)
	F (Annex V); for other products, Module B + C1 (Annex VI) / E (Annex VII); for other products, Module A (Annex VIII); for other products, Module G (Annex IX)	the designed product or uses it for own purposes.	to be used for their own use; and Art. 6.2 Manufacturers of components shall accompany such component by "attestation of conformity" instead of EU DoC.
Radio Equipment Directive	Article 17 – for essential requirements in Article 3.1, any of Module A (detailed in Annex II), Module B + C (Annex III) or Module H (Annex IV). For essential requirements in Articles 3.2 and 3.3, Module B + C (Annex III) or Module H (Annex IV).	Minor differences, such as additional definitions: e.g. "put into service"	No
Low Voltage Directive	Referred to in Articles 6 and 15 – detail in Annex III, which presents Module A only	No	No
Pressure Equipment Directive	Article 14 - CA procedure determined by equipment categories: Cat 1 - Module A Cat 2 - Modules A2, D1 or E1 Cat 3 - Modules B + D/F/E/C2, or Module H Cat 4 - Modules B + D/F, Module G or Module H1	Minor differences, apart from additional definitions: e.g. "European approval for material", "putting into service"	No
Marine Equipment Directive	Article 15 - Module B + D/E/F, or Module G	Minor differences: e.g. "notified body"	Minor. Manufacturers not located in MS need to appoint an authorised representative. An importer or distributor is considered a manufacturer for the purposes of this Directive
Construction Products Regulation	Declaration of performance demonstrating assessment and verification of constancy of performance, rather than conformity assessment (see Recital 29)	No	No
Cableway Installations Regulation	Article 18 – Module B (detailed in Annex III) + D (Annex IV) / F (Annex V); or Module G (Annex VI); or Module H1 (Annex VII)	Minor differences: e.g. "manufacturer" or "technical specification"	Minor: time for importers to keep the EU declaration of conformity available is 30 years after the subsystem/safety component has been placed on the market
Medical Devices	Article 52 – as for the *In Vitro* Diagnostic Medical Devices Regulation. CA	Minor differences: e.g. "authorised representative", "putting into service",	Major differences:

Legislation	Conformity assessment modules used	Differences in the definitions used (Chapter R1, Decision No 768/2008/EC)	Differences in the obligations of economic operators (Chapter R2, Decision No 768/2008/EC)
Regulation	procedures set out in Annexes IX-XI; modules depend on device classification.	"notified body", “post-market surveillance” or “sponsor”.	- Manufacturers not located in the EU must appoint an authorised representative. - Manufacturers shall have a system for risk management as described in Section 3 of Annex I and a quality management system, registration of products on the UDI system, manufacturers not located in MS need to appoint an authorised representative. - Additional provisions expand on the obligations of manufacturers without contradicting the NLF provisions (e.g. Manufacturers shall [...] have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC), manufacturers need to have one person responsible for regulatory compliance (art 15) and register devices on the UDI system - Authorised representative has more tasks/responsibilities, e.g. "the right to terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation", "authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer" - Importers need to forward complaints to manufacturer and authorised representative
In Vitro Diagnostic Medical Devices Regulation	Article 48 – as for Medical Devices Regulation. CA procedures set out in Annex IX-XI; modules depend on device classification	Minor differences: e.g. "authorised representative", "putting into service", "notified body", "post-market surveillance" or "sponsor".	Major differences: - Manufacturers not located in the EU must appoint an authorised representative - Manufacturers shall have a system for risk management as described in Section 3 of Annex I and a quality management system, registration of products on the UDI system, manufacturers not located in MS need to appoint an authorised representative - Additional provisions expand on the obligations of manufacturers without contradicting the NLF provisions (e.g. Manufacturers shall [...] have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC), manufacturers need to have one person responsible for regulatory compliance (art 15) and register devices on the UDI system - Authorised representative has more tasks/responsibilities, e.g. "the right to terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation", "authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer"

Legislation	Conformity assessment modules used	Differences in the definitions used (Chapter R1, Decision No 768/2008/EC)	Differences in the obligations of economic operators (Chapter R2, Decision No 768/2008/EC)
			- Importers need to forward complaints to manufacturer and authorised representative
Personal Protective Equipment Regulation	Article 19 - modules vary by risk categories of product: Cat 1 - Module A (Annex IV) Cat 2 - Module B (Annex V) + C (Annex VI) Cat 3 - Module B (Annex V) + C2 (Annex VII) / D (Annex VIII)	No	Minor differences: - The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed - Importers can if asked provide the documentation to demonstrate the conformity of PPE in paper or electronic form
Gas Appliances Regulation	Article 14 – For certain products, Module B + C2/D/E/F; for certain products, Module G is also possible	No	No
EU Fertilising Products Regulation	Article 15 refers to Annex IV, which refers to CA procedures: For certain products, Module A, Module A1, Module B + C, Module D1	Minor differences: e.g. "technical specification"	Minor differences: - Manufacturers/importer shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered has been placed on the market

Legislation	Differences in the reference provisions related to conformity of the product and the DoC (Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on CE marking (Regulation (EC) No 765/2008 & Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on notification of conformity assessment bodies (Chapter R4, Decision No 768/2008/EC)
Toy Safety Directive	No	Minor differences in R11 and R12 on CE marking	Minor (e.g. no provisions on accredited in-house bodies)
Transportable Pressure Equipment Directive	Minor – specific requirements on conformity (e.g. certificates of conformity; requirements for periodic inspections, intermediate inspections and exceptional checks); no DoC	Minor – specific Pi marking provisions; however, similarities to Regulation (EC) No 765/2008	No provisions on notification (R14), presumption of conformity, formal objection, subsidiaries of and subcontracting by notified bodies, accredited in-house bodies Slight differences in 'Requirements relating to notifying authorities' Significant differences in 'Requirements relating to notified bodies' – specific rules under Directive 2008/68/EC Sector-specific details throughout related to inspections
Restriction of Hazardous Substances in Electrical	Minor differences (e.g. location of Art 16(1) text is different	No	Minor differences: e.g. Art.9 RoHS compared to Article R4; and Art.9(e) refers to keeping a register of non-compliant

Legislation	Differences in the reference provisions related to conformity of the product and the DoC (Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on CE marking (Regulation (EC) No 765/2008 & Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on notification of conformity assessment bodies (Chapter R4, Decision No 768/2008/EC)
and Electronic Equipment Directive	from other legislations); no difference on DoC		EEE and EEE recalls, not to sample testing or investigation.
Pyrotechnic Articles Directive	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, DoC includes provisions related the possibility of products being subject to multiple legislations, and requires specific information on registration number)	No	Minor variation on 'notifying authorities' No provisions on formal objection to a harmonised standard or accredited in-house bodies Obligation for notified bodies to maintain a register of pyrotechnic articles that have been subject to conformity assessment Additional provisions on 'Appeal against decisions of notified bodies'
Recreational Craft and Personal Watercraft Directive	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation; additional provisions related to Post-Construction Assessment – Annex V); also, on DoC (e.g. requirement to provide the DoC with certain products; includes reference to private importer; additional specific information requirements)	Minor (e.g. infringements covered under Art. 53)	No provisions on 'Formal objection to a harmonised standard' for NBs or 'accredited in-house bodies'
Civil Explosives Directive	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	Minor (e.g. product specific requirements)	Minor variation on 'notifying authorities' No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging the competence of notified bodies Provisions on 'Appeal against decisions of notified bodies'
Simple Pressure Vessels Directive	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations); and specific provisions in the conformity assessment procedures that go beyond the NLF modules.	No	No provisions on 'Formal objection to a harmonised standard' for NBs or 'accredited in-house bodies'. Different provisions on challenging the competence of notified bodies Provisions on 'Appeal against decisions of notified bodies'
Electromagnetic Compatibility Directive	Minor (e.g. no provisions on formal objection to harmonised standard, although referenced in Recitals); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	No	No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging competence of NBs

Legislation	Differences in the reference provisions related to conformity of the product and the DoC (Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on CE marking (Regulation (EC) No 765/2008 & Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on notification of conformity assessment bodies (Chapter R4, Decision No 768/2008/EC)
			Provisions on 'Appeal against decisions of notified bodies'
Non-automatic Weighing Instruments Directive	Minor (e.g. no provisions on formal objection to harmonised standard, although referenced in Recitals); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	Minor (e.g. related to additional, product specific metrology marking)	No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
Measuring Instruments	Minor (e.g. use of normative documents, alongside harmonised standards for presumption of conformity; specific tests noted in legal provisions; no provisions on formal objection to harmonised standard, although referenced in Recitals); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	Minor (e.g. related to additional, product specific metrology marking; requirements for NB identification number to be indelible or self-destructive if removed)	No provisions on formal objection to a harmonised standard Additional sector-specific information within the notification procedure Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
Lifts Directive	Minor on legal provisions (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations) Extensive differences in DoC template (e.g. additional info, different structure, separate forms for lifts and safety components for lifts)	Minor (e.g. product specific provisions)	No provisions on formal objection to a harmonised standard for NBs or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
ATEX Directive	Minor (e.g. promotion of national standards and technical specifications in the absence of harmonised standards; no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	Minor (e.g. specific additional explosion protection and other information markings)	No provisions on formal objection to a harmonised standard for NBs or accredited in-house bodies.
Radio Equipment Directive	Minor (e.g. no provisions on formal objection to harmonised standard, although referenced in Recitals); also, on DoC legal provisions (e.g. provisions related to the possibility of products being subject to multiple legislations; provisions for a simplified DoC) On DoC Annex, minor divergences (e.g. additional information required – a description of accessories and components which allow the radio equipment to operate as	Minor (e.g. product specific general principle; CE marking shall be affixed to both the product and the packaging)	No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies' *Additional information obligations under Annexes III and IV*

Legislation	Differences in the reference provisions related to conformity of the product and the DoC (Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on CE marking (Regulation (EC) No 765/2008 & Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on notification of conformity assessment bodies (Chapter R4, Decision No 768/2008/EC)
	intended)		
Low Voltage Directive	Minor (e.g. additional provisions on presumption of conformity based on international and national standards; no provisions on formal objection to harmonised standard, although referenced in Recitals); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	No	No NB and thus notifying requirements (clearly stated in Recitals)
Pressure Equipment Directive	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations); and specific provisions in the conformity assessment procedures that go beyond the NLF modules.	Minor (e.g. product specific provisions on affixing CE marking)	Sector specific requirements on user inspectorates and lists of recognised third-party organisations and user inspectorates. No provisions on formal objection to a harmonised standard for NBs or accredited in-house bodies. Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies etc.'
Marine Equipment Directive	Major (e.g. Article 35 empowers the Commission to indicate by means of Implementing Acts mandatory standards, no presumption of conformity, no provisions on formal objection to harmonised standard); also, on DoC (e.g. product specific provisions). The reason for this is the need to apply the IMO instruments without providing the notified bodies with the possibility to deviate from them.	Major (e.g. use of different mark – 'Wheel mark', rather than CE marking, although provisions are similar)	Significantly different structure (e.g. notification procedure, requirements for notifying authorities and notified bodies all included as separate Annexes) Specific monitoring timeline (2 years) Additional requirements for notified bodies related to ISO standards No provisions on presumption of conformity, formal objection to a harmonised standard or accredited in-house bodies
Construction Products Regulation	No differences related to R8 & R9; specific requirements instead of DoC (e.g. Declaration of performance - Annex III; Assessment and Verification of constancy of performance - Annex V)	Minor differences (e.g. requirement to include two last digits of the year in which the CE marking was first affixed and other additional information alongside the CE marking; no provisions on mechanisms to ensure correct application)	Well aligned; with sector-specific wording (e.g. on constancy of performance) No explicit provisions on formal objection and accredited in-house bodies Specific provisions on 'Use of facilities outside the testing laboratory of the notified body'
Cableway Installations Regulation	Minor (e.g. no provisions on formal objection to harmonised standard); also, on DoC (e.g. provisions related to the	No	No provisions on formal objection to a harmonised standard or accredited in-house bodies

Legislation	Differences in the reference provisions related to conformity of the product and the DoC (Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on CE marking (Regulation (EC) No 765/2008 & Chapter R3, Decision No 768/2008/EC)	Differences in the provisions on notification of conformity assessment bodies (Chapter R4, Decision No 768/2008/EC)
	possibility of products being subject to multiple legislations)		Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
Medical Devices Regulation	Minor (e.g. R8 provisions under heading 'use of harmonised standards; no provisions on formal objection); on DoC legal provisions (e.g. differences in the text and structure; provisions related to the possibility of products being subject to multiple legislations; possibility of delegated acts) On DoC Annex - major differences in structure and content (e.g. requirements for product specific information, such as the Basic UDI-DI, risk class etc.)	Minor (e.g. different structure; CE marking required on product / packaging and instructions for use and sales packaging; no provisions on ensuring the correct application, but penalties for infringements in Art. 113)	Significant differences in the structure and approach to stipulating the rules for notification, notifying authorities ('authorities responsible for notified bodies') and notified bodies
In Vitro Diagnostic Medical Devices Regulation	Minor (e.g. R8 provisions under heading 'use of harmonised standards; no provisions on formal objection); on DoC legal provisions (e.g. differences in the text and structure; provisions related to the possibility of products being subject to multiple legislations; possibility for delegated acts) On DoC Annex - major differences in structure and content (e.g. requirements for product specific information, such as the Basic UDI-DI, risk class etc.)	Minor (e.g. different structure; CE marking required on product / packaging and instructions for use and sales packaging; no provisions on ensuring the correct application, but penalties for infringements in Art. 106)	Significant differences in the structure and approach to stipulating the rules for notification, notifying authorities ('authorities responsible for notified bodies') and notified bodies
Personal Protective Equipment Regulation	Minor (e.g. no provisions on formal objection to harmonised standard); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations) On DoC Annex - minor (e.g. additional information required on which conformity assessment module used)	No	No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
Gas Appliances Regulation	Minor (e.g. no provisions on formal objection to harmonised standard as regulated by Standardisation Regulation); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations, specific provisions for fittings and requirement to provide DoC with fittings)	Minor (e.g. specific information to be placed alongside the CE marking)	No provisions on formal objection to a harmonised standard for NBs or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'
EU Fertilising Products Regulation	Minor (e.g. no provisions on formal objection to harmonised standard); also, on DoC (e.g. provisions related to the possibility of products being subject to multiple legislations)	No	No provisions on formal objection to a harmonised standard or accredited in-house bodies Different provisions on challenging competence of NBs Provisions on 'Appeal against decisions of notified bodies'

ANNEX XI. SUBSTANTIAL MODIFICATION – AN OVERVIEW OF THE DIVERS DEFINITIONS OF MODIFICATION OF PRODUCTS FOLLOWING THEIR PLACING ON THE MARKET

The examples below demonstrate that there is a **diversity in terminology** to describe the products the modifications of the products following their placing on the market in such a way that compliance with the applicable requirements is affected (e.g. refurbishment, remanufacturing, repurposing, substantial modifications).

Article 2(13), (14) and (15) of Directive 2009/125/EC for the setting of ecodesign requirements for energy-related products defines the '**life cycle**'[145], '**reuse**'[146] and '**recycling**'[147].

Article 2(1)(31) of Regulation (EU) 2017/745 on medical devices and Article 2(24) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices define **'fully refurbishing'** as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with the respective Regulation, combined with the assignment of a new lifetime to the refurbished device.

Article 3(1)(16) of the Proposal of the machinery regulation defines '**substantial modifications'** as a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected.

The Proposal for the regulation on batteries and waste batteries recognizes that at the end of the first life, used batteries are considered waste (except for reuse). **Repurposing**[148] is considered a waste treatment operation. Repurposed (second life) batteries are considered as new products which have to comply with the product requirements when they are placed on the market. The Proposal also defines the '**reuse**'[149] and '**lifetime**'[150] of batteries.

According to Article 3(23) of the Proposal for a Regulation on artificial intelligence **'substantial modification'** is a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the essential requirements set out in the Proposal or results in a modification to the intended purpose for which the AI system has been assessed.

Article 12(2) of the Proposal for the general product safety regulation sets out that a modification should be deemed to be substantial where a) the modification changes the intended functions, type or performance of the product in a manner which was not foreseen in the initial risk assessment of

[145] Life cycle' means the consecutive and interlinked stages of a product from raw material use to final disposal
[146] Reuse: means any operation by which a product or its components, having reached the end of their first use, are used for the same purpose for which they were conceived, including the continued use of a product which is returned to a collection point, distributor, recycler or manufacturer, as well as reuse of a product following refurbishment;
[147] Recycling: means the reprocessing in a production process of waste materials for the original purpose or for other purposes but excluding energy recovery
[148] Article 2 of the Proposal defines 'repurposing' as any operation that results in parts or the complete battery being used for a different purpose or application than the one that the battery was originally designed for.
[149] Article 2(40) of the Proposal defines 'reuse' as the complete or partial direct re-use of the battery for the original purpose the battery was designed for.
[150] Article 2(47) of the Proposal defines the 'lifetime' of the battery as the period of time that starts when the battery is placed on the market, and ends when the battery becomes waste.

the product; b) the nature of the hazard has changed or the level of risk has increased because of the modification; c) the changes have not been made by the consumer for their own use.

Article 2 of the Proposal for a Regulation establishing a framework for setting eco-design requirements for sustainable products defines the terms of 'life cycle'[151], remanufacturing[152] 'refurbishment'[153] and 'repair'[154] of the product.

[151] Article 2(12) of the Proposal defines 'life cycle' as the consecutive and interlinked stages of a product's life, consisting of raw material acquisition or generation from natural resources, pre-processing, manufacturing, storage, distribution, installation, use, maintenance, repair, upgrading, refurbishment and re-use, and end-of-life;
[152] Article 2(16) of the Proposal defines 'remanufacturing' as an industrial process in which a product is produced from objects that are waste, products or components and in which at least one change is made to the product that affects the safety, performance, purpose or type of the product typically placed on the market with a commercial guarantee;
[153] Article 2(18) of the Proposal defines 'refurbishment' as preparing or modifying an object that is waste or a product to restore its performance or functionality within the intended use, range of performance and maintenance originally conceived at the design stage, or to meet applicable technical standards or regulatory requirements, with the result of making a fully functional product;
[154] Article 2(20) of the Proposal defines 'repair' as returning a defective product or waste to a condition where it fulfils its intended use;