Supporting Study for the evaluation of certain aspects of the New Legislative Framework

(Decision No 768/2008/EC and Regulation (EC) No 765/2008)

Written by Centre for Strategy & Evaluation services and Centre for Industrial Studies
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List of acronyms and key terms

Acronyms	Meaning of acronym and / or description of term
AI	Artificial intelligence
BaU	Business as Usual costs
B2B	Business-to-business
B2C	Business-to-consumer
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
DPP	Digital Product Passport
DSM	Digital Single Market
EA	European co-operation for Accreditation
EEA	European Economic Area
EFTA	European Free Trade Association
EIP-RM	European Innovation Partnership on Raw Materials
EMCD	Electromagnetic Compatibility Directive 2014/30/EU
EO	Economic operators
ESO	European standardisation organisation (CEN, Cenelec, ETSI)
ETSI	European Telecommunication Standards Institute
GDPR	General Data Protection Regulation (EU) 2016/679
GPSD	General Product Safety Directive 2001/95/EC
GPSR	Proposal for a Regulation on General Product Safety
GVC	Global Value Chains
hEN	Harmonised standard
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Commission
IoT	Internet of Things
ISO	International Organization for Standardization
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
NAB	National Accreditation Body
NB	Notified Body
NLF	New Legislative Framework
ODM	Original Design Manufacturer

Acronyms	Meaning of acronym and / or description of term
OEM	Original Equipment Manufacturer
OJEU	Official Journal of the European Union
PLD	Product Liability Directive 85/374/EEC
PPE	Personal Protective Equipment
RAPEX	Rapid Exchange of Information System
RED	Radio Equipment Directive 2014/53/EU
RoHS	Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SAR	Specific Absorption Rate
SBS	Eurostat's Structural Business Statistics
SCM	Standard Cost Model
SME	Small and medium-sized enterprises
SPI	Sustainable Product Initiative
SUD	Single-Use Device
TSD	Toy Safety Directive 2009/48/EC
UHL	Union harmonisation legislation

1. Introduction

The *New Approach to technical harmonisation and standards* was adopted in May 1985 with the aim of preventing divergent EU product legislation. It established a common regulatory toolbox and an approach to legislative harmonisation based on the principles of essential safety requirements and technological neutrality.[1]

To strengthen the New Approach, the EU adopted the **New Legislative Framework (NLF)** in 2008. The NLF aims to provide a horizontal legal framework to support the development and implementation of EU product legislation, and comprises the following pieces of legislation:

- **Decision No 768/2008/EC on a common framework for the marketing of products**, which provides a horizontal approach to aligning EU product legislation with a set of common principles and reference provisions.
- **Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance of products**, which stipulates rules for the accreditation of conformity assessment bodies and the general principles of the CE marking regime.
- **Regulation (EU) 2019/1020 on market surveillance and compliance of products**, which has been in application since 16th July 2021 and aims to improve market surveillance and compliance with product legislation. *As detailed below, the market surveillance aspects of the NLF are not covered by this evaluation study, as they were evaluated in 2017 and amended through this Regulation.*

The Centre for Strategy & Evaluation Services (CSES) and its partner CSIL were commissioned to conduct the ***'Supporting Study for the evaluation of certain aspects of the New Legislative Framework (Decision No 768/2008/EC and Regulation (EC) No 765/2008)'***. This document presents the **final report** of this study. First, this report presents the objectives and scope of the study, before providing detailed information on the background and context to the evaluation, including an analysis of the NLF's intervention logic and implementation to date. On this basis, the report provides an assessment of the key evaluation issues across all evaluation criteria.

1.1 Evaluation study objectives

The main study objective is 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[2] in 2017 and have since been amended by Regulation 2019/1020.[3] 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 will be **retrospective**, providing an informed assessment of the NLF's current performance and an evidence-based assessment of the above-mentioned evaluation criteria. However, there will also be a **forward-looking dimension** to the evaluation, which will form an important part of the assessment of the NLF's relevance. As discussed further below, market and product trends related to the digital and green transitions necessitate an assessment of the NLF's ongoing fitness for purpose.

[1] Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, *OJ C 136, 4.6.1985.*
[2] European Commission. (2018) Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) No 765/2008
[3] 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

In this context, the below table presents the key evaluation questions to be addressed through this report, and the chapter in which the relevant discussion can be found. The evaluation question numbers are also used throughout to signpost the answers to each key evaluation question.

Table 1-1: Summary of key evaluation questions and report location

Question #	Key evaluation questions	Chapter
	Effectiveness	
EQ1.1	To what extent have the original **specific objectives** of the NLF been achieved? • Covering: reinforcing the New Approach (technology-neutral essential requirements); supporting the consistency and coherence of EU harmonisation legislation; strengthening the quality of conformity assessment services; and ensuring a clear meaning and enhanced credibility of CE marking. • What are the **factors** that have influenced positively and negatively the achievements observed? Has the NLF had **unintended consequences** or collateral effects?	Chapter 4.1.1
EQ1.2	To what extent have the original **general objectives** of the NLF been achieved? • Covering: providing a high level of protection of public interests (e.g. health and safety, consumer and environmental protection); fostering the free movement of products within the single market; and establishing a common harmonisation framework. • What are the **factors** that have influenced positively and negatively the achievements observed? Has the NLF had **unintended consequences** or collateral effects?	Chapter 4.1.2
	Efficiency	
EQ2.1	What are the **regulatory and administrative costs** associated with the NLF and are they affordable for the various stakeholder groups (and SMEs in particular)? Is there evidence that the NLF has cause **unnecessary regulatory burden**?	Chapter 4.2.3
EQ2.2	What are the **benefits** and how beneficial are they for the various stakeholder groups (and SMEs in particular)? To what extent has the **simplification potential** expected at the time of the adoption of the NLF been achieved?	Chapter 4.2.4 & 4.2.5
EQ2.3	To what extent **are the costs incurred proportionate to the benefits** attained? What are the **factors** influencing the proportionality of costs?	Chapter 4.2.6
	Coherence	
EQ3.1	Are there any inconsistencies, overlaps or gaps within the different provisions of Decision 768/2008 and Regulation (EU) No 765/2008 (**internal coherence**)?	Chapter 4.3.1
EQ3.2	To what extent is the NLF still consistent with other EU legislation, including new proposed legislation (e.g. the GPSR proposal, Machinery Regulation proposal and the AI Act)? (**external coherence**)?	Chapter 4.3.2
	EU Added Value	
EQ4.1	What is the added value of the NLF compared to what could be achieved at merely national level?	Chapter 5
EQ4.2	What would be the most likely consequences of repealing the NLF?	Chapter 5

Question #	Key evaluation questions	Chapter
EQ4.3	Do the needs and challenges addressed by the NLF continue to require (harmonisation) action at EU level?	Chapter 5
Relevance & fitness for purpose		
EQ5.1	To what extent are the **objectives of the NLF still appropriate** today?	Chapter 6.1 & 6.2
EQ5.2	To what extent has the NLF followed / allowed for technological, scientific, environmental and social development? • Covering: the way products may be changing during their lifetime to both support the take-up of smart, connected or remanufactured products; and the roles and responsibilities of different economic operators in the context of new models of production and manufacturing practices (e.g. remanufacturing and reuse, 3D printing).	Chapter 6.3
EQ5.3	To what extent does the **lack of a crisis instrument** render the NLF less effective or efficient?	Chapter 6.4

1.2 Study scope

Regarding the **material scope,** the evaluation will need to conduct an evidence-based review of the performance of the NLF in the following key areas:

- **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 and notified bodies.
- **CE marking** and administrative requirements.

The assessment of these issues will feed into the overall assessments of the five core evaluation criteria named above. Beyond the retrospective examination of the NLF's provisions and outputs, various issues relating to the NLF's ongoing fitness for purpose will be investigated under the relevance criterion. More specifically, the **evaluation will consider the extent to which the NLF has been and continues to 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, 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.
- Changes in manufacturing value chains and the 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 products on the market following their repair, refurbishment, and remanufacturing.

This assessment of fitness for purpose is particularly pertinent considering **ongoing EU policy and legislative developments** related to both the digital and green transitions. Examples include:

- **Digital transition:** In October 2021, a Delegated Act concerning the cybersecurity of internet-connected products was adopted under the Radio Equipment Directive (RED)[4] – an NLF-aligned law. Furthermore, recent legislative proposals that cover related issues include the proposed AI Act[5] and the proposal for a Machinery Regulation[6].
- **Green transition:** Key developments include the European Green Deal and Circular Economy Action Plan and the resulting regulatory pressure to integrate environmental aspects into product legislation, as illustrated in the proposal for the General Product Safety Regulation (GPSR)[7].

The **geographic scope** of the evaluation will be the EU-27 Member States and the 3 EEA-EFTA Members (Norway, Iceland and Liechtenstein). In addition, limited international benchmarking has be undertaken to consider how selected third countries tackle specific issues examined through the evaluation.

The **temporal scope** will span the period 2014-2020. Although the NLF was adopted in 2008, this timeframe is relevant, as it complements an earlier evaluation from 2014[8] and considers that most of the legislation aligned with the NLF to date was recast and aligned in or after 2014. Only a few pieces of legislation were aligned before 2014.

1.3 Methodological overview

The evaluation study was conducted over the following three phases from March 2021 to March 2022:

- **Phase 1 – Inception Phase:** Following a kick-off meeting on 9th March 2021, the evaluation team conducted a range of preparatory tasks aimed at: i) finalising the methodological approach and research tools; and ii) preparing an inception report. The inception report was submitted on 19th April 2021.
- **Phase 2 – Data collection & preliminary analysis:** Using the research tools developed through Phase 1, the second phase focused on data collection and iterative analytical activities. The main data collection activities were a desk research exercise, including a comprehensive mapping of legislative provisions across NLF-aligned laws, 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.

  Based on the data collected through the above means, preliminary analytical activities were conducted in phase 2, including initial versions of: the intervention logic, the implementation of the NLF and legislative mapping, the analysis of the targeted consultation responses, a small number of case studies, the cost-benefit analysis and the assessments of all evaluation criteria. These initial analytical activities were included in an interim report submitted on 6th December 2021.
- **Phase 3 – Final analysis & reporting:** In the final phase, the above analytical activities enhanced

[4] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

[5] 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.

[6] Proposal for a Regulation of the European Parliament and of the Council on machinery products.

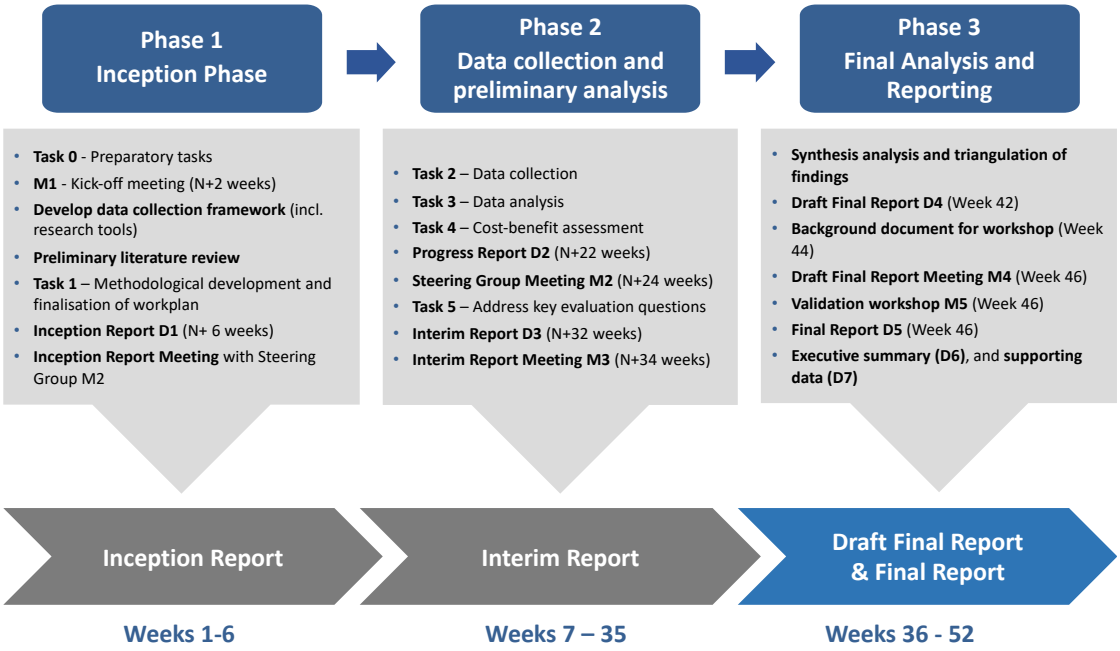
[7] Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council.

[8] SWD(2014)23 accompanying the Commission Communication COM(2014)25 on 'A vision for the internal market for industrial products'

and were finalised, alongside the analysis of the public consultation responses, the full set of case studies, and quantitative analyses of the NANDO and Safety Gate databases. On this basis, the assessments of each evaluation criterion were refined and included in the draft final report, submitted on 2nd February 2022. To validate and further develop the findings presented through the draft final report, a stakeholder validation workshop was organised and delivered on 9th March 2022, and this final report was submitted on 29th March 2022.

The below figure presents an overview of the work plan for this evaluation study.

Figure 1-1: Overview of work plan for the evaluation study



1.4 Report structure

The main report is structured in the following way:

- Chapter 1: Introduction
- Chapter 2: What was the expected outcome of the NLF?
- Chapter 3: How has the situation evolved over the evaluation period?
- Chapter 4: To what extent was the NLF successful and why?
- Chapter 5: How did the NLF make a difference?
- Chapter 6: Is the NLF still relevant?
- Chapter 7: Conclusions and lessons learned

The annexes are structured as follows:

- Annex 1: Bibliography
- Annex 2: Evaluation methodology
- Annex 3: Overview of costs and benefits
- Annex 4: Case studies
- Annex 5: International accreditation standards
- Annex 6: Analysis of Safety Gate data
- Annex 7: Mapping of NLF-aligned legislation

2. What was the expected outcome of the NLF?

This **chapter details the NLF's intervention logic**, which aims to examine the inter-relationships between the different components of the NLF; namely, the **needs and problems** the NLF is trying to address, the **general** and **specific** objectives it seeks to achieve, the **inputs** (e.g. human and financial resources) required in order to achieve these objectives, the **activities implemented** 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 logic mapping allows an exploration of how the NLF was intended and expected to work as a horizontal legal framework, combining general principles and common reference provisions to strengthen the coherence of individual pieces of Union harmonisation legislation (that have been aligned with the NLF). The point of departure is therefore the NLF as originally conceived in 2008, considering the aspects of Regulation (EC) No 765/2008 (on accreditation and market surveillance) and Decision No 768/2008/EC (common framework for the marketing of products) that are in scope. As noted in Chapter 1, the specific provisions of the NLF on market surveillance, evaluated in 2017 and now enshrined in Regulation (EU) 2019/1020, are excluded from the scope of this evaluation study. However, these provisions are important context and will be relevant to consider as part of the overarching framework.

Beyond the different components of the NLF, the intervention logic also considers the **roles and responsibilities of different stakeholders** in the implementation of the NLF, as well as the impacts on these stakeholders. Specifically, the key stakeholders include:

- **Economic operators** (manufacturers, importers, distributors, authorised representatives) are subject to the general principles stipulated in Decision No 768/2008/EC, as well as the provisions of NLF-aligned EU product legislation. In this respect, mapping the roles of and impacts on small and medium-sized enterprises (SMEs), alongside large enterprises, is particularly important.
- **Conformity assessment bodies (CAB)** perform conformity assessment activities including calibration, testing, certification, and inspection. **Notified bodies (NB) are a specific subset of CABs** that may fulfil certain requirements according to Union product legislation and have been notified to the Commission and the other Member States. Both CABs and NBs can receive accreditation to carry out specific conformity assessment activities from a national accreditation body, as per Regulation (EC) No 765/2008.
- **National accreditation bodies:** Under Article 4 of Regulation (EC) No 765/2008, each Member State is required to appoint a single national accreditation body that is responsible for the assessment and accreditation of the technical competence of CABs across all NLF-aligned legislation. National accreditation bodies may also: i) take responsibility for monitoring notified bodies; and ii) act as notifying authority; however, in such cases, they are only permitted to notify CABs that have been accredited.
- **National notifying authorities**, appointed by each Member State, are responsible for the political act of notifying conformity assessment bodies to the Commission and the other Member States, as well as monitoring of notified bodies. Under specific product legislation, national notifying authorities may be permitted to decide that their assessment and monitoring tasks shall be conducted by the national accreditation body.
- **Market surveillance authorities (MSAs)**, as defined in Article 10 of Regulation 2019/1020, are appointed by each Member State to conduct specific market surveillance and enforcement tasks,

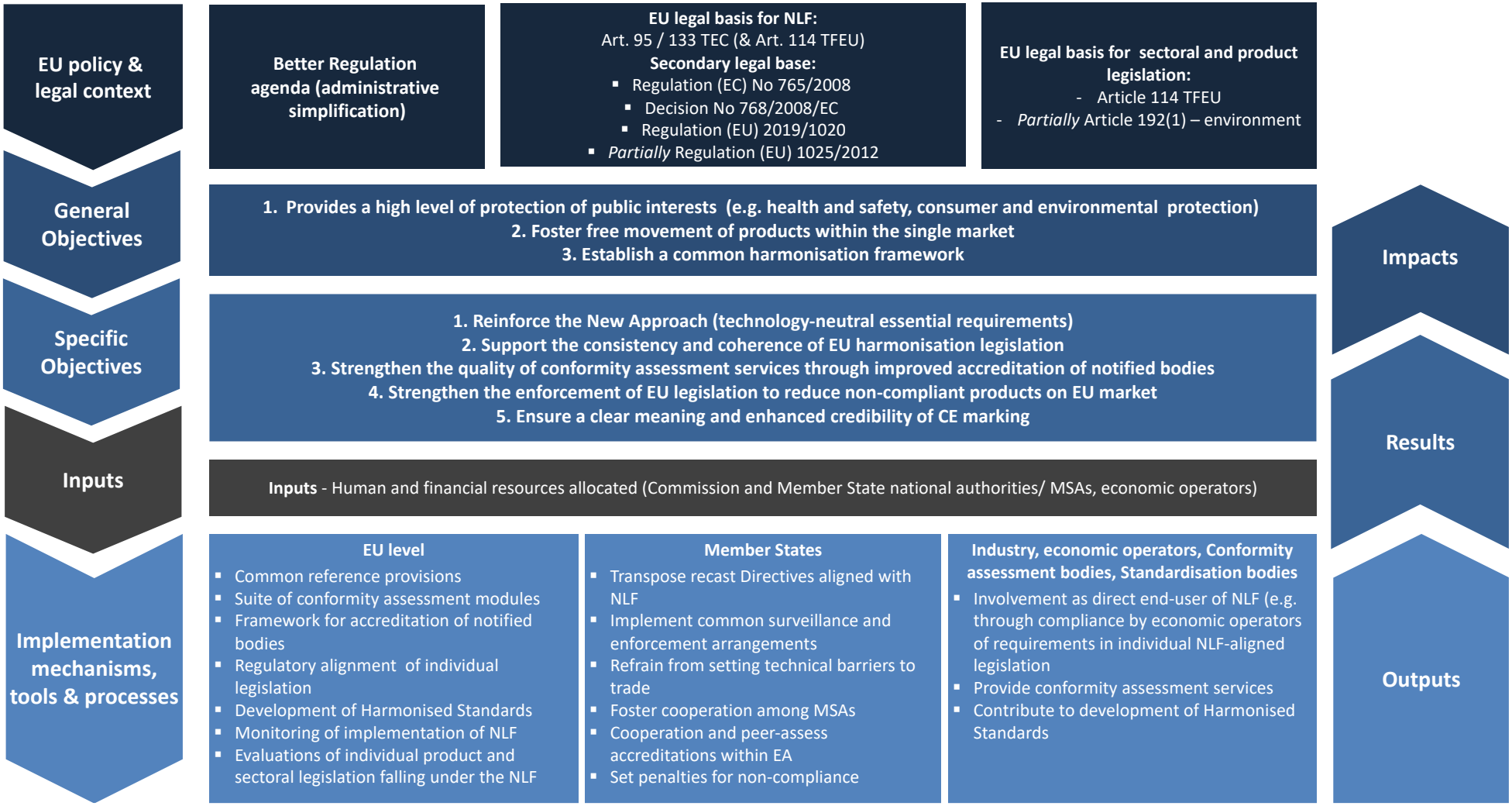
such as performing documentary, as well as physical and laboratory, checks on products and taking corrective action.

- **National competent authorities** are the Member State authorities responsible for the implementation of sector and product specific Union harmonisation legislation.
- **European authorities.** The Commission of the European Union plays a particularly important role in relation to the NLF. First and foremost, the Commission is the guardian of the EU Treaties. As for all EU primary and secondary legislation, the Commission therefore has responsibility for monitoring and ensuring the uniform application of Decision No 768/2008/EC and Regulation (EC) 765/2008, as well as all Union harmonisation legislation for products. However, the Commission also has a second role in relation to the NLF; the Commission and its policymakers are essentially end-users of the NLF, which provides a toolbox of regulatory measures to support policymakers in the development of sector and product specific Union harmonisation legislation and its alignment with the NLF.

In addition, **consumers and end-users of products**, although not subject to legal provisions within the context of the NLF, are important stakeholders. As detailed in Article 1 of Regulation (EC) No 765/2008, supported by Article 3 of Decision No 768/2008/EC, the NLF aims to contribute to providing a high level of protection of public interests, including the protection of consumers, health and safety in general and health and safety at the workplace. In this context, it is important to assess the impacts of the NLF on consumers and end-users.

The following figure provides a visual overview of the NLF's intervention logic, before it is detailed through the remainder of the chapter.

Figure 2-1: Intervention logic for the New Legislative Framework (NLF)



2.1 EU legal and policy context

Regarding the **legal context and scope of the mapping**, the logic diagram outlines both the **primary and secondary legal basis for regulatory intervention.** Regarding the primary legal base, the NLF was adopted in 2008 and is therefore based on Articles 95 and 133 TEC, as it pre-dated the adoption of the Treaty on the Functioning of the European Union (TFEU) in December 2009. However, it effectively draws on the same legal basis as other Union harmonisation legislation, but from the previous EU Treaty. Much of the recent updating of EU legislation to align Union harmonisation legislation with the NLF refers to Article 114 (ex-95) and Article 207 (ex-133) of the TFEU.

The **secondary pieces of legislation** concerned are Decision No 768/2008/EC, Regulation (EC) No 765/2008 and Regulation (EU) 2019/1020. Whilst evaluating market surveillance aspects of the NLF is outside the formal study scope, the fact that the NLF addresses market surveillance is mentioned in the figure for the purposes of completeness. The study focus will however be on assessing the appropriateness of the intervention logic of Decision No 768/2008/EC on a common framework for the marketing of products and Regulation (EC) No 765/2008 (but covering accreditation procedures only and excluding market surveillance). It can be noted that the Regulation has greater legal weight than the Decision.

Summaries of these secondary pieces of legislation are presented in the below table.

Table 2-1: Regulatory framework underpinning the NLF

Regulations and Decisions	Summary description of objectives
Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance of products	Strengthen the protection of public interests by reducing the number of non-compliant products on the EU Internal Market and ensuring a level playing field among economic operators. The Regulation also strengthened accreditation through the introduction of a new accreditation framework for notified bodies and through clarification of the use of CE marking.
Decision No 768/2008/EC on a common framework for the marketing of products	Defines a common framework for placing goods on the European market. Includes reference provisions to be incorporated whenever product legislation is revised. Provides a horizontal template to underpin the approach to the development of future product harmonisation legislation.
Regulation (EU) 2019/1020 on market surveillance and compliance of products *Outside the scope of this evaluation*	*In application since 16th July 2021.* Aims to improve market surveillance and compliance across all products subject to EU harmonisation legislation indicated in Annex I. In particular, the regulation sets the following requirements: **Online sales:** • Sales online are subject to surveillance when an economic operator directs its activities to a Member State market by any means. • Non-EU vendors are required to have a representative in the EU. • The fulfilment service provider becomes responsible when there is no representative in the EU. **Market surveillance:** • National authorities have been granted strengthened market surveillance powers. • The tasks of market surveillance are defined and powers, such as taking samples and imposing penalties, have been harmonised. • Market surveillance authorities (MSAs) may reclaim all cost of their activities in case of non-compliant products.

Regulations and Decisions	Summary description of objectives
	• A harmonised approach for surveillance at EU borders by customs and surveillance authorities has been adopted.

The broader **EU policy and legal context in which the NLF** was developed is also important to mention. This includes not only EU industrial policy-related interventions and goals, such as having an efficient and effectively functioning internal market in which European manufacturers and SMEs can thrive, but also the Better Regulation agenda. The rationale for putting in place the NLF was driven by the need to strengthen regulatory coherence across the body of Union harmonisation legislation, but also administrative simplification to promote efficiency savings for industry by removing inconsistencies and tackling incoherence between different pieces of EU harmonisation legislation that had emerged over time due to the growing body of such legislation.

Furthermore, given the NLF's broad and horizontal nature, it is important to highlight the legislative context beyond the above legislation. A total of 23 pieces of Union harmonisation legislation, comprising 16 Directives and 7 Regulations, have been aligned with the NLF, with reference to the provisions of Decision No 768/2008/EC. Moreover, the NLF interlinks to varying degrees with the following types of legislation:

- **Non-NLF-aligned product or sectoral legislation**, such as the Machinery Directive 2006/42/EC and the Outdoor Noise Directive 2000/14/EC.
- **Industrial and consumer policy-related horizontal legislation**, such as the General Product Safety Directive (GPSD) 2001/95/EC and the Product Liability Directive (PLD) 85/374/EEC.
- **Environmental legislation**, such as the Waste from Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU and the Ecodesign Directive 2009/125/EC.
- **Other relevant legislation**, such as the General Data Protection Regulation (EU) 2016/679, the Services Directive 2006/123/EC and the Occupational Health and Safety (OSH) Framework Directive 89/391/EEC.

The evaluation examines the interplay between the NLF and these pieces of legislation, as well as recent legislative proposals, such as the proposals for an AI Act, a Machinery Regulation, and a General Product Safety Regulation.

2.2 Needs and problems

In 2008, there were six key needs and problems facing the EU that the NLF sought to address. These included:

- Recognition that the **New Approach to (sectoral and product) harmonisation legislation** needed to be updated. Whilst the New Approach has been widely acknowledged in previous evaluation studies as having successfully supported the implementation of individual pieces of safety and other harmonisation legislation,[9] it was recognised by the Commission, as well as industry, market surveillance and broader stakeholders that the New Approach would benefit from modernisation and a more common and harmonised approach across the body of legislation. In particular, there was a need to strengthen the overall coherence and consistency of the legislation and eliminate any inconsistencies and duplication between different pieces of law.
- Need to **ensure the free movement of goods within the single market** in the most efficient and effective way. Having a horizontal framework setting out general principles and common

[9] See for example Evaluation of the LVD (2020), Evaluation of the Machinery Directive (2018), Evaluation of the EMCD (2021), among others.

reference provisions was seen as a means of helping to ensure greater commonality across different pieces of Union harmonisation legislation, such as to help facilitate, and to avoid hindering the free movement of goods. As such, the NLF addressed the identified need of removing obstacles to the free circulation of products.

- Gradual accretion of different pieces of harmonisation legislation applicable to products developed over a 30-year period, resulting in **inconsistencies in the administrative requirements between different pieces of legislation**. 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 to promote 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, market surveillance *per se* is outside the scope of this evaluation, as it was covered in a 2017 evaluation.[10]
- **Conformity assessment practices** in 2008 were perceived to be sub-optimal, with **insufficient attention across the EU Member States 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 seen as imperative.
- Need to **enhance the credibility of CE marking.** Whilst the CE marking was widely recognised internationally and had been a tremendous success in contributing to the development of the single market, industry stakeholders in previous evaluations of Union harmonisation legislation perceived that the CE marking was being undermined by low levels of full compliance with all the applicable EU legislation that allows the manufacturer to affix the CE marking in the first place, especially among some manufacturers in Asia.[11] Evidently, MSAs and customs authorities play a crucial role here, in that active and effective market surveillance and border controls help to detect instances of the misuse of CE marking, but clear rules related to CE marking were also important. Furthermore, the meaning of the CE marking indicated compliance rather than quality was reportedly not clear to consumers and end-users.

Within this context, many economic operators and industry stakeholders taking part in stakeholder consultations in previous evaluation studies perceived that there is a problem regarding high levels of non-compliant products being placed on the single market. This is perceived to undermine both the internal market itself and the level playing field between economic operators.

As mentioned above, the EU market for products has developed significantly since the NLF was adopted in 2008, resulting in the **emergence of new needs over time**. In this respect, key market trends include the ever-increasing digitalisation of products, the emergence and growth of the IoT market, the integration of AI and machine learning into products, changes in manufacturing value chains and the evolution of alternative means of production, as well as circular economy-related developments and the growth of e-commerce. These new needs are examined in more detail in Chapter 6, which examines the ongoing relevance of the NLF.

2.3 General and specific objectives

As the legal texts that comprise the NLF do not explicitly state the framework's objectives, the starting point in assessing the NLF's **general and specific objectives** was to map and analyse the general and

[10] See REFIT evaluation (SWD(2017) 469 final).

[11] See for instance the Evaluation of the Electromagnetic Compatibility Directive, 2021, Evaluation of the Low Voltage Directive, 2019.

specific objectives identified in the 2007 impact assessment study.[12] It was then necessary to review the legal texts of Regulation (EC) No 765/2008 and Decision No 768/2008/EC, respectively. The objectives, as interpreted by the evaluation team based on this review exercise and validated with the Commission, are outlined in the below box:

General objectives of the NLF

1. Provide a high level of protection of public interests (e.g. health and safety, consumer and environmental protection)
2. Foster the free movement of products within the single market
3. Establish a common harmonisation framework

Specific objectives of the NLF

1. Reinforce the New Approach (technology-neutral essential requirements)
2. Support the consistency and coherence of EU harmonisation legislation
3. Strengthen the quality of conformity assessment services through improved accreditation of notified bodies
4. Strengthen the efficiency / effectiveness of enforcement of EU harmonisation legislation to reduce non-compliant products on EU market
5. Ensure a clear meaning and enhanced credibility of CE marking

2.3.1 General objectives of the NLF

The **general objectives** have also been checked against the description of the subject matter of Regulation (EC) No 765/2008 and Decision No 768/2008/EC, respectively. General objectives 1 and 2 correspond to the high-level legal base established in primary legislation in the TFEU; namely, Article 114 (ex. Article 95 TEC) on harmonisation measures aimed at the establishment and functioning of the internal market and Article 207 (ex. Article 133 TEC) on common commercial policy based on uniform principles.

Within this context, the first general objective is to **provide a high level of protection of public interests** within the internal market (e.g. health and safety, consumer protection, environmental protection). This corresponds to Article 1(2) of Regulation (EC) No 765/2008, which states that among its central objectives are: to provide 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, the protection of the environment, and security.

The second general objective is to **foster the free movement of products within the single market** to allow businesses to operate more efficiently, increase competition in the marketplace and offer consumers a greater choice of goods and related services at lower prices. The NLF supports individual pieces of legislation by reinforcing efforts to ensure that the single market works effectively. Specifically, Regulation (EC) No 765/2008 (as noted in Recital 1) aims to **ensure that the free movement of products is not restricted to a greater extent than that already allowed under individual pieces of EU harmonisation legislation.** This supports the general objective of harmonising the conditions for the marketing of products at EU level. This is an important element of the NLF, as the reference provisions provided by Annex I to Decision No 768/2008/EC are meant to ensure that,

[12] See Commission Staff Working Document, SEC(2007) 173/2.

when revising existing, or designing new harmonisation legislation, EU regulators do not introduce any additional divergence (unless this can be justified due to product-specific risks).

The third general objective is to **harmonise the conditions for the marketing of products at EU level.** This objective stems from the legal base in Regulation (EC) No 765/2008, but is complemented by Decision No 768/2008/EC. It should be noted that individual pieces of sectoral legislation applicable to products foster the free movement of goods within the internal market, whereas the NLF provides a framework to ensure that EU regulators do not introduce any further requirements that would hinder the free movement of goods. It aims to achieve this, as indicated above, by providing a toolbox that defines the parameters in which the regulator should update existing, and design new legislation.

These general objectives broadly correspond to the objectives set out in individual pieces of sectoral legislation, which are derived from Art. 114 TFEU (ex. Art. 95 TEU). This is not surprising, given it is the same legal base, and given the need to ensure close alignment between the horizontal legal framework provided through the NLF, and individual pieces of Union harmonisation legislation. This aim is also largely shared with Directive 2001/95/EC on general product safety (the GPSD) that focuses on consumer protection for products not covered by individual pieces of sectoral legislation.

2.3.2 Specific objectives of the NLF

The **specific objectives** are more operational and, in turn, intended to support the achievement of the general objectives.

The first specific objective is to **reinforce the implementation of the New Approach principles**, such as setting technology-neutral essential requirements and leaving detailed technical aspects of implementation to the development of non-mandatory harmonised standards. It should be noted that the **New Approach** principles are not new, as they have been around since the 1990s. Rather, the NLF provides support to strengthen their implementation by ensuring that EU regulators do not diverge from these core principles, which underpin the entire body of legislation.

The second specific objective is to **strengthen the consistency and coherence of Union harmonisation legislation.** The NLF aims to facilitate the removal of inconsistencies, incoherence, and duplication between such EU legislation, which was often relatively minor at the level of individual Directives and Regulations, but which, when seen from the perspective of the cumulative body of legislation, was considerable.

The NLF is therefore intended to provide economic operators with a clear and consistent legal framework to ensure better overall coherence of EU legislation and to simplify its implementation. The regulatory toolbox established by the NLF to revise existing and develop new Union harmonisation legislation is linked to the overarching objective of Regulation (EC) No 765/2008; namely, to foster the efficient and effective functioning of the internal market for economic operators.

A third specific objective is to **strengthen the quality of conformity assessment services through the improved accreditation of notified bodies** and improving the monitoring of notified bodies by national authorities. A problem identified in the 2007 impact assessment was the trend that some conformity assessment services ostensibly delivered by notified bodies based in Europe were, in reality, provided by subcontractors in third countries. Furthermore, there was evidence of insufficient supervision and monitoring by national notifying authorities across the Member States, who were constrained in exercising their monitoring function, given their physical distance from where the services were being provided.

This was viewed as threatening to undermine the quality of the provision of such services and raising the question of unfair competition and a level playing field. Conformity assessment services in third countries are less subject to monitoring and scrutiny compared with the services of notified bodies being provided in a specific Member State, where the national authority can more easily carry out

monitoring activities to check the quality of services being delivered. The NLF was therefore designed to strengthen the monitoring of notified bodies by notifying authorities through the development of a new accreditation framework to ensure that notified bodies deliver high-quality services on a consistent basis. However, it should be noted that accreditation is not compulsory.

The fourth specific objective is 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, for instance by introducing more common arrangements for surveillance and enforcement across the EU-27. Whilst outside the scope of this evaluation study, this is a crucial element of the NLF.

The fifth specific objective is to **ensure a clear meaning and enhanced credibility of CE marking**. All products in certain categories – those for which EU-wide requirements exist and provide for CE marking – must carry the CE marking to be legally sold in the EU. The CE marking is the final stage in the conformity assessment process performed by manufacturers. It is affixed to the product and attests to the compliance of a manufacturer's product with the relevant essential requirements. For some products, conformity checks are carried out by conformity assessment bodies or notified bodies, which may be accredited or not. CE marking was not new in the NLF; rather, the NLF aimed to reinforce its importance, and enhanced its clarity. Looking ahead, the increasingly pervasive use of digital technologies in Europe raises issues regarding the possibilities for delivering product information, including product markings, in digital formats.

2.4 Implementation mechanisms, tools and activities

To implement the NLF, and to achieve its general and specific objectives, there are a range of different supporting implementation mechanisms, tools, and activities, including:

The **regulatory toolbox for the design of future Union harmonisation legislation.** An interesting feature of Decision No 768/2008/EC is that it is not addressed to the Member States. Instead, the Decision primarily targets EU regulators, as it provides common requirements and reference provisions that regulators must consider when recasting or revising existing and designing new Union harmonisation legislation. Whilst doing this, EU regulators need to ensure that legislation is lean and flexible, involving tools such as the use of harmonised standards to confer presumption of conformity for the free circulation of goods in the EU/EEA market.

More specifically, the regulatory toolbox includes: the suite of conformity assessment modules from which the regulator can select the most appropriate modules for their specific piece of sectoral legislation; reference provisions related to product conformity; a set of common definitions, including of economic operators; a set of general common obligations for economic operators; as well as reference provisions related to the notification of conformity assessment bodies and the requirements for national notifying authorities and notified bodies. This is supported by harmonised conformity assessment tools for use in all NLF-aligned legislation, such as the technical file, the Declaration of Conformity (DoC), and CE marking arrangements.

In the first instance, the **toolbox supports the activity of legislative alignment implemented by the European Commission**. However, the resulting inclusion of these elements in specific Union harmonisation legislation also supports the implementation of key activities related to the notification of conformity assessment bodies, such as the establishment of national notifying authorities and the activities they conduct, and the provision of conformity assessment services.

The **common framework for accreditation** detailed in Regulation (EC) No 765/2008 complements the abovementioned toolbox and activities, forming a crucial dimension of the European conformity assessment system. Accreditation aims to ensure that conformity assessment bodies (e.g. laboratories, inspection or certification bodies), including those that are notified as notified bodies,

have the necessary competence, technical capacity and resources to perform conformity assessment services and assess the compliance of products with the essential requirements contained in Union harmonisation legislation. The common accreditation framework was designed to increase trust in conformity assessment by supporting the implementation of key activities, including the:

- Establishment of national accreditation bodies and the activities they conduct.
- Recognition and funding of a European accreditation body (see Articles 14 and 32-33, Regulation (EC) No 765/2008) – namely, the European co-operation for Accreditation (EA). The aim of EA is to support national accreditation bodies and the accreditation framework through the implementation of peer evaluation activities (Articles 10-11, Regulation (EC) No 765/2008), sectoral accreditation schemes, and other support.

Harmonised standards are another important tool within the NLF system that support the implementation of individual pieces of Union harmonisation legislation. Whilst their use is generally non-mandatory under NLF-aligned legislation,[13] the NLF advocates, in line with the New Approach, that legislation should be kept high-level and confined to essential requirements on the basis that harmonised standards provide the detailed technical specifications through which economic operators can achieve compliance with the essential requirements. Therefore, the use of harmonised standards contributes to the specific objective of ensuring that products on the market covered by Union harmonisation legislation fulfil the essential requirements. Moreover, their use contributes to a further objective, which is to allow for technological evolution, innovation, and the take-up of the latest 'state of the art', as the NLF requires that only essential requirements should be set in line with the objective of technology-neutral legislation. Harmonised standards in the EU have a specific legal feature: when their references are cited in the *Official Journal of the European Union* (OJEU), their use confers presumption of conformity of the concerned product with the legal requirements of the directive or regulation the harmonised standard aims to cover. As such, the development of harmonised standards is also a key activity linked to the NLF.

There are also **further tools**, such as common arrangements for CE marking, not mentioned in the intervention logic mapping that form part of the overall NLF, some of which are not directly within study scope. Examples are achieving consistent, transparent and effective enforcement / compliance by enhancing cooperation between relevant actors involved in checking CE marking and compliance with the essential requirements (e.g. CABs), and promoting a more uniform approach to compliance through closer cooperation between MSAs across the EU-27 (and between MSAs and customs authorities). Such activities should contribute to enhancing the credibility of CE marking.

Last, as part of the overall implementation of the NLF, the provisions on the **monitoring and evaluation** of the legal framework (Article 36, Regulation (EC) No 765/2008) and the related activities are important. These rules stipulate that the relevance of the conformity assessment, accreditation, and market surveillance activities the receive EU funding shall be evaluated by 1 January 2013 and every five years thereafter.

2.5 Outputs, results, and impacts

The implementation of the NLF's activities (described in the previous sub-section) are expected to produce a range of effects that contribute towards the achievement of the NLF's general and specific objectives. The effects can be further disaggregated into **outputs, results,** and **impacts**. Examples of the types of outputs, results, and impacts that are expected are now provided.

[13] The mandatory use of harmonised standards is foreseen in a limited number of NLF-aligned legislation; namely the Construction Products Regulation and the Regulations on Medical Devices and on *In Vitro* Diagnostic Medical Devices.

Outputs are the **immediate and short-term outcomes** that the NLF's activities might be expected to produce or contribute towards. These could include relatively easily measurable indicators, such as:

- Number of pieces of product legislation (directives and regulations) that have been aligned with the NLF.
- Number of pieces of product legislation (directives and regulations) that have not been aligned, but could have been aligned, with the NLF.
- Number of pieces of product legislation (directives and regulations) that have been aligned with the NLF, but nonetheless present divergences from the NLF.

The assessment of the latter bullet will also include proposed new legislation, such as the proposal for a Machinery Regulation, the proposal for a GPSR and the proposal for an AI Act, which have introduced new elements that may have implications for how the NLF could be updated in future to reflect digitalisation and circular economy-related developments (e.g. changes to products post market placement, increasing remanufacturing and refurbishment).

Divergences are, in theory, negative from the point of view of what the NLF is seeking to achieve as a horizontal legal framework designed to strengthen the coherence and consistency of EU legislation. However, divergence may be necessary in certain cases; for instance, in case of specific sectoral needs or if there are technological trends and developments with implications for key concepts in the legal regime.

Other **relevant outputs resulting directly or indirectly from the activities of the NLF** could include:

- Use of different conformity assessment modules across NLF-aligned legislation.
- Number of EA outputs produced, such as the number of peer evaluations conducted, publications and guidance documents produced and cooperation activities.
- Number of national accreditation bodies recognised.
- Number of accredited conformity assessment bodies.
- Number of notifying authorities, by Member State and by legislation.
- Number of notified bodies, by Member State and by legislation.
- Number of cooperation and monitoring activities implemented (e.g. expert groups, notified body groups).
- Number of evaluations and other studies conducted.

Results, which represent intermediate outcomes that are linked to the achievement of the NLF's **specific objectives,** might include:

- Continued implementation of the principle of technological neutrality.
- More harmonised approach to marketing products on the single market, covering definitions and obligations of economic operators, as well as rules on CE marking, conformity assessment and notification.
- Simplification of administrative compliance with Union harmonisation legislation and related cost savings.
- Greater levels of compliance with the essential requirements stated in Union harmonisation legislation.
- Improved consumer trust.
- More level playing field across the single market.

- Greater coherence and consistency of the criteria and procedures for the accreditation of CABs and the notification of NBs.
- Improved quality and consistency of conformity assessment services provided by CABs and NBs.
- Enhanced credibility of the CE marking.

Turning to **impacts,** the higher-level objectives in Regulation (EC) No 765/2008, along with the common reference provisions included in the NLF (Decision No 768/2008/EC), aim to achieve or contribute to a range of longer-term impacts and outcomes. These include:

- Strengthened protection of public interests (e.g. health and safety, including at the workplace, consumer and environmental protection).
- Improvements in the effectiveness of the internal market for goods through the removal of market barriers.
- More consistent and coherent Union harmonisation legislation.
- Increased simplification in the implementation of Union harmonisation legislation across the body of product legislation.

In addition to these anticipated impacts, the NLF could also:

- Facilitate EU industrial competitiveness.
- Facilitate innovation by European industry.
- Enhance the standing of the EU regulatory approach in global commerce.

Furthermore, outside the scope of this evaluation, results and impacts that the NLF could contribute to include: improved coordination and effectiveness of market surveillance and enforcement at an EU level in respect of Union harmonisation legislation; and the timely availability of harmonised standards.[14]

The outputs achieved by the NLF since its adoption are further examined in Chapter 3, before the assessments on the NLF's effectiveness and efficiency are presented in Chapter 4.

[14] Whilst harmonised standards are developed by the ESOs on the basis of specific requests by the Commission, as they are a tool to help deliver the NLF's regulatory objectives, their timely availability and citation in the OJEU is a central issue from an industry perspective.

3. How has the situation evolved over the evaluation period?

This chapter first presents the **state of play in the implementation of the NLF**, focusing on the concrete outputs achieved, before detailing key **market and regulatory developments** that are relevant to the evaluative assessments of the NLF presented in the subsequent chapters.

3.1 Implementation of the NLF

In line with the NLF's intervention logic, presented in Chapter 2, the **main outputs of the NLF** to date are presented in this section. The presentation of the NLF's outputs is structured by the main specific objectives; namely:

- Supporting the consistency and coherence of EU harmonisation legislation through the process of legislative alignment and reinforcing the New Approach principles (Chapter 3.1.1.1).
- Strengthening the quality of conformity assessment services through improved accreditation of notified bodies (Chapter 3.1.1.2).
- Ensuring a clear meaning and enhanced credibility of CE marking (Chapter 3.1.1.3).

3.1.1.1 Legislative alignment to the NLF & the New Approach principles

The alignment of directives and regulations falling under Union harmonisation legislation with the common framework provided by the NLF. To date, a total of 23 pieces of EU law, comprising 16 Directives and 7 Regulations, have been recast or revised to improve alignment with the NLF. The following table presents an overview of these laws:

Table 3-1: Summary of harmonised EU product legislation aligned with the NLF

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

EU Legislation	Description
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

Source: *European Commission's DG GROW.*

Note ** *– Conformity assessment in construction product legislation does not follow Decision No 768/2008/EC and harmonised standards in support of the Construction Products Regulation (CPR) are mandatory; although the legislation does make provision for CE marking. This discrepancy is a source of current challenges in application that the upcoming revision of the CPR aims to resolve.*

Certain general trends in the alignment process can be observed.

- Whilst directives remain more common than regulations, there has been a growing trend in the past ten years towards the increased use of regulations over directives. This primarily reflects the fact that, as regulations are directly applicable and do not need to be transposed into national law by the Member States, industry has a general preference for regulations, as there is less scope for ambiguity and divergence in interpretation and implementation. Examples of pieces of EU harmonisation law that were converted from directives to regulations when they were revised include the Construction Products Regulation, the Regulations on Medical Devices and on *In Vitro* Diagnostic Medical Devices and the Gas Appliances Regulation, among others. In addition, the proposal for a Machinery Regulation, published in April 2021, aims to replace the Machinery Directive and continue this trend.
- A small number of 'New Approach' directives, as well as directives which are based on certain elements of the New Approach,[15] have not been aligned to the NLF. In some cases, the pre-NLF versions of these laws are still in force (i.e. Council Directive 92/42/EEC on hot water boilers; Directive 2000/14/EC relating to noise emission; Directive 2000/55/EC on energy efficiency requirements for ballasts for fluorescent lighting; and Directive 96/62/EC on packaging and packaging waste). Other laws have been repealed and replaced since the adoption of the NLF without formal alignment to the NLF (e.g. Directive 2009/125/EC on ecodesign requirements; Regulation (EU) 2019/2019 on ecodesign requirements for refrigerating appliances; and Directives (EU) 2016/797 and 2016/798 relating to rail interoperability and rail safety, respectively). In addition, although the Machinery Directive is not formally aligned to the NLF, as it was adopted before the NLF, its provisions are very similar and the recent proposal for a Machinery Regulation does envisage formal alignment. Furthermore, three laws that were not characterised as New Approach directives have been aligned to the NLF, thereby widening the scope of the regulatory approach; namely, the Directives on the Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Pyrotechnic Articles, and the Regulation on EU Fertilising Products.
- In addition to the non-alignment of certain 'New Approach' directives, a range of other sectoral Union harmonisation legislation has not been aligned to the NLF, including (non-exhaustive): Directive 2012/19/EU on waste electrical and electronic equipment (WEEE); Regulation (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery; and Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers.
- Across all NLF-aligned legislation, the influence of the reference provisions for community harmonisation legislation for products stipulated in Annex I to Decision No 768/2008/EC on the

[15] Based on the list of directives included in Annex II of the Impact Assessment 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).

revised or recast laws is clear. As illustrated in the mapping of NLF-aligned legislation presented in Annex 7 to this report, and discussed in greater detail in Chapter 4.1.1.1, aligned legislation, for the most part, strongly reflects the content and structure of the common reference provisions.

- There are a small number of implementation differences across the alignment process that have resulted from a range of market and regulatory developments, as discussed further below. These differences do not necessarily result in divergent provisions across the body of NLF-aligned legislation, but amend how and where certain provisions are incorporated legally by these laws. More specifically, they include: how NLF-aligned laws incorporate the reference provisions relating to rules on ensuring the correct application of the regime governing the CE marking and providing for infringements – Article R12(4); the inclusion of references to the possibility of products being subject to multiple laws; and specific provisions on formal objections to standards.

To further support the alignment process and improve harmonisation across the legal framework, the Guide to the implementation of directives based on the New Approach and Global Approach (the 'Blue Guide'), published in 2000, was updated in 2016. The updated 'Blue Guide'[16] noted that, although much of the 2000 edition remains valid, the guide needed to be updated to cover new developments (such as the changes introduced by the Lisbon Treaty) and ensure a common understanding on the implementation of the NLF. More specifically, the updated guide included new text on the obligations of economic operators and on accreditation, and revised text on standardisation and market surveillance.

Considering relevant **monitoring and evaluation activities**, an evaluation of internal market legislation for industrial products was conducted in 2014. Although an aim of this evaluation was to take stock of progress being made through the NLF, it was conducted at a time: a small number of industrial product laws had been aligned to the NLF (e.g. those recast between 2009-2012); others were subject to ongoing legislative initiatives (e.g. on Pressure equipment, and Cableway installations); and many others were yet to be aligned. As such, the scope of the evaluation was overarching and broad in nature, covering many New Approach directives, but also excluding some recently aligned NLF laws (e.g. Construction Products Regulation, Medical Devices Regulation). 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'.[17]

Beyond this overarching evaluation, the market surveillance aspects of Regulation (EC) No 765/2008 were subject to a REFIT evaluation in 2017, which ultimately led to the adoption of Regulation (EU) 2019/1020.[18] As a result, these aspects are out of scope for this evaluation.

Monitoring and evaluation activities have also been conducted in relation to specific NLF-aligned legislation. These include the 2020 evaluation of the Toy Safety Directive 2009/48/EU, the 2021 evaluation of the RoHS Directive 2011/65/EU and the 2019 evaluation of the Low Voltage Directive 2014/35/EU.

3.1.1.2 Conformity assessment system and accreditation framework

Moving to the **conformity assessment system and the accreditation framework**, the key developments include the establishment and recognition of the European cooperation for

[16] The 'Blue Guide' on the implementation of EU products rules 2016, (2016/C 272/01).
[17] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'A vision for the internal market for industrial products', COM(2014) 25 final.
[18] REFIT evaluation of the application of the market surveillance provisions of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

Accreditation (EA) as the body recognised under Article 14 of Regulation (EC) No 765/2008; the allocation of national responsibilities for accreditation and notification of CABs; and implementation of activities related to the accreditation and notification of CABs.

According to Regulation (EC) No 765/2008, **EA** should: provide its members (national accreditation bodies) with peer evaluation services satisfying Articles 10 and 11; and cooperate with the Commission in concluding a public agreement on its specifications and requests stemming from Article 13, 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.[19] This agreement aimed to strengthen cooperation on accreditation and "stabilise the position of accreditation [and] accreditation bodies in EU and EFTA Member States"[20]. 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.

EA currently has **49 NAB members** covering the EU-27, EEA-EFTA countries and third countries, and has implemented the following key activities:

- Implementing the **peer evaluation system**. In this respect, EA has developed a procedure for the evaluation of NABs; the most recent version was approved in July 2019.[21] The following table presents data related to the peer evaluations conducted in the period 2015-2020. As can be seen, EA has performed a total of 94 peer evaluations over the six-year period. However, given the geographical membership of EA has expanded over the years, it is not clear the extent to which these peer evaluations relate to EU Member States and EEA-EFTA countries.

Table 3-2: Overview of peer evaluations conducted in 2015-2020[22]

	2015	2016	2017	2018	2019	2020	Total
Total number of evaluations performed [23]	10	19	18	18	16	13*	**94**
Total number of reports discussed [24]	10	9	21	14	17	31**	**102**
Total man-days for evaluation	583	1,138	1,080	1,393	935	353**	**5,482**

***** 13 evaluations, out of which only 8 document review for the peer evaluations were postponed to 2021.
****** 31 reports, out of which 18 were related to transition to ISO/IEC 17011:2017
******* Includes also the man-days for the participation of EA evaluators in IAF/ILAC evaluations

- **Publication of accreditation guidance and mandatory procedural documents**. Since its inception, EA has published a wide range of mandatory, guidance and informative documents to support its members. Recent examples from 2020 include: the guidance document on Consultancy, and the Independence of CABs[25]; the document listing the risks of accreditation processes and operation of NABs[26]; and the document on Accreditation for Notification Purposes[27].

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52009XC0521%2804%29
[20] European Accreditation (EA). (2019). EA MLA Report 2019.
[21] https://european-accreditation.org/publications/ea-2-02/
[22] See: European Accreditation (EA). (2019). EA MLA Report 2019; and https://european-accreditation.org/mutual-recognition/peer-evaluation/
[23] Includes initial evaluations, re-evaluations with or without scope extensions and extraordinary evaluations (performed on site in the specific year).
[24] Reports of evaluations, but not necessarily conducted in the specific year.
[25] https://european-accreditation.org/publications/ea-2-20/
[26] https://european-accreditation.org/publications/ea-2-19/
[27] https://european-accreditation.org/wp-content/uploads/2018/10/ea-2-17-m.pdf

- **Cooperation activities**. Beyond its collaborations with the Commission, EA cooperates closely with the ESOs (CEN-CENELEC and ETSI) and the European Association of National Metrology Institutes (EURAMET) at the European level, as well as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) at the international level.

In addition, EA maintains data on the **number of accredited CABs** across a range of accreditation types. Although the number of CABs notified in the Member States is clearly documented through the Commission's New Approach Notified and Designated Organisations (NANDO) database (see data below), the number of CABs accredited in the EU is more difficult to assess, as no publicly available data presents disaggregation by region or country. As such, no figures for the EU market are available. At the level of all EA members, however, more than 36,758 accreditations were delivered in 2020 across 10 accreditation types (including calibration, testing, inspection, and medical examinations). This figure has risen by 37% since 2013.[28]

Table 3-3: Total number of accreditations across all EA members in 2020, by type

Accreditation type	Number of accreditations
Testing	18,833
Inspection	6,089
Medical examinations	3,910
Calibration	3,258
Products Certification	2,026
Management Systems Certification	1,453
Persons Certification	748
Proficiency Testing Providers	219
Greenhouse Gas Validation & Verification	155
Reference Material Producers	67

Beyond the work of EA, a range of other **bodies and authorities have been appointed and established within the context of the NLF**. These are summarised here:

- **Appointment of national accreditation bodies** under the NLF. Although in many cases these organisations 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.
- **Establishment of national notifying authorities**. Across the body of NLF-aligned legislation, 160 notifying authorities are in operation,[29] with 139 based across the EU-27, 12 in the EEA-EFTA countries[30] and nine spanning seven third countries[31]. These notifying authorities may have responsibility for one or multiple NLF-aligned laws. In terms of coverage:
  - **Coverage by Member State:** Not all Member States have notifying authorities for each of the 21 NLF-aligned legislation for which notification of CABs is relevant.[32] 25 countries have established notifying authorities for most NLF-aligned laws (between 17 and 21); the exceptions are Cyprus, which covers 13 of the 21 relevant NLF-aligned laws, and Malta, which only covers eight. In some instances, Member States have multiple notifying authorities with

[28] https://european-accreditation.org/mutual-recognition/peer-evaluation/

[29] *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).

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

[31] 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.

[32] 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.

responsibility for one NLF-aligned law. For example, in Poland, both the Ministry of Economic, Development, Labor and Technology and the Ministry of Infrastructure have responsibility for the Transportable Pressure Equipment Directive.

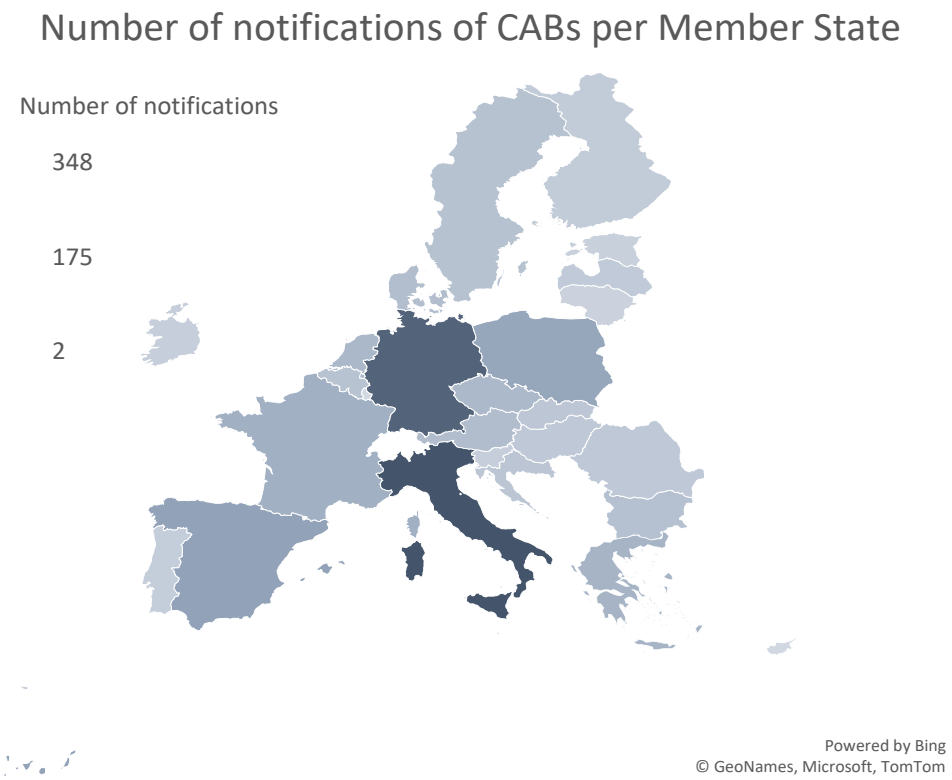
  - **Coverage by NLF-aligned law:** The Toy Safety Directive and the Construction Products Directive are the only laws with a notifying authority in all 27 EU Member States. Most NLF-aligned laws are covered in most Member States (between 24-27 countries); the remaining laws are the Marine Equipment Directive (23 Member States), the Radio Equipment Directive (22), the Civil Explosives Directive (21) and the Cableway Installations Regulation (18).

- **Notification of an estimated 1,649 individual NBs across the 21 relevant NLF-aligned laws** (as of November 2021). The vast majority (1,489) 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 (131); these NBs account for 1.7% (40) and 7.7% (186) of the total notifications, respectively. 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.

  Considering notifications across the different NLF-aligned laws by EU Member States, 54% of the notifications related to three laws; 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). Beyond these three laws, the highest number of notifications for a single law is 175 (8% – Transportable Pressure Equipment Directive). The laws with the fewest notifications at the time of analysis are the EU Fertilising Products Regulation (1 notification) and the *In vitro* Diagnostic Medical Devices Regulation (6 notifications).[33]

[33] *NB* Since the data was extracted for analysis in November 2021, the number of notifications under the EU Fertilising Products Regulation has risen to three.

Figure 3-1: Number of notifications of CABs per Member State



3.1.2 CE marking and other information obligations

The **NLF introduced specific legislative provisions on CE marking** within Regulation (EC) No 765/2008. These legal provisions state, *inter alia*, that the "*CE marking shall be affixed only by the manufacturer or his authorised representative*" and that the "*CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant [Union] harmonisation legislation providing for its affixing*".

These general principles are further supplemented by:

- Annex II to Regulation (EC) No 765/2008, which provides the requirements for the CE marking itself; and
- Annex I to Decision No 768/2008/EC, which provides 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 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.[34] As summarised in the 2017 report on the implementation of Regulation (EC) No 765/2008, 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

[34] Commission staff working document SWD(2014)23 on the evaluation of the internal market legislation for industrial products, accompanying Communication COM(2014)25 on a vision for the internal market for industrial products

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"[35].

The legal mapping conducted for this evaluation found that the reference provisions on CE marking are largely implemented in specific NLF-aligned legislation with limited amendments. However, **product markings** other than the CE mark are used in certain NLF-aligned laws (e.g. the 'Wheel mark' under the Marine Equipment Directive, and the 'Pi marking' under the Transportable Pressure Equipment Directive); and **additional markings and inscriptions** are required across some NLF-aligned laws (e.g. under the Construction Products Regulation, manufacturers are required to add the two last digits of the year in which the CE mark was first affixed).

3.2 Market developments and trends impacting the NLF

Since the NLF was adopted in 2008, the European market for industrial products has developed and changed in ways that introduce new NLF-relevant needs and may challenge the fitness for purpose of the framework. These new needs result from changes to products and production practices in line with the ongoing digital and green transitions being undertaken by industry.

The growing importance of the **digital economy** has already had a significant impact on product markets, bringing challenges to the legal concepts and provisions of specific product legislation and the NLF:

- **Placing a good on the market.** Products are increasingly subject to changes post market placement, whether as a result of software updates and upgrades, which are common to digital products for several years after their placement on the market, or the impact of new technologies, such as AI and machine learning being integrated into products. Common rules for the marketing of products may therefore need to be reviewed to consider the implications of changes to the concept of placing on the market that recognises the tendency for changes to occur to products post-market placement.
- **Cybersecurity.** Many internet-connected or smart products exist in a complex ecosystem of interacting products. This complexity, as well as the integration of internet-connectivity across a broad range of products, brings new and enhanced cybersecurity (including privacy) risks. As such, questions exist regarding how the current framework deals with the relationship between product safety (a key objective of the NLF and its aligned product legislation) and security, and thus the issue of cybersecurity.
- **Complex value chains.** Changes in manufacturing value chains and the emergence of alternative means of production, such as 3-D printing, bring challenges related to how clear the divisions of responsibilities are within value chains. For instance, there are issues regarding the appropriate distribution of obligations across digital value chains. In the context of complex digital products, there is an issue as to who is the manufacturer and more broadly, how to deal with the possible division of roles in the design and development phases of products that are dependent on embedded or third-party software and / or applications to operate.
- **Servitisation.** Linked to the above challenges, the dividing line between products and services has become increasingly blurred. For instance, as highlighted above, software-driven products are consistently being maintained throughout their lifetime by the updates and upgrades published by manufacturers and software developers. Furthermore, products and related services are increasingly being marketed alongside one another. This brings challenges to the distinctions in

[35] 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.

Union legislation between products and services.

- **E-commerce.** The primary challenges related to e-commerce are related to: i) market surveillance, concerning non-compliant goods being sold on the Union market by third country producers; and ii) equal treatment of products sold online and offline. Although market surveillance aspects are outside the scope of this evaluation, the impact of this market trend raises additional questions for the framework as a whole, related to the definitions of economic operators and their obligations under the NLF (for instance, on traceability).

Likewise, there are potential challenges related to the impact of the **circular economy** on the ongoing fitness for purpose of the NLF. For instance, the trend towards more sustainable approaches to product usage, including the growing roles of repairers, refurbishers and remanufacturers call into question issues such as whether changes made to products post market placement involve substantial modifications, and therefore effectively require the product to be placed on the market once more, or whether a lighter regulatory regime for such products would be appropriate.

Moreover, product shortages experienced during the first phases of the **COVID-19 pandemic** raised questions as to whether the conformity assessment system implemented by the NLF was adequate for crisis situations.

However, beyond the challenges brought by these market developments, there are also **opportunities and positive impacts** that are important to note. For instance, this includes the possibilities related to enhancing the legal framework for products through the adoption and use of digital technologies. This has various dimensions, including moving from physical hard copies to e-labelling, digitalised communication and product information to ensure strengthened traceability of the responsible economic operator within value chains using digitalisation (including the possible future role of digital passports), all aspects that require acceptance by Market Surveillance Authorities (MSAs).

In addition, the importance and standing of the conformity assessment system implemented by the NLF, and the key role played by CABs, has resulted in significant growth in the testing, inspection, and certification industry. According to an analysis of the Testing, Inspection and Certification (TIC) industry commissioned by the TIC Council, the European TIC market is the largest globally, estimated to be worth a third of the global market in 2017 (around USD 67 billion / EUR 60 bn).[36] Furthermore, this analysis forecasted that the European market would increase to around USD 71 bn by the end of 2020 (around EUR 64 bn) and to USD 85-98 bn by the end of 2024 (EUR 76-87 bn). Although this analysis included TIC activities outside the scope of the NLF (e.g. on food safety), it illustrates the importance of the market and its growth in recent years.

3.3 Regulatory developments impacting the NLF

Alongside the alignment of Union harmonisation legislation with the NLF (as detailed in Chapter 4.1.1), the **wider EU legal framework for industrial products has also been subject to important developments since the adoption of the NLF**. Most prominently, concerning EU primary law, the Treaty of Lisbon entered into force in December 2009, changing the primary legal base referred to by NLF-aligned legislation from Article 95 TEC to Article 114 TFEU.

In addition to this amendment of EU primary law, the last few years has seen **developments in EU secondary law** related to the question of how the wider EU legal framework addresses the challenges of the market and industry trends highlighted above. Although these developments are further detailed elsewhere in this report, this chapter presents an overview of key developments:

- **Adoption of an updated legal framework on European standardisation.** Regulation (EU) No 1025/2012 was adopted in October 2012. It aimed to simplify and adapt the legal framework for

[36] Based on an exchange rate of 1 USD = 0.89 EUR.

European standardisation to cover emerging developments in the field and potential future challenges; namely "the increased development of standards for services and the evolution of standardisation deliverables other than formal standards". One change of key relevance to the implementation of the NLF was the move from *ex-post* control of standards (i.e. through a Formal Objection) to *ex-ante* control.[37] As discussed further in Chapter 6, the changes to the standardisation approach have resulted in practical implementation problems across the body of NLF-aligned legislation.

- **Adoption of an updated legal framework for market surveillance.** Following the 2017 REFIT evaluation noted earlier, the market surveillance aspects of Regulation (EC) No 765/2008 were amended through the adoption of Regulation (EU) 2019/1020. A key objective of the updated Regulation was to address the challenges of increasingly complex supply chains and increasing direct to consumer e-commerce sales. For that purpose, the Regulation introduced the concept of a responsible person in the EU. More specifically, Article 4 of Regulation (EU) 2019/1020 stipulates that products subject to the three regulations and 15 directives listed can only be placed on the EU market if there is an economic operator established in the Union, who takes on responsibility for certain tasks, including verifying and maintaining the DoC and cooperating with MSAs. In practice, this has increased the prominence of the role played by authorised representatives across the body of Union harmonisation legislation and introduced 'fulfilment service providers' as a new type of economic operator. Although market surveillance activities are out of scope of this evaluation, the introduction of new economic operators and increased obligations to the wider legal framework are relevant to the performance of the NLF.
- **Delegated Regulation supplementing the Radio Equipment Directive (RED) 2014/53/EU.** When first adopted, Article 3(3) of the RED provided the Commission with the possibility of adopting delegated acts to enact additional essential requirements beyond those stipulated in Article 3(1) and 3(2). This included the possibility to enact additional essential requirements listed in the Article. In 2021, following the completion of related impact assessment studies, the Commission adopted the Delegated Regulation supplementing Directive 2014/53/EU with regard to the application of essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive.[38] In particular, these essential requirements focus on improving the cybersecurity of products (namely wireless devices) subject to the RED by ensuring network resilience, better protecting consumers' privacy and improving protection against fraud.[39] This development highlights the importance of considering product (cyber)security alongside product safety, which is core to the NLF.
- **Proposal for a Regulation on machinery products**[40] to replace the Machinery Directive 2006/42/EC. The proposal, published in April 2021, aims to address challenges stemming from the market developments detailed above, including: i) new risks originating from emerging technologies (such as connected machinery and human-robot collaboration); ii) legal uncertainty regarding the scope and definitions of the legislation (including relating to the concept of a 'substantial modification'); iii) insufficient provisions for high-risk machines (including machinery embedding AI systems); iv) monetary and environmental costs due to paper-based documentation; and v) non-alignment with the NLF. As such, this proposal has high relevance for this evaluation of the NLF.
- **Proposal for a Regulation on general product safety (GPSR)**, repealing the current General Product Safety Directive (GPSD) 2001/95/EC. As for the Machinery Regulation proposal, the

[37] Call for expression of interest for Harmonised Standards (HAS) Consultants.
[38] Commission Delegated Regulation (EU) of 29.10.2021 supplementing Directive 2014/53/EU of the European Parliament and of the Council with regard to the application of the essential requirements referred to in Article 3(3), points (d), (e) and (f), of that Directive.
[39] https://ec.europa.eu/commission/presscorner/detail/en/IP_21_5634
[40] https://ec.europa.eu/docsroom/documents/45508

proposal for a GPSR, published in June 2021, aims to update and modernise the product safety framework for non-harmonised products to address digital challenges. In particular, this includes proposed provisions supporting the rules in the Market Surveillance Regulation on responsible persons and fulfilment service providers, and introduces the concept of substantial modification; both of which are highly relevant to the NLF. The GPSR also introduces obligations for online marketplaces, traceability obligations for distance sales and accident reporting for all products, including products subject to UHL, as these aspect are not currently covered by the NLF.

- **Proposal for a Regulation laying down harmonised rules on Artificial Intelligence** (AI), the AI Act. Published in April 2021, the proposed AI Act aims to: i) facilitate the realisation of the many benefits associated with the adoption of AI technologies; while ii) ensuring the EU legal framework provides protection against the new risks or negative consequences AI technologies can bring for individuals and society. As the AI Act would become part of the body of Union harmonisation legislation and stipulate conformity assessment requirements for high-risk AI systems, it is important to ensure coherence and consistency with the NLF. This is illustrated most clearly in Recital 52, which states that "As part of Union harmonisation legislation, rules applicable to the placing on the market, putting into service and use of high-risk AI systems should be laid down consistently with [the NLF]".

In addition, further policy and legal developments, such as the Product Liability Directive, the Cybersecurity Act[41] and Cyber Resilience Act, the proposed Digital Services Act[42], the Circular Economy Action Plan, and commitments on the adoption of digital labelling practices, ensure that the NLF operates in a complex environment. This environment and its impact on the NLF's coherence and fitness for purpose is examined further in Chapters 4.3 and 6, respectively.

[41] Regulation (EU) 2019/881 on ENISA (the European Union Agency for Cybersecurity) and on information and communication technology cybersecurity certification.
[42] Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC.

4. To what extent was the NLF successful and why?

Building on the analysis of the NLF's intervention logic, this chapter presents the findings from the assessments of the **effectiveness (Chapter 4.1), efficiency (Chapter 4.2) and coherence (Chapter 4.3) criteria**, thereby answering the question: to what extent was the intervention successful and why?

4.1 Effectiveness

The assessment of the effectiveness criterion examines the **extent to which the NLF has achieved its general and specific objectives**, based on an analysis of its effects (i.e. outputs, results and impacts). As detailed in Chapter 2.3, the NLF's general and specific objectives are **not explicitly documented in the legal text**; however, they have been interpreted as follows:

- **General objectives of the NLF:**
  - **General objective 1:** Provides a high level of protection of public interests (e.g. health and safety, consumer and environmental protection).
  - **General objective 2:** Foster the free movement of products within the single market.
  - **General objective 3:** Establish a common harmonisation framework.
- **Specific objectives of the NLF:**
  - **Specific objective 1:** Reinforce the New Approach (technology-neutral essential requirements and risk-based conformity assessment procedures supported by the use of harmonised standards).
  - **Specific objective 2:** Support the consistency and coherence of EU harmonisation legislation.
  - **Specific objective 3:** Strengthen the quality of conformity assessment services through improved accreditation of notified bodies.
  - **Specific objective 4:** Strengthen the efficiency/ effectiveness of enforcement of EU legislation to reduce non-compliant products on EU market.
  - **Specific objective 5:** Ensure a clear meaning and enhanced credibility of CE marking.

This chapter focuses on an assessment of the key components of the NLF, linking them to the specific objectives, before providing an assessment of the achievement of the NLF's general objectives.

4.1.1 Achievement of the NLF's specific objectives

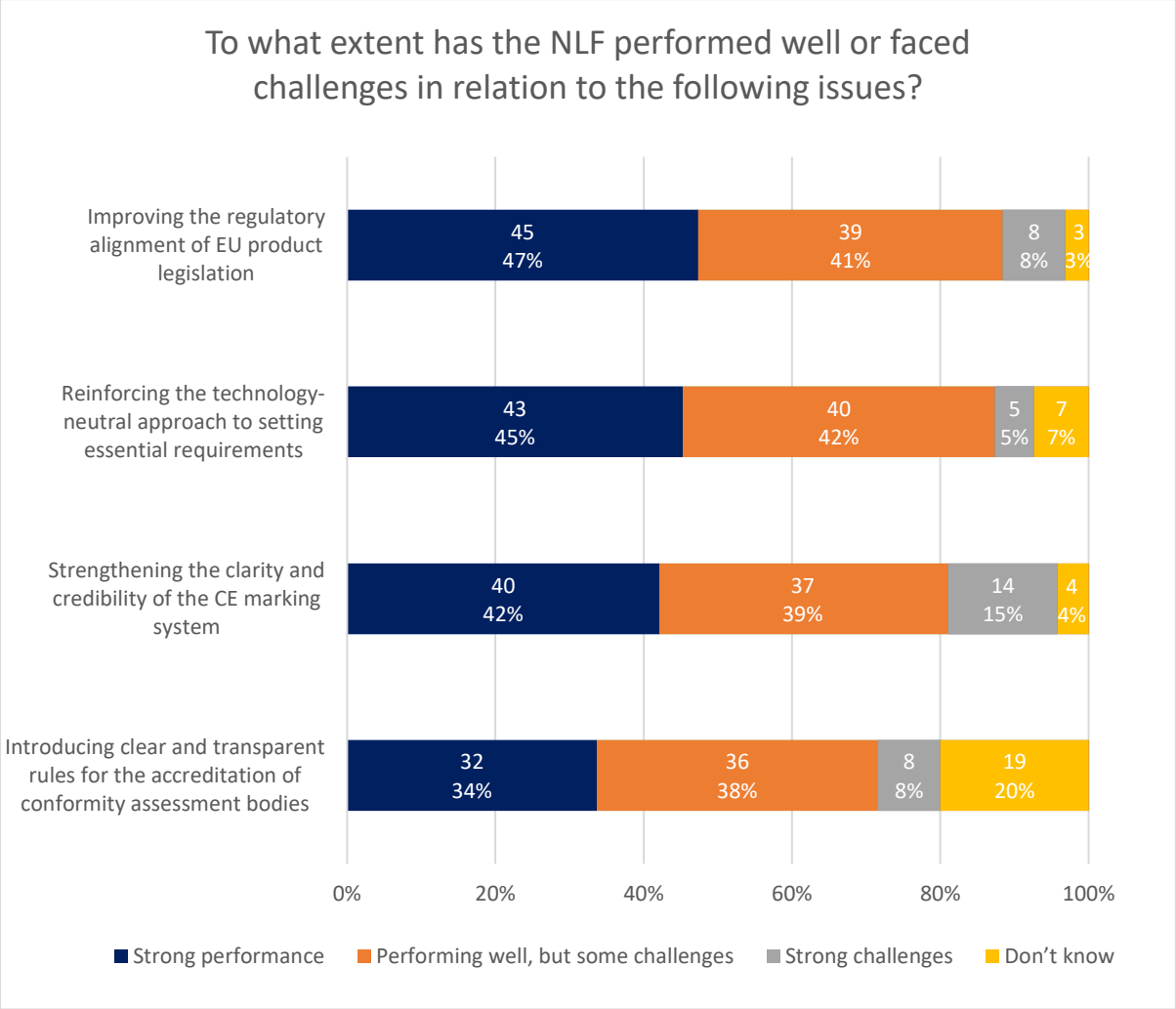
This chapter examines the performance of the key components of the NLF and the results of the NLF, as linked to the specific objectives; thus, this chapter responds to **EQ1.1 – 'To what extent have the original specific objectives of the NLF been achieved?'**

To achieve this, this chapter first analyses overarching responses from the stakeholder consultations before examining the achievement of each specific objective in turn: the process of aligning product legislation with the provisions of the NLF and continued implementation of the New Approach principles (Chapter 4.1.1.1), the conformity assessment system, including the accreditation framework and the rules on notification (Chapter 4.1.1.2), and the CE marking and other information obligations (Chapter 4.1.1.3).

Through the public consultation, all stakeholders, with the exception of citizens, were asked for their views on the **extent to which the NLF has performed well or faced challenges across its specific objectives**. As illustrated below, the response was positive; for three of the objectives, the majority of

respondents (42-47%, N=95) felt the NLF had performed strongly with no notable challenges. The most positive sentiment related to the objective to improve the regulatory alignment of EU product legislation (47% of respondents selected strong performance). Furthermore, only 8-15% of respondents across the objectives felt the NLF had experienced strong challenges.

Figure 4-1: Performance of the NLF in relation to its specific objectives (N=95)



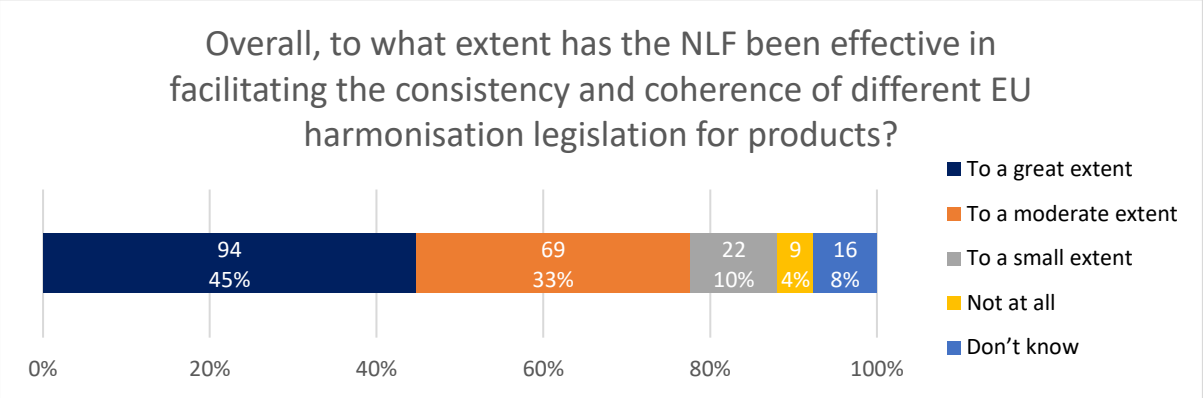
4.1.1.1 Level of alignment of product harmonisation legislation with the NLF

Through Annex I to Decision No 768/2008/EC, the NLF provides reference provisions covering: definitions (Chapter R1); obligations of economic operators (Chapter R2); conformity of the product (Chapter R3); and notification of conformity assessment bodies (Chapter R4). This chapter first examines the overarching performance of the NLF in the process of aligning Union harmonisation legislation to the reference provisions, before exploring the legislative alignment of the specific reference provisions.

In general, the **alignment of product legislation to the NLF has resulted in limited differences** across the 23 pieces of NLF-aligned legislation, 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. More than 75% of respondents to the targeted consultation perceive that the **NLF has been effective in facilitating the**

consistency and coherence of different EU harmonisation legislation to a moderate (32.9%, 69 responses) or a great extent (44.8%, 94 responses) (Figure 4-2).

Figure 4-2: Overall effectiveness of the NLF in facilitating the consistency and coherence of different EU harmonisation legislation for products (Question 15, N=210)



However, as documented throughout this chapter, **divergent requirements have been identified** between NLF-aligned legislation and the NLF reference provisions, as well as between different pieces of NLF-aligned legislation. Furthermore, there are a range of laws applicable to products that are not aligned to the NLF, including:

- New Approach directives that have not been updated since the NLF was adopted and have therefore not been aligned (i.e. Council Directive 92/42/EEC on hot water boilers; Directive 2000/14/EC relating to noise emission; Directive 2000/55/EC on energy efficiency requirements for ballasts for fluorescent lighting; and Directive 96/62/EC on packaging and packaging waste).
- Updated versions of New Approach directives that have been repealed and replaced since the adoption of the NLF without formal alignment (e.g. Directive 2009/125/EC on ecodesign requirements; Regulation (EU) 2019/2019 on ecodesign requirements for refrigerating appliances; and Directives (EU) 2016/797 and 2016/798 relating to rail interoperability and rail safety, respectively).
- Laws that were not part of the New Approach, but are applicable to products, such as Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive).

As documented further in Chapter 4.3 (on the NLF's coherence), these laws introduce further divergence between laws applicable to products.

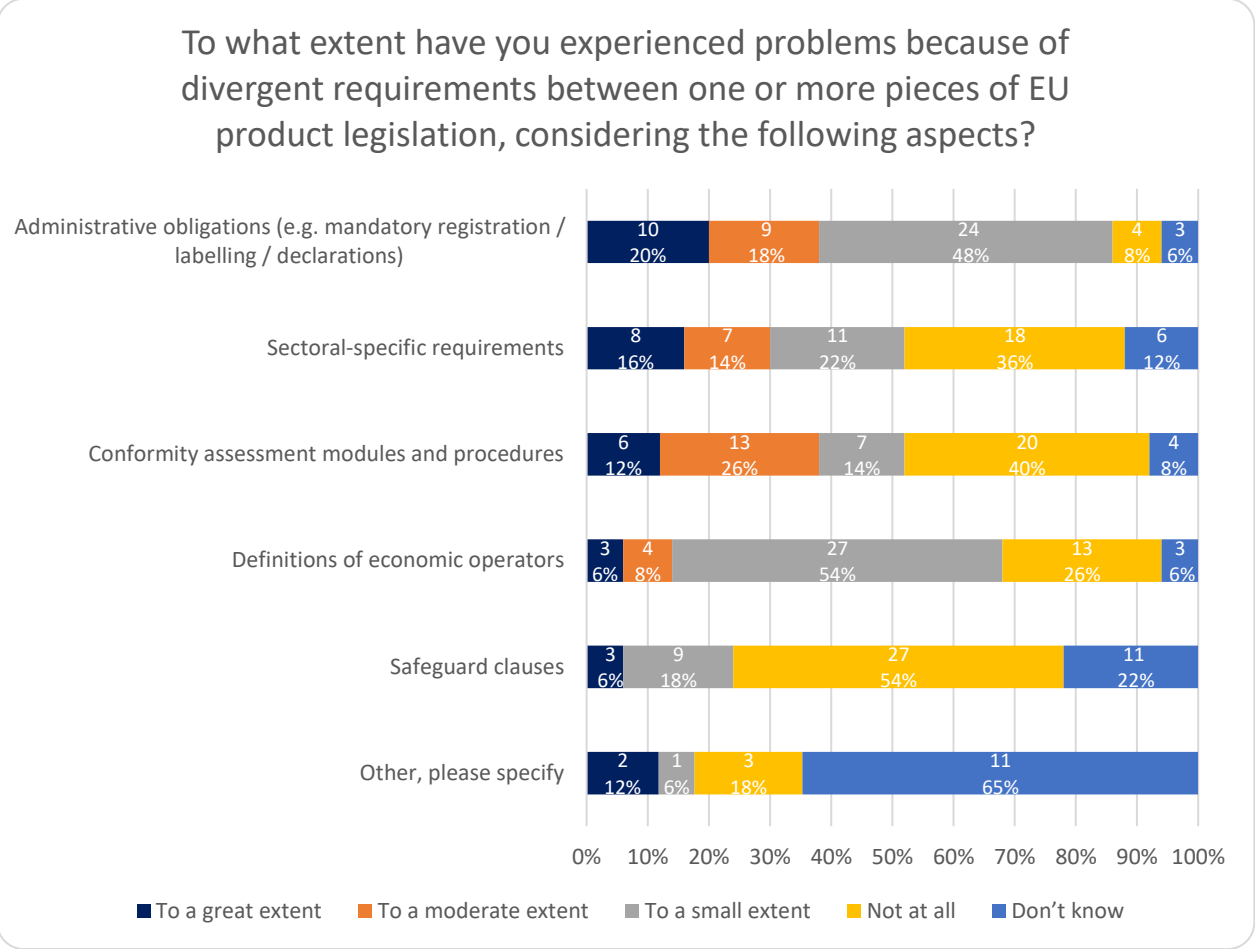
In this respect, the targeted consultation asked economic operators and industry associations to what extent they had **experienced problems because of divergent requirements between EU product legislation** in the following areas: administrative obligations; sectoral-specific requirements; conformity assessment modules and procedures; definitions of economic operators; and safeguard clauses.

Across all areas combined, most respondents have either experienced problems to a small extent (29.6%, 79 respondents) or not at all (31.8%, 85 respondents). However, a total of 24.3% of respondents (65) have experienced problems to either a moderate or a great extent (see Figure 4-3).

Divergences in administrative obligations were most likely to be problematic to a great extent (20%, 10 responses), while divergences related to conformity assessment were most likely to be problematic when combining the responses 'to a moderate extent' (26%, 13 responses) and 'to a great extent'

(12%, 6 responses). In contrast, divergences related to safeguard clauses and definitions of economic operators were considered to cause no or only minor problems.

Figure 4-3: Problems experienced because of divergent requirements between one or more pieces of EU product legislation (Question 16, N=50)



Definitions established by the NLF

Chapter R1 of Annex I 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 four additional definitions related directly to the provisions of the Regulation.

Looking back, this set of definitions **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 "importer" referred more to an intra-EU cross-border importer than to an international trader importing products from all over the world.

Second, 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, 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.
- 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 consideration of 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.

Therefore, although the remainder of this chapter examines NLF-aligned legislation, later chapters, notably those on relevance (Chapter 6) and coherence (Chapter 4.3), discuss: i) the potential need for additional definitions within the context of the NLF as a result of market trends and emerging Union legislative proposals; and ii) the alignment between the NLF's definitions and those of non-NLF-aligned, but relevant Union harmonisation legislation.

Overall, according to the majority of stakeholders, the **NLF has provided a satisfactory benchmark for sectoral legislation** that has been aligned since 2008, particularly considering the omnibus alignment of ten sectoral directives adopted in 2014. In addition, these stakeholders perceive that, for the most part, the included definitions are clear, fit for purpose and have brought greater coherence to the application of legislation and its interpretation when enforced by Member State authorities.

This perspective is validated by the legislative mapping of the 23 pieces of NLF-aligned legislation presented in Annex 7. The mapping, which compares the legal text of each NLF-aligned legislation with the NLF reference provisions, demonstrates **only minor differences across the entire body of NLF-aligned legislation**.

These minor differences generally consist of: i) additional definitions, such as the definition for the economic role of 'dealer' in the Civil Explosives Directive; or ii) slight changes to the wording of a definition, as is the case for the definition of 'placing on the market' in the Lifts Directive. In most cases, these amendments have been implemented for sector-specific reasons. For instance, in the example of the Lifts Directive, the amendment reflects the fact that lifts may be supplied for use on the Union market in the course of commercial activity rather than as standalone products.

Beyond these minor differences, **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. The following table illustrates this in more detail.

Table 4-1: Varying interpretations of the concept of accreditation

Varying interpretations of the concept of accreditation
In Regulation (EC) No 765/2008 (referred to by Annex I to Decision No 768/2008/EC), accreditation is defined as "*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 concept of accreditation is further clarified in the policy document "EA-2/17 M: 2020" but 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". Certification bodies have commented that the accreditation of Conformity Assessment Bodies (CABs) cannot be reduced to notification purposes only, with a focus on EN ISO/IEC 17065:2012 on "*Conformity assessment — Requirements for bodies certifying products, processes and services*". This **definition is considered as too vague by several categories of stakeholders**, especially certification bodies, because it refers to harmonised standards (hEN) without specifying which ones. Although some stakeholders argued that specifying the required standards in the NLF would divergence from the New Approach principles, others noted the impacts of this vague definition; namely, a situation where Member States have different interpretations of the criteria and procedures for accreditation, such as on the objection period for a notification. A specific example illustrating the scope of different requirements was highlighted by the German Federal Maritime and Hydrographic Agency (BSH), which stated that, in the Marine Equipment Directive (MED) 2014/90/EU, compliance with the hEN EN ISO/IEC 17065:2012 is one of 19 requirements for notified bodies defined in its Annex III. As documented in greater detail below and in case study 2 on the accreditation process (see Annex 4), divergent accreditation requirements have emerged across different pieces of NLF-aligned legislation and across the EU as the suit of conformity assessment modules does not align well with the difference hENs covering the provision of different conformity assessment services. Subsequently, this can have **negative impacts on individual businesses and the functioning of the single market**. For instance, NAB and CAB stakeholders highlighted that the lack of harmonised requirements and practices 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. This practice of 'forum shopping' can thus result in variable competence across CABs, unfair competition and can ultimately impact the trustworthiness of conformity assessment services, certificates and product compliance.

Furthermore, the **NLF has faced challenges in acting as a benchmark for definitions beyond NLF-aligned product legislation**. Many stakeholders, from all relevant groups, raised issues related to the coherence of the NLF definitions with those detailed in non-NLF-aligned product and sectoral legislation. These issues are explored further in Chapter 4.3 on the NLF's coherence with the wider EU legal framework.

Obligations of economic operators established in the NLF

Chapter R2 (Annex I to Decision No 768/2008/EC) provides reference provisions on the **obligations of the four different types of economic operators** defined in Chapter R1, as well as rules related to 'Cases in which obligations of manufacturers apply to importers and distributors' and the 'Identification of economic operators'. The obligations for manufacturers, for instance, cover issues such as ensuring products are in line with relevant essential requirements, responsibilities related to conformity assessment procedures and technical documentation.

As evidenced by the legislative mapping exercise, the **majority of NLF-aligned laws follow the reference provisions closely**, with the following types of divergence identified:

- **Addition of sector-specific obligations**. In some instances, these sector-specific obligations can be minor amendments or additions, such as in the case of the Transportable Pressure Equipment Directive, which includes additional obligations for 'owners' and 'operators'; economic roles not foreseen in the NLF. In some instances, for instance in the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), major differences exist with the reference provisions in the NLF; for instance:
  - Article 10(16) of the MDR and Article 10(15) of the IVDR stipulate that "manufacturers shall […] have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC" (the Product Liability Directive).
  - Article 15(1) of both the MDR and the IVMDR stipulate that "manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite experience in the field".
- **Reduced obligations**. For instance, due to the specificity of the phenomenon being regulated, the Electromagnetic Compatibility Directive (EMCD) does not include the obligation for 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*".
- **Role of authorised representatives**. The approach to authorised representatives differs across the body of NLF-aligned legislation. Following the introduction of the Market Surveillance Regulation 2019/1020, and specifically the provisions of Article 4, a product that is subject to one or more of the 18 laws noted in Article 4(5) may only be placed on the Union market if there is an economic operator established in the Union. This economic operator may be a manufacturer, importer, authorised representative, or, in the absence of these entities, a fulfilment service provider. This obligation was introduced to ensure MSAs have recourse to an EU-based entity under the legal system of a Member State.

  Consequently, it increased the use of authorised representatives by economic operators based in third countries for the purpose of fulfilling their obligations under Article 4. The MDR, the IVDR and the Marine Equipment Directive already placed this obligation on economic operators based in third countries. Trade stakeholders, including online marketplaces, have noted the impact of this change; they provided evidence that, due to this requirement, third country SMEs have withdrawn from selling to the EU market, thus reducing competition and consumer choice. They have further highlighted that, should this regulatory trend be replicated in other geographies, it could impact the will and ability of EU-based economic operators to export to those markets. However, the scale of these impacts is difficult to assess.

  Furthermore, the remaining five pieces of NLF-aligned legislation[43] include provisions on the obligations of authorised representatives, but do not require that products are placed on the single market by a responsible person in the EU. As such, the use of authorised representatives by non-EU-based economic operators is less strongly supported by these laws. Given the recency of Regulation 2019/1020, and the ongoing discussions regarding the future of the PLD and proposed GPSR, the impact of this divergence on the role and obligations of authorised representatives will need to be closely monitored in future.

[43] Transportable Pressure Equipment Directive; Civil Explosives Directive; Lifts Directive; Cableway Installations Regulation; and EU Fertilising Products Regulation.

Conformity of the product

Chapter R3 (Annex I to Decision No 768/2008/EC) contains reference provisions related to:

- **Presumption of conformity**. Article R8 states that products in conformity with harmonised standards, the reference of which have been published in the OJEU, shall be presumed to be in conformity with the essential requirements or other requirements aimed to be covered by the harmonised standard and included within Union harmonisation legislation.
- **Formal objection to a harmonised standard** (Article R9). Given the presumption of conformity, the provisions provide for a process by which Member States and the Commission can object to a harmonised standard and require a revision.
- **EC (EU) declaration of conformity** (Article R10) provides for the standing and location of the declaration of conformity and its meaning.
- **CE marking.** Articles R10 and R11 present provisions referring to the general principles of the CE marking detailed in Article 30 of Regulation (EC) No 765/2008 and the rules and conditions for affixing the CE marking.

As for the reference provisions discussed above, **minor differences exist across the body of legislation as a whole related to provisions on the conformity of the product**. The legal mapping exercise demonstrates that, for the most part, they are implemented with minor amendments. Where amendments exist, they relate to the following points:

- **Specific product markings**. Certain NLF-aligned laws use markings other than the CE marking to attest to the conformity of the products subject to those laws. For instance, the 'Pi marking' is required under the Transportable Pressure Equipment Directive; additional metrology markings are required under the Measuring instruments Directive and the Non-Automatic Weighing Instruments Directive; and the 'Wheel mark' is required under the Marine Equipment Directive. However, although the markings are different, the legal provisions are similar to those detailed in the NLF across these laws.
- **Additional marking and inscription requirements.** Some laws have additional marking and / or inscription requirements beyond those provided for in the NLF. These requirements can include adding other information alongside the CE marking (e.g. addition of the two last digits of the year in which the CE mark was first affixed under the Construction Products Regulation), or they can relate to where the marking is to be located (e.g. under the Radio Equipment Directive, the CE marking needs to be placed on the product and, not or, the packaging). An example of problems for manufacturers stemming from divergent requirements related to product markings is presented in the below table.

Table 4-2: Example: Impact of different requirements across NLF-aligned legislation

Example: Different product marking requirements and its impact

When the Pressure Equipment (PED) and ATEX Directives are applicable to the same product, a stakeholder highlighted administrative rules that can cause confusion. Both laws require manufacturers to affix the number of the notified body on the product. Although the configuration of these rules does not diverge from the NLF's reference provisions and principles, industry stakeholders highlighted that it can result in a **lack of certainty** for manufacturers. For instance, if the notified body (and the role of the notified body) is different for both laws (e.g. certifying QMS under ATEX and the product under PED), manufacturers may be unsure whether to place the number of one or both notified bodies on the product, and how to do this.

Furthermore, as highlighted below, manufacturers have highlighted an increase in the number of information obligations to be affixed to the product or packaging, which can bring issues with space on smaller products.

- **Sector-specific rules** are included in some pieces of legislation, such as additional types of tests and inspections (e.g. the requirement for a post-construction assessment in the Recreational Craft and Personal Watercraft Directive).
- Certain NLF-aligned legislation makes reference to the **standing of international or national standards and technical specifications** with regard to the presumption of conformity. For instance, the Low Voltage Directive (Articles 12-13) stipulates provisions for the presumption of conformity on the basis of the use of international and national standards, respectively, when European harmonised standards are not available.
- Differences exist in the approach of a small number of laws to the **EU Declaration of Conformity (DoC) provisions and related template**. For instance, the Lifts Directive requires different forms for manufacturers of safety components for lifts (Annex II.A) and installers of lifts (Annex II.B), as well as using different terminology and structure, and requiring additional information (such as the year of manufacture / installation and a statement of conformity).[44]

In addition, the following trends that do not necessarily alter provisions, but amend where they sit within the context of an NLF-aligned legal text have emerged since the introduction of the NLF:

- How NLF-aligned laws approach covering the reference provisions on ensuring the correct application of the regime governing the CE marking and providing for infringements – Article R12(4). For instance, the Recreational Craft Directive and the Medical Devices Regulation do not have specific provisions on this point, but refer to infringement possibilities elsewhere in the legal text. In the case of the Medical Devices Regulation, rules on CE marking are stipulated in Article 20, including reference to the applicable provisions of Regulation (EC) No 765/2008. However, provisions on penalties for infringements of the Regulation as a whole are covered through Article 113.
- Inclusion of references to the possibility of provisions being subject to multiple EU laws; an example is Article 21(3) of the Civil Explosives Directive, which states that "Where an explosive is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts". Although not explicitly noted in Article R10, these provisions reflect the meaning of Article 5 of Decision No 768/2008.

[44] *NB*: Due to the specificity of lifts, this Lifts Directive extends some responsibility to the installer-assembler of the equipment and parts for lifts, beyond those of the manufacturer who is responsible for the design and manufacturing of these equipment and parts, that is before their placing on the market at the time of their installation at the end-user premises.

- Specific provisions on formal objections to standards (Article R9) are absent from all NLF-aligned legislation adopted following the implementation of Regulation (EU) No 1025/2012 on European standardisation, which updated the legal framework on European standardisation and established harmonised rules on this issue. Instead, these laws include reference to this Regulation, for information, in their Recitals.

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 on the cumulative impact of many little differences. These stakeholders highlight that, when a product is subject to multiple Union harmonisation laws, any increases in the complexity of conformity assessment, due to an accumulation of minor differences in rules, also increases the costs of compliance. This is illustrated further in case study 1 on coherence of non-aligned UHL legislation with NLF-aligned legislation.

Notification of conformity assessment bodies

Chapter R4 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.

As for the implementation of the other reference provisions, the legal mapping illustrates that **most NLF-aligned laws closely follow the reference provisions of Decision No 768/2008/EC**. Four main trends emerged from the mapping. These trends do not necessarily represent a departure from the reference provisions or the principles of the CE marking, but more a reflection of wider developments in the legal framework and application of NLF-aligned laws:

- Minor changes to the provisions on **challenging the competence of notified bodies**. The reference provisions simply require the Commission to inform the relevant national authority and request it to take the necessary corrective measures when a notified body no longer meets the requirements for its notification (Article R26). However, under the Radio Equipment Directive and many other laws, the Commission are required to adopt an implementing act in such circumstances.
- Many NLF-aligned laws include provisions, within the context of the obligations on notified bodies, obliging Member States to ensure that an **appeal procedure against decisions of notified bodies** is implemented. Although such provisions are included within Article 4 of Decision No 768/2008/EC, reference text on this issue for inclusion in specific harmonisation legislation is not detailed within the NLF reference provisions (i.e. Annex I to Decision No 768/2008/EC).
- In many cases, the specific product laws extend the responsibilities within and requirements on notified bodies beyond top level management, to also cover the **personnel responsible for carrying out the conformity assessment tasks**.
- As noted above in relation to the conformity of a product, the reference provisions providing for **formal objections to harmonised standards** under Article R19 (i.e. related to the conformity of conformity assessment bodies) are not directly included in NLF-aligned legislation following the adoption of Regulation 1025/2012.

Beyond these trends, a few pieces of legislation display more significant differences to the NLF's reference provisions. These include the Medical Devices Regulation and the *In Vitro* Diagnostic Medical Devices Regulation, which both have significantly different structures for and approaches to stipulating the rules for notification, 'authorities responsible for notified bodies' (the equivalent of notifying authorities), 'designating authorities' and notified bodies.

Conclusion

In summary, the **NLF has performed well in its achievement of the specific objectives of supporting the consistency and coherence of EU harmonisation legislation and reinforcing the implementation of the New Approach principles**. In turn, stakeholders across many areas have highlighted the contribution of this performance to other positive impacts on which progress has been made since the implementation of the NLF in 2008, such as the simplification of administrative and substantive compliance requirements and related cost savings, greater compliance with the essential requirements across NLF-aligned laws, improved consumer safety and trust and a more level playing field.

However, as identified above, a few examples of weaknesses exist in relation to this specific objective; namely, a few pieces of NLF-aligned legislation (e.g. the MDR, the CPR) diverge significantly from the NLF, and a low level of minor divergences and differences has been identified across the body of NLF-aligned legislation. Furthermore, as discussed in Chapter 4.3 (on coherence), there is a wide range of legislation applicable to products that is not aligned to the NLF. This has limited the scale of the positive achievements highlighted above.

4.1.1.2 Conformity assessment and the accreditation framework

The **conformity assessment system detailed in the NLF underpins the entire internal market**, as it represents the means by which economic operators assess and demonstrate the compliance and conformity of their products with the essential requirements laid down in specific product legislation and the supporting use of harmonised standards for that purpose. Key to the functioning of this system are: the suite of conformity assessment modules and procedures; the use of harmonised standards as means to claim presumption of conformity; the empowerment and competence of conformity assessment bodies; the framework for the accreditation of conformity assessment bodies; and the process for the notification of notified bodies.

This chapter examines the performance of the conformity assessment system and its components, first discussing the conformity assessment modules and procedures before examining the accreditation framework, the performance of conformity assessment bodies and the notification procedures.

Conformity assessment procedures

Through Article 4 of Decision No 768/2008/EC, the NLF **establishes rules on the integration of conformity assessment procedures into Union harmonisation legislation**. Targeted at the legislator, this Article stipulates the following key provisions:

- Conformity assessment procedures are to be selected from the modules set out and specified in Annex II to Decision No 768/2008/EC.
- Selection of the conformity assessment procedures relevant to each Union harmonisation legislation should be conducted in line with certain criteria (e.g. the nature of the risks associated with the product).
- In situations where a product is subject to several Union harmonisation laws, the legislator should ensure consistency between conformity assessment procedures.
- Guidance and flexibility is provided for legislators on the application of the conformity assessment modules (e.g. allowing requirements for additional information, possibility of using accredited in-house body, period of validity for EC-type examination, etc.)
- Ensure that an appeal procedure against decisions of the notified body is available.

These provisions are supported by Annex II to Decision No 768/2008/EC, which details the **different conformity assessment modules available** to the legislator. A summary of the suite of modules is presented in the below table.

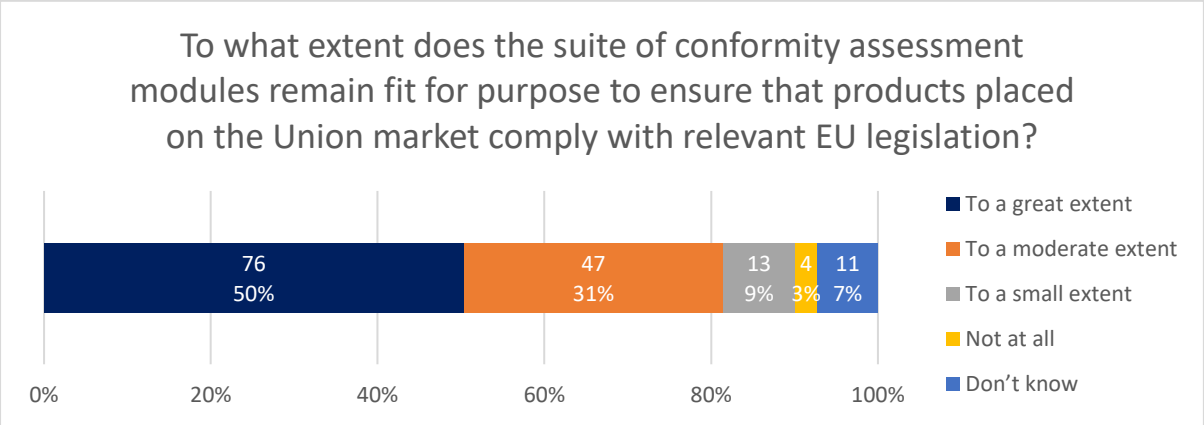
Table 4-3: Summary of the conformity assessment modules under the NLF

Conformity assessment modules under the NLF
Conformity assessment procedures are composed of either one or two conformity assessment modules, which cover both the design and production phase of product manufacturing. As such, a module may cover: • Either one of the two phases (in such cases, the procedure will be composed of 2 modules). • Or both phases (in such cases, the procedure will be composed of 1 module). Annex II details 8 different overarching modules (A-H); however, as some modules include variants, the total number of possible combinations is 15. The purpose of the variants is to ensure the necessary level of protection for products presenting higher levels of risk while avoiding the imposition of a more extensive module. The details of each module cover: i) the responsibilities of manufacturers (and authorised representatives); and ii) the degree of involvement of an in-house accredited or notified conformity assessment body.

Overall, **stakeholders across all groups have stated that the NLF approach remains fit for purpose to ensure the safety and compliance of products placed on the single market**. More specifically, industry noted that the continuity in conformity assessment procedures between the New Approach and the NLF is positive, further highlighting that the opportunity to use module 'A' (Internal production control) is very important and should be maintained.

These overarching findings are validated by the targeted consultation results. As illustrated below, 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.

Figure 4-4: Fitness for purpose of the suite of conformity assessment modules under the NLF (Question 20, N=151)



Question 20 was asked to: economic operators, industry associations, MSAs, national competent authorities, national accreditation bodies, national notifying authorities and notified bodies / conformity assessment bodies.

Furthermore, this is in a context where industry has noted the following key legislative trends that they perceive could increase the burden related to conformity assessment:

- **Inclusion of more extensive conformity assessment procedures within product legislation**. Industry stakeholders interviewed noted that, in certain recent legislative proposals, the legislator had tended towards more extensive conformity assessment procedures for some products. For instance, under the Machinery Regulation, industry stakeholders noted that the updated list of high-risk machinery products includes general coverage of software and AI systems ensuring safety functions. As one stakeholder put it, if all AI or software is considered to have a safety function, there is risk of movement towards "generalised third-party conformity assessment", which would change the system on which the internal market is based, increase the burden and costs for industry and hinder innovation. These stakeholders recognise that the need to increase trust in AI across the EU is important, but believe it can be done in a more proportionate and nuanced way, particularly considering the speed at which the state of the art develops.
- **Inclusion of detailed technical specifications within product legislation.** The NLF model provides for technology-neutral essential requirements set by law. However, industry stakeholders reported that more granular technical requirements are more readily being incorporated directly into Union legislation. An example highlighted was that of a non-NLF-aligned law – the proposal for a Regulation concerning batteries and waste batteries, where very specific requirements have been included within the legal text.[45] The impact of this trend, 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 and resulting negative impacts on innovation and competitiveness.

Beyond these emerging trends, certification stakeholders noted that, in the context of the changes brought by the digital and green transitions and more specifically the ability for products to change post market placement, 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.

Accreditation framework and performance of conformity assessment bodies / notified bodies

Bodies that have been notified by the authority of a Member State have a key role in verifying the safety and the compliance of products placed on the market. In some cases, the involvement of notified bodies is required by NLF-aligned sectoral legislation (e.g. for categories II, III and IV of pressure equipment under Directive 2014/68/EU). In other cases, notified bodies are voluntarily solicited by manufacturers for products falling under UHL when module 'A' conformity assessment is required (e.g. electrical products, radio equipment or toys). Consumer associations have reported that the role of notified bodies is key to ensuring the protection of consumers.

As it is essential that notified bodies work in a competent and independent manner, the NLF established, through Regulation (EC) No 765/2008, a European accreditation system to ensure the mutual recognition of test reports and certificates issued by accredited notified bodies. The provisions in this regard are detailed in the below table.

Table 4-4: Summary of rules on accreditation and notification in the NLF

Accreditation and notification in the NLF
As detailed in Chapter 4.1.1.1, Regulation (EC) No 765/2008 provides a definition of the concept of 'accreditation'. The main stipulations on the accreditation framework, targeted at national authorities,

[45] 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, COM/2020/798 final.

are set in Chapter II. This chapter includes provisions on the framework's scope, general principles (including the requirement for each Member State to appoint a single national accreditation body), rules on its operation, and requirements and obligations for national accreditation bodies. It also provides legal standing for a European accreditation infrastructure (under Article 14).

However, Regulation (EC) No 765/2008 does not define 'notification' and its corresponding stipulations are provided in the blueprint of Annex I to Decision No 768/2008/EC. Chapter R4 of this Annex details reference provisions for the notification of conformity assessment bodies, which have been incorporated into NLF-aligned product legislation.

According to the Blue Guide 2016, "Notification is the act of the notifying authority informing the Commission and the other Member States that a conformity assessment body has been designated to carry out conformity assessment according to a Union harmonisation act, and fulfils the requirements relating to notified bodies set out in that Union harmonisation act."[46]

In other words, the NLF provides for a single system of accreditation that aims to ensure the **competence** of conformity assessment bodies (CABs) but leaves up to Member States to transpose in their legislation rules for the **legal empowerment** of those CABs to evaluate conformity against Union law: i.e. only 'notified bodies' can deliver valid certificates, but not all notified bodies have had their technical competence accredited at EU level.

Consequently, the NLF has **two key weaknesses** that affect harmonisation across the accreditation and notification systems:

1. The accreditation system is harmonised across all EU Member States but refers to unspecific "harmonised standards and where applicable additional requirements", leaving room for varying interpretations.
2. 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.

Generally, sectoral legislation contains a relationship between accreditation and notification – **accreditation for the purpose of notification** – which requires that notified bodies fulfil specific requirements to obtain their notification, depending on the notification scope (except for medical devices where accreditation is not considered in the same way).

Manufacturers mainly make use of Notified Bodies (NB) when it is required by conformity assessment modules referred to by the applicable product legislation. Beyond that, manufacturers may decide to make use of third-party conformity assessment bodies (CAB), test houses or similar organisations on a voluntary basis in the following instances:

- They do not have all the necessary competences or infrastructure (e.g. laboratories) to place a product on the market.
- To have a technical "guarantee" and justify the fact that they are willing to apply the rules.
- When they want to gain market access.
- Where the use of notified bodies is not required and a manufacturer's declaration of conformity (DoC) is sufficient (e.g. under the LVD, certain low-risk products, such as Category I PPE etc.), manufacturers sometimes use CABs to obtain a third-party mark or an informative test report in support of their CE documentation.

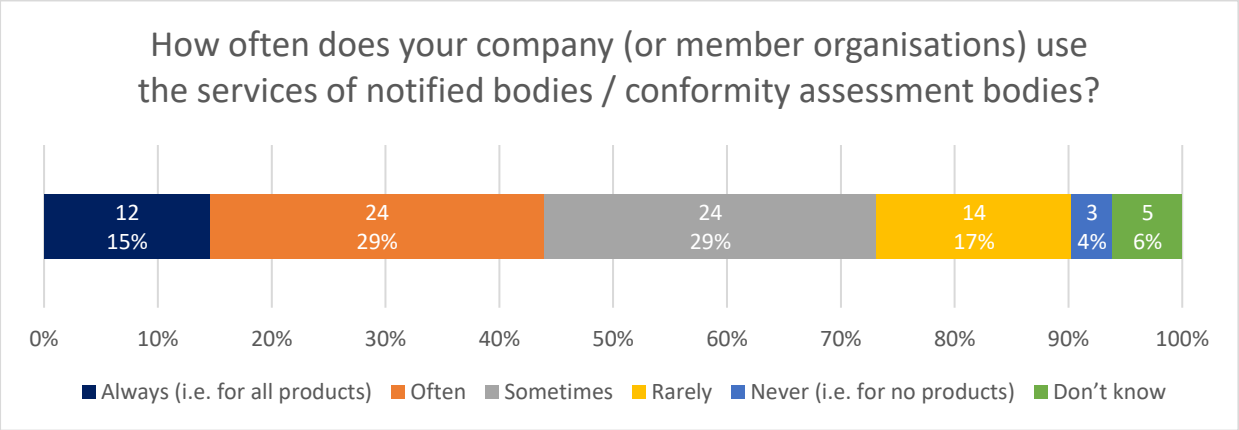
An example of equipment that may need the assessment of different notified bodies is equipment for which multiple product regulations or directives apply, such as machinery or electromagnetic

[46] Blue Guide 2016: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.272.01.0001.01.ENG

compatibility. In principle, several notified bodies offer this as a one stop shop (i.e. the notified body offers to carry out the required conformity assessment procedures under two or more directives or regulations in one project) if they are appropriately notified under such legislative acts and for the related procedures.

The frequency with which industry stakeholders use the services of NBs / CABs (whether required or not) was examined through the targeted consultation. As the below figure illustrates, just under 50% of industry respondents (individual economic operators or industry associations) reported that they or their member organisations use NBs / CABs 'Always' (14.6%, 12 responses) or 'Often' (29.3%, 24 responses). Only 3 respondents reported that they 'Never' use the services of NBs / CABs.

Figure 4-5: Use of notified bodies/ conformity assessment bodies by economic operators and industry associations (Question 7, N=82)



Question 7 was asked to: economic operators and industry associations.

In most Member States, the **application of a CAB for notification shall be accompanied by an accreditation certificate**, issued by the national accreditation body, attesting that the CAB fulfils the requirements laid down in the specific Union harmonisation legislation to become a notified body; however, this is not necessary across all Member States.

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 are sufficiently guaranteed. This has been confirmed by the target consultation, where:

- 73% of stakeholders (116 of 159 respondents) perceive that the NLF requirements for notified bodies remain appropriate to a great (37.1%, 59 respondents) or moderate extent (35.8%, 57 respondents);[47] and
- 78.5% of stakeholders (106 of 135 respondents) perceive that the overall requirements set by the NLF are robust enough to ensure the competence of NBs and CABs to at least a moderate extent, including 46.7% (63 respondents) who considered this to be the case to a great extent.[48]

In support of that feedback, the most frequent arguments are that the NLF has both **improved mutual confidence in test reports and certificates of conformity for cross-border trade**, as well as considerably **reducing the process associated with notification and designation**. Industry

[47] Results of Question 25 (N=159): To what extent do the NLF requirements for notified bodies remain appropriate?
[48] Results of Question 23 (N=135): To what extent do you consider the overall requirements set by the NLF to be robust enough to ensure the competence of notified bodies / conformity assessment bodies? This question was asked to: economic operators, industry associations, national competent authorities, national accreditation bodies, national notifying authorities and notified bodies / conformity assessment bodies.

stakeholders further highlighted that this reduction of differences in the activities carried out by notified bodies has increased fair competition between businesses, although not at an entirely satisfactory level (see below discussion). The remainder of this chapter examines the effectiveness of the accreditation framework, including the provisions on subcontracting and the accreditation and notification procedures.

Effectiveness of the accreditation framework

According to EA – a not-for-profit association supporting mutual recognition of accreditation across the EU and formally appointed under Article 14 of Regulation (EC) No 765/2008 – the **NLF has been very effective, because, before the Regulation, there was no real European legal framework for accreditation**.

However, under the application of the subsidiarity principle, the NLF at the time of its adoption refrained from proposing the obligation for all bodies to be accredited first before receiving a notification. This is a key discussion point arising from the interviews and the targeted consultation.

Stakeholders across all groups (including authorities, industry, certification and consumer organisations) link this decision to a number of **application problems** experienced in the subsequent years. More specifically, stakeholders highlighted the following issues:

- Absence of a harmonised system that would better interface the accreditation process with the notification process.
- Lack of clarity across Member States and laws regarding how the competence of a notified body is assessed, particularly noted by consumer associations and notified bodies.
- Manufacturers reported that they are confronted with NBs that do not have the level of competence they need to support the placement of their products on the market, and that the same product may receive a different assessment from two different CABs.
- Consequently, stakeholders highlighted unequal levels of competence of accredited CABs across Europe (for instance, in the fire and emergency equipment sector), and companies reported being exposed to different level of control by MSAs, which in some cases require manufacturers of certified products to re-test a product or undergo new certification.

As a result, industry stakeholders noted that this **situation is damaging the trustworthiness of conformity assessment certificates**. Others noted that the situation is unlikely to get better at the pace required by innovation, due to the monopolistic position of accreditation bodies, which does not encourage them to compare across the EU and improve their approaches.

The following box explores the key role of harmonised standards for conformity assessment services.

The key role of harmonised standards for product conformity assessment: An essential reference point for mature technologies, but a bottleneck for innovation

Several European trade associations emphasised the key role of harmonised standards, if listed in the OJEU in a timely manner, for conformity assessment services to perform well, irrespective of the conformity assessment procedure adopted. Harmonised standards, as for any standards, provide all parties with the same set of technical references; manufacturers under module 'A', certifiers when required by law (e.g. under module 'B' for a gas appliance), market surveillance authorities and other stakeholders. This feature of the NLF is greatly appreciated from the perspective of all stakeholders and economic operators in particular. Where a referenced standard is not available, a manufacturer may rely on a third-party opinion, even when not required by law, but may face two different opinions from NBs in two different countries.

A large European association active in the digital sectors cited the example of the entry into force of the Radio Equipment Directive. Article 17(4) obliges all manufacturers of radio equipment to undergo a

third-party EU-type examination, if the harmonised standards are not used. However, approximately a third of the updated RED standards were not cited in time in the OJEU. As such, accredited CABs had a capacity issue to face certification requests from manufacturers, which added costs and delays for placing products on the market.

A renowned pump manufacturer stressed that the function of NBs is useful when a company has doubts about compliance. In this regard, an NB can in particular provide value to SMEs that do not have the in-house expertise of larger manufacturers. However, the same industry stakeholder noted that NBs have also become an artificial bottleneck in certain instances; for example, when the market is moving faster than the development of standards that are used as a reference by NBs to perform their service. 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, they appreciate the flexibility of the NLF that, as a result of module 'A', prevents NBs from imposing standards, technical specifications or procedures that do not match market needs, and could ultimately constitute a barrier to trade or to innovation.

While certifiers report that there are significantly higher rates of non-conformity for products under module 'A' compared to those where a NB is involved, industry stakeholders do not support the idea of an NLF evolution that would only include conformity assessment modules with mandatory third-party involvement. They challenge, in particular, the idea that in case no harmonised standards are available, it would be up to the notified body to decide what is needed, asking questions such as: why should they know better than the manufacturer, who eventually is the only one responsible for placing the product on the market?

Subcontracting by accredited conformity assessment bodies

An additional issue discussed through the interviews relates to the **subcontracting of conformity assessment services by CABs / NBs to third countries subsidiaries**, as national authorities may face difficulties monitoring such services.

On this point, some conformity assessment bodies do have subsidiaries within the EU or in third countries. As the overall responsibility lies with the CAB, certain accreditation standards allow subcontracting. The Blue Guide 2016 provides a number of clarifications on the scope and conditions of such contracts in its Section 5.2.5. For instance, 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.

In the case of a CAB that outsources work to foreign-based subsidiaries, accreditation bodies are tasked with assessing the procedures that these CABs have for ensuring that their subsidiaries have the right level of competence. The **limitation is that EU accreditation bodies have no authority to directly assess any CAB subsidiaries or their facilities**, whether established in the EU or abroad. For instance, stakeholders working in accreditation noted that there are non-EA members, such as India, that offer their accreditation services according to the standard EN ISO/IEC 17065:2012 on the EU territory for a very low price. On this point, the stakeholders noted that there is a lack of clarity on whether this is permitted.

In addition, 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. 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 Chinese manufacturer can obtain access to the EU market by relying entirely on Chinese conformity assessment infrastructure, raising questions about the EU's autonomy in this area.

According to interviewed notified bodies, however, the **subcontracting of conformity assessment activities is a well-established and necessary instrument and does not constitute a problem**. This perspective was validated to some extent by one national accreditation body; neither they, nor the MSAs in their Member State, have experienced any major problems with assessed CABs with foreign subsidiaries or received complaints from customers.

Effectiveness of accreditation procedures within the NLF

Accreditation for product certification is not the same as accreditation for testing or for inspection. As detailed in case study 2 on the accreditation process, different standards apply for the provision of different conformity assessment services.

According to EA, there are **common criteria for the notification of CABs in Decision No 768/2008/EC which were and will continue to be sufficient**. However, some industry and NB stakeholders believe that the harmonisation of accreditation criteria throughout Europe is needed to ensure that each notified body is accredited and notified along the same set of rules. The following box explains in more detail, building on case study 2.

Effectiveness of the accreditation rules under Regulation (EC) No 765/2008 and application issues for certification bodies

All interviewed stakeholders that responded to the questions on accreditation have stressed that, while there is nothing wrong with the accreditation rules as such, there is a weakness in the system. More specifically, these rules are not applied and enforced in a uniform and harmonised manner by national notifying authorities and accreditation bodies across the single market.

The key factor contributing to this challenge relates to the **definition of conformity assessment activities and thus the hEN against which CABs should be accredited**. As highlighted in Chapter 4.1.1.1, the definition of accreditation in Regulation (EC) No 765/2008 only includes a general reference to "harmonised standards and where applicable additional requirements". Furthermore, NAB and CAB stakeholders have highlighted discrepancies between the descriptions of conformity assessment activities and procedures in the suite of conformity assessment and aligned UHL, with the hEN applicable to different conformity assessment services.

Consequently, stakeholders noted that this leads to:

- **Varying interpretations of standards for the accreditation process.** Given the above, it is the responsibility of Member State NABs, with support from EA, to determine which standards should be used for accreditation of a CAB in relation to a particular conformity assessment module or NLF-aligned legislation. As detailed in Annex 4, the hENs used could include EN ISO/IEC 17025 for testing and calibration laboratories, EN ISO/IEC 17020 for inspection bodies, EN ISO/IEC 17065 for product certification bodies or others.
- **Additional nomination, supervision and assessment requirements for notified bodies** that are imposed at national level and differ between Member States. These additional requirements add costs for notified bodies, which are passed on to their clients.

In combination, these factors lead to divergent accreditation requirements for the purposes of notification across the EU. Although EA has taken steps to address this challenge, most prominently through document EA-2/17, which maps the preferred alignment of hENs per module and per law, this document is reportedly not being implemented across the EU.

In some cases, this situation can **severely distort the EU level playing field between CABs** with consequences for economic operators.[49] 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 (see also above the table on the key role of harmonised standards for product conformity assessment). According to CABs, 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.

Effectiveness of notification procedures within the NLF

In addition to the above, **stakeholders involved in accreditation report that national level notification procedures for the notification of NBs also diverge** across the EU. EA, for instance, noted geographic differences between the expectations of notifying authorities. Besides, these stakeholders raised the question of who assesses the competence of notifying authorities and, consequently, how non-accredited NBs are assessed, on what basis and by whom.

Moreover, while accredited notified bodies are monitored by the accreditation body, the monitoring of non-accredited notified bodies is conducted by national notifying authorities using alternative means. Consequently, the majority of respondents to the targeted consultation (43.8%, 57 of 130 respondents) agreed that the **NLF does not ensure that the procedures for monitoring non-accredited NBs are sufficiently reliable and appropriate for the purposes of notification**. In contrast, only 15.4% (20) of respondents considered these procedures to be reliable and appropriate.[50]

Furthermore, most respondents (53.8%, 70 of 130 respondents) noted that the **existence of non-accredited notified bodies retains limited appropriateness**; 27.7% (36 respondents) stated that the existence of non-accredited notified bodies was 'not at all' appropriate and 26.2% (34) states that this practice was only appropriate 'to a small extent'.[51]

Some of the reasons provided by stakeholders on these points are detailed in the table below.

Effectiveness of the notification rules under Regulation (EC) No 768/2008 and application issues for certification bodies

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.

According to (mostly accredited) **notified bodies** (NBs):

- There is **no harmonisation of the procedures** for assessing and monitoring the non-accredited NBs, for instance regarding the frequency of checks or the extent of the monitoring activities.
  - On the one hand, the monitoring procedures diverge between Member States, for historical, cultural and economic or political reasons.
  - On the other hand, no one controls the implementation of such procedures, as the legislator

[49] See also the tables on "the role of standards in product conformity assessment" and on "effectiveness of the notification rules under Regulation (EC) No 768/2008 and application issues for certification bodies"

[50] 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, national notifying authorities.

[51] 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, national notifying authorities.

often lacks knowledge of the NLF system.

- The **competence and impartiality of notifying authorities are not demonstrated** as is done for national accreditation bodies through a peer evaluation system performed by EA. Within this context, NBs raised the following perceived challenges:
  - Several of the notifying authorities lack competence and experience regarding conformity assessment linked to the activities of NBs that they are supposed to monitor. They often ignore the applicable European / international standards. Besides, notifying authorities operate without checks and are not subject to a peer evaluation system for them to show evidence of their competence.
  - There are conflicts of interests: some NBs and the notifying authorities are part of the same governmental entities.
  - Some stakeholders stress the lack of resources of notifying authorities to conduct their mission.
- According to these NBs, these discrepancies lead to unfair competition between accredited and non-accredited NBs and could end-up stimulating rogue trading. As put by a large certification body, different levels of competence among notified bodies may ultimately invite rogue operators to have their products checked by less competent bodies. This can result in a higher number of non-compliant products placed on the internal market and a lack of trust in EU products.

National accreditation bodies confirm that notifying authorities:

- Rarely use harmonised standards to check on non-accredited notified bodies nor a robust peer-evaluation system.
- Checks are not made as frequently and in-depth as under the EU accreditation system.
- Cooperation between NBs and market surveillance authorities is not mandatory. Besides, according to authorities there is a lack of:
  - Handling of the correction of erroneously issued certificates.
  - Clear status of certificates for products subject to an EU-wide safeguard clause measure.
  - Central registry for certificates issued by non-accredited NBs.

Although the discussion of potential future solutions to these challenges is not within the scope of this evaluation, a key discussion point stemming from the consultations with national accreditation bodies, notifying authorities and conformity assessment bodies related to **whether accreditation should be mandatory for the purposes of notification**.

Under the application of the subsidiarity principle, a decision was taken at the time of the NLF's adoption to not mandate accreditation for the purposes of notification. However, as highlighted through the above, many stakeholders believe key weaknesses of the conformity assessment system could be improved by ensuring all NBs are accredited. This question is now analysed.

Different perspectives have been put forward by interviewed stakeholders on the question of whether stricter requirements should be introduced for accreditation. On the one hand, accreditation costs money, so it could discourage certain CABs from seeking accreditation. However, on the other hand, if mandatory accreditation was introduced, stakeholders remarked that all CABs would be bound by the same rules.

In addition, stakeholders noted that it would also be conducive to have the same requirements applying to CABs in the different EU Member States. Stakeholder views on the question of whether and how accreditation should become mandatory are presented and discussed in the following box.

Should accreditation become mandatory and why?

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 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 difficult for it to achieve this accreditation. For instance, in Slovenia, the accreditation body does not accredit organisations without evaluating its 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, notified 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 using the same model as in the food sector, either in the form of 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.

Conclusion

In summary, the **NLF has performed well overall in terms of strengthening the quality of conformity assessment services**. Stakeholders strongly believe in the effectiveness of the suite of conformity assessment modules and the findings indicate strong positive impacts of the accreditation system compared with the pre-NLF system. More specifically, stakeholders highlighted: i) greater coherence and consistency of the criteria and procedures for the accreditation and notification of NBs; and ii) greater quality and consistency of conformity assessment bodies across the EU. These positive results can subsequently contribute to higher-level effects, such as greater compliance with the essential requirements across laws (and thus improved product safety), improved consumer protection and trust, and fairer competition across the single market for both economic operators and conformity assessment bodies.

However, as detailed through this section, there are clear **weaknesses in the conformity assessment framework** and many stakeholders believe that the European accreditation system could be **strengthened and significantly improved through greater harmonisation and definition of uniform minimum procedures**. These weaknesses limit the scale of the positive impacts achieved and include the following:

- Current framework does not ensure full harmonisation of practices across the framework for the accreditation of conformity assessment bodies. For instance, ambiguities and differences between the requirements for accreditation applied across the EU create challenges for NABs establishing and CABs seeking accreditation. Moreover, the nature of accreditation (whether mandatory or not) differs across the Member States.
- Current framework does not ensure full harmonisation of notification practices across the EU.
- Challenges exist at the interface between the accreditation and notification systems.
- Lack of formal cooperation between national notifying authorities.
- Gaps in the rules on subcontracting and use of subsidiaries, resulting in uncertainty across the EU in terms of what is permissible.

Furthermore, stakeholders highlighted the following **risks related to legislative and market trends that they perceive could impact, and potentially increase the burden associated with, conformity assessment services**: i) the inclusion of more extensive conformity assessment procedures within product legislation; ii) the inclusion of detailed technical specifications within product legislation, which goes against the principles of the New Approach; and iii) the need to incorporate certain developments brought by digital and circular economy trends in the existing suite of conformity assessment modules.

4.1.1.3 CE marking and other information obligations

Clarifying the meaning of the CE marking and enhancing its credibility, particularly within the EU, was considered a key need of the internal market when the NLF was developed. The CE marking was already a vital component of the system for demonstrating compliance with applicable EU product legislation; however, challenges existed prior to the NLF's adoption – specifically, misunderstanding of the meaning of the CE marking – that may have induced a lack of credibility among some stakeholders within the EU.

As summarised in the 2017 report on the implementation of Regulation (EC) No 765/2008, the most recent assessment of internal market legislation for industrial products, conducted in 2014[52], "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"[53].

This finding is reinforced by the research and consultations conducted for this evaluation, including interviews with all stakeholder groups. **Most stakeholders maintain the CE marking holds significant value and works well**. For instance, 70% of respondents to the targeted consultation (158 of 226 respondents) perceive the NLF to have been either somewhat effective (32%, 72 Respondents) or very effective (38%, 86 respondents) in strengthening the visibility and use of the CE marking system. In

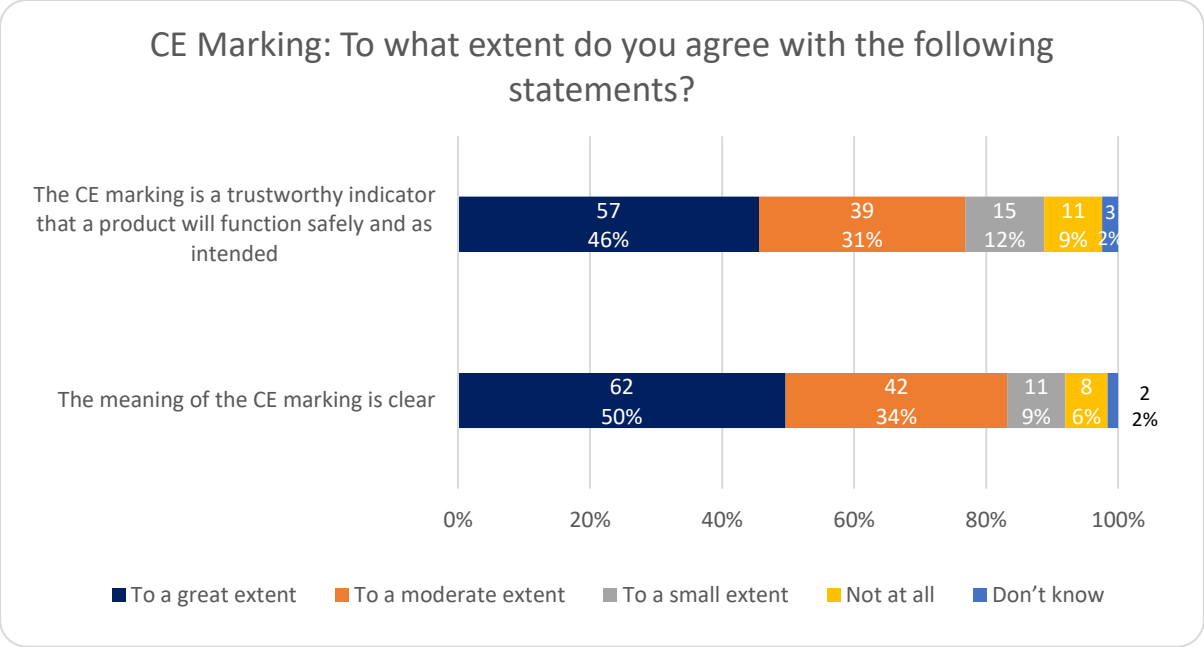
[52] Commission staff working document SWD(2014)23 on the evaluation of the internal market legislation for industrial products, accompanying Communication COM(2014)25 on a vision for the internal market for industrial products

[53] 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.

particular, stakeholders highlighted the CE marking's strong global reputation and the global benefit of having a common approach.[54]

Similarly, in response to the public consultation, **stakeholders strongly supported the clarity and trustworthiness of the CE marking**. As illustrated below, 83.2% of respondents (104 of 125) perceive the meaning of the CE marking to be clear, to a great or moderate extent, and 76.8% of respondents (96 of 125) perceive, to either a great or moderate extent, that the CE marking is a trustworthy indicator that a product will function safely and as intended.

Figure 4-6: Clarity and trustworthiness of CE marking (N=125)



However, in this context, a **few challenges have been highlighted by stakeholders which can limit the positive results achieved by the NLF**. Consumer associations, for instance, still share concerns related to understanding the purpose of the CE marking. 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**. These stakeholders noted a proliferation of different conformity, quality, and certification markings in recent years, with many nations or regions across the globe developing their own markings and requirements. For instance, examples in the area of electromagnetic compatibility include the KC (Korea Certification) mark in Korea and the PSE mark in Japan. The need to indelibly mark products differently for different regions brings 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.

In this respect, as discussed further in Chapter 4.2.5, stakeholders from all groups agree that digitalisation offers a potential solution, and that the digitalisation of information requirements related to the CE marking, as well as other compliance and consumer information, could bring significant benefits.

[54] Results of Question 10 (N=226): Overall, to what extent has the NLF been effective in achieving the following objectives?

4.1.2 Achievement of the NLF's general objectives

Following the detailed examination of the achievement of the NLF's speabove, this chapter focuses on the extent to which this performance has resulted in progress towards the NLF's general objectives. As summarised in Chapter 2.3.1, the general objectives of the NLF are as follows:

- **Provide a high level of protection of public interests** (e.g. health and safety, consumer and environmental protection).
- **Foster the free movement of products** within the single market.
- **Establish a common harmonisation framework**.

Assessing the extent to which the NLF has contributed to the achievement of the first two general objectives is challenging. As detailed in Annex 2, a range of conceptual evaluability challenges are important to consider and hinder the clear identification and validation of causal chains between the NLF's provisions, its application and implementation, and the achievement of its objectives. More specifically, the nature of the NLF as a horizontal framework that influences the provisions adopted in specific Union harmonisation legislation means that the NLF's impact is primarily indirect and raises questions related to the attribution of any impacts to the NLF rather than aligned UHL.

However, establishing logical impact chains, building on the intervention logic, helps clarify the role of the NLF in the overall achievement of these two general objectives by the wider EU legal framework applicable to products.

In this chapter, we first examine the achievement of the third general objective – namely, to establish a common harmonisation framework – as this is more directly related to the purpose and nature of the NLF. Subsequently, we map the logical impact chains and indicate the extent of the NLF's success for the first and second general objectives based on the assessments of the outputs of the NLF (detailed in Chapter 3.1) and the performance of its key components (as detailed in Chapter 4.1).

Establish a common harmonisation framework

The NLF was introduced to prevent divergence by providing a common set of reference provisions in the form of a regulatory toolbox that could be used to ensure that EU legislators revised existing, and developed any new sectoral legislation in a way that did not lead to divergent, non-NLF requirements being introduced. As detailed above, this was mainly achieved by putting in place tools such as common obligations for economic operators and a menu of conformity assessment modules for the regulator to select from and implement.

The extent to which divergence has been prevented, and conversely examples of legislation where divergence has arisen and can be justified, have both been examined in Chapter 4.1.1.1.

First, as demonstrated in the regulatory mapping in Annex 7, there have not been that many changes to most individual pieces of sectoral legislation applicable to products. Typically, the essential requirements, conformity assessment modules, and many of the sector and product-specific elements of the legislation have remained the same following their alignment with the NLF. This reflects the fact that the NLF was not designed to lead to significant changes to the core legislation itself, but rather to integrate common elements to the legislation, such that this would prevent divergent requirements from emerging, while also ensuring that the general principles of Union harmonisation legislation developed under the NLF were reinforced.

The mapping of changes to NLF-aligned legislation found that **the NLF has been successful in ensuring that, in general, the main new additions to legislation that was aligned with the NLF in incremental steps from 2008 onwards have been those common elements**, such as the common requirements for economic operators. The NLF has nonetheless had a positive impact, even though the changes to

individual pieces of legislation were generally minor, for instance in ironing out administrative inconsistencies between different sectoral legislation in the requirements for economic operators.

Furthermore, the legal mapping illustrates that, in most cases, the **divergence between the legal provisions of NLF-aligned legislation and the NLF's reference provisions are minor**. This is true across all relevant topics, including on the definitions, the obligations of economic operators, the conformity of the product, and the notification of conformity assessment bodies. This was confirmed by stakeholders from all groups, who considered that the system established by the NLF, as well as the process of alignment of product legislation has been successful.

Beyond the reference provisions, the NLF introduced the **accreditation framework**, which has also contributed to improving and harmonising the system and conditions for the marketing of products within the internal market. In this regard, stakeholders from all relevant groups have highlighted the NLF's effectiveness, noting that the accreditation system generally functions well and ensures an overall satisfactory level of competence of notified bodies.

However, as highlighted through Chapter 4.1.1, there are a range of current challenges that limit the achievement of this general objective. These can be grouped as follows:

- **Application and implementation challenges.** Although only minor differences between the provisions of NLF-aligned legislation and the NLF exist, these minor differences can, if cumulative across different laws applicable to a product, lead to more significant impacts on the complexity and costs of compliance and thus potentially compliance itself. Furthermore, considering the accreditation framework, stakeholders across all relevant groups highlighted application challenges related to, for instance, in some cases, unequal competence of accredited bodies across the EU.
- **Non-alignment of other EU legislation applicable to products**. It is clear that, in some areas, legislation that is applicable to products alongside NLF-aligned legislation has diverged from the principles and provisions of the NLF, including both 'New Approach' directives and other sectoral Union harmonisation legislation. For instance, considering environmental legislation, the definition of 'manufacturer' in Directive 2009/125/EC (ecodesign for EUP) has been found to significantly diverge from the NLF definition. However, this issue of coherence is discussed further in Chapter 4.3.

Furthermore, as detailed in Chapters 3 (on market and regulatory developments) and 6 (on the NLF's relevance), stakeholders across all groups have highlighted a range of **emerging market trends (and Commission efforts to tackle them) that are beginning to undermine the NLF's common provisions**. For instance, many stakeholder groups, including EU consumer and industry associations interviewed, argued that, whilst the NLF was effective from 2008 until around 2015, there has been an increasing raft of new proposed EU legislation which go beyond the 2008 regulatory framework. Examples cited were the proposal for the GPSR (to replace the GPSD), the proposal for a Machinery Regulation, the proposal for an AI Act, the activation of the delegated acts under the RED, and the web accessibility directive.

Although these legislative updates are based on the NLF principles and reference provisions, many stakeholders perceive that the harmonisation work of the NLF has been undermined in recent years and requires modernisation due to: i) the need for the Commission to ensure the relevance of these new legislative developments to current market and industry practices, which have developed significantly since the adoption of the NLF; and ii) the fact that the NLF was built on a legislative approach originally developed in the 1980s according to the New Approach. This is explained further in the chapters analysing the ongoing relevance of the NLF (Chapter 6) and its coherence with the wider EU body of legislation (Chapter 4.3).

Provide a high level of protection of public interests and foster the free movement of products

This chapter examines the logical impact chains linking the NLF's key components and their achievements to related results and impacts. This is done using the framework of the NLF's specific and general objectives. Given the indirect nature of the relationship, this assessment is primarily qualitative.

As detailed in Chapter 3.1, the **main outputs** of the NLF are as follows: i) the common reference provisions on definitions, obligations of economic operators, conformity of the product, and notification; ii) the conformity assessment system, including the conformity assessment procedures, the accreditation framework for conformity assessment bodies, and the rules on notification and notified bodies; and iii) the rules on CE marking.

The primary **results achieved by these outputs include clearer and more robust rules on the conformity assessment system, and better alignment across the body of EU legislation** applicable to products for both the conformity assessment system itself and the related reference provisions. More specifically, stakeholders have highlighted the following results of the NLF:

- Considering the specific objectives related to reinforcing the New Approach and supporting the consistency and coherence of EU harmonisation legislation, key results include: ensuring technological neutrality across the legal framework; improved alignment across EU product legislation; and **administrative simplification of the compliance process** and, consequently, the prevention of significant divergences. In turn, this simplification has **reduced the costs of compliance** for economic operators, considering both costs of familiarisation with Union harmonisation legislation and costs of conformity assessment procedures.
- For the specific objective on strengthening the quality of conformity assessment services, the establishment of clear rules and better alignment across accreditation and notification procedures has resulted in **higher quality and more consistent third-party conformity assessment services** across the internal market.
- The improved clarity and better alignment of the rules for CE marking **has reinforced the strength of the CE marking and improved internal and global trust** in the Union market.
- Furthermore, according to industry stakeholders, the combination of greater administrative simplification for economic operators and greater consistency of conformity assessment services across the market has resulted in: i) **increased fair competition between economic operators**; ii) **increased levels of compliance** with applicable product legislation; and iii) **improved implementation of product safety and other essential requirements**.

Although challenges have been identified across these elements (as explained above), these **results have, for the most part, been validated by stakeholders from all groups**.

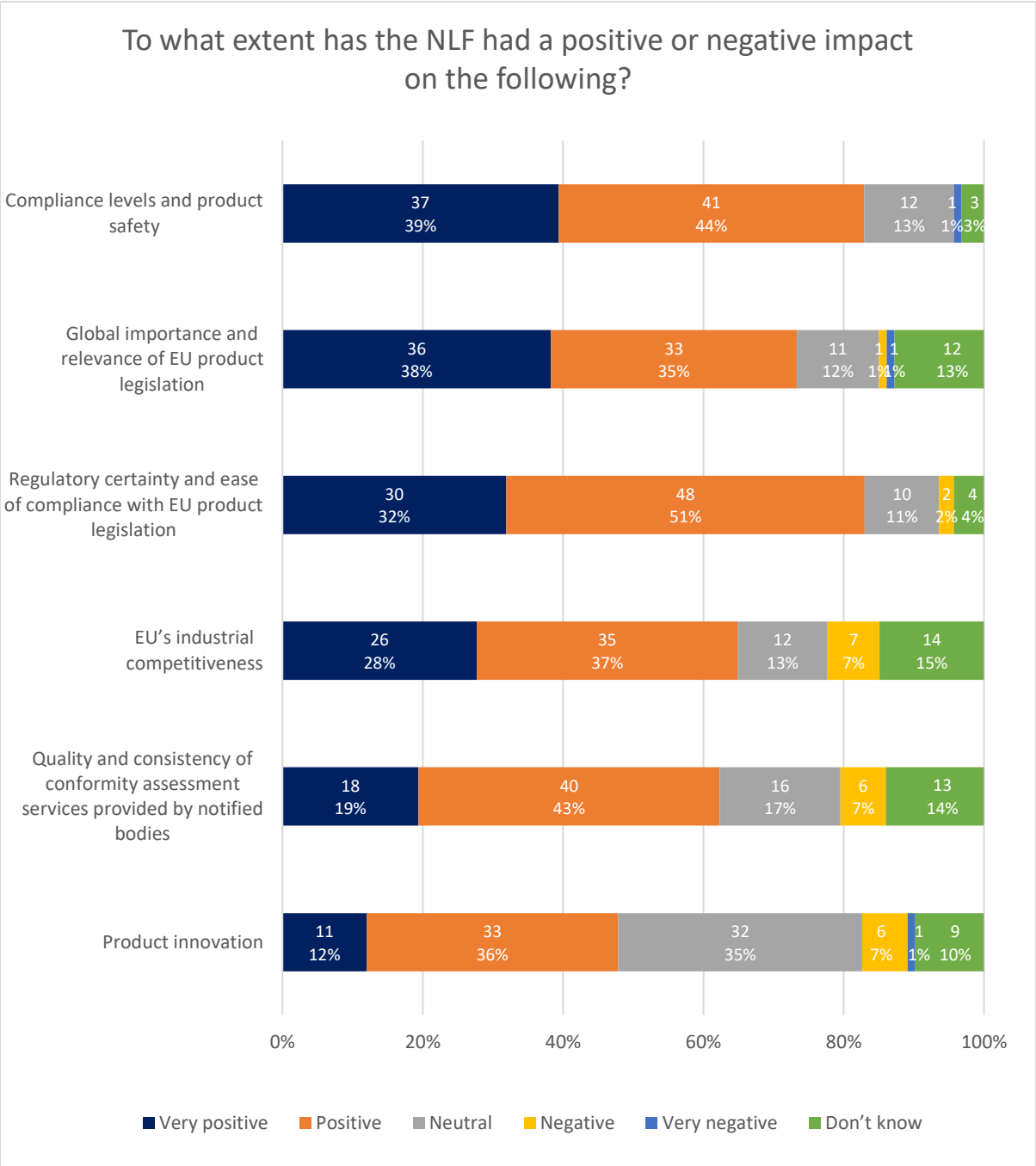
Beyond these more directly attributable outputs and results, the potential **impacts** are more difficult to assess, as many are achieved indirectly via the implementation of specific Union harmonisation legislation and overall performance of the internal market. In summary, stakeholders have highlighted the following as positive indirect impacts of the NLF:

- **Increased protection of the public interests**, following on from the increases in compliance and improved implementation of product safety and other essential requirements.
- **More effective and efficient internal market for products**, because of the positive results achieved in relation to the operation of the conformity assessment system, and the improvements in compliance rates and product safety.
- **Enhanced global standing of the EU in global commerce**, because of the ability of EU legislation to elevate standards and shape practices worldwide.

- **Support for industry innovation**. Industry stakeholders highlight that the simplification and improved clarity of the regulatory framework supports the capacity for innovation, as industry can: i) spend more resource on innovation; and ii) have certainty about the laws with which innovative products will need to be compliant.
- **Support to Europe's industrial competitiveness**. Improvements in all the elements of the legal framework in a flexible and technology-neutral manner, as well as the achievement of the above impacts, support the ability of European industry to compete globally.

The public consultation results further support this assessment. Although there is variation in the perceived extent of the impacts, the below figure clearly illustrates the **positive stakeholder perceptions on the contribution of the NLF to these impacts**. More specifically, the vast majority of respondents thought the NLF had a positive or very positive impact on compliance levels and product safety; regulatory certainty and ease of compliance (both 83%, 78 responses); the global importance and relevance of EU product legislation (73.4%, 69 responses); and the EU's industrial competitiveness (64.9%, 61 responses). In contrast, a maximum of only seven stakeholders reported any level of negative impacts across these areas.

Figure 4-7: Stakeholder perceptions on the impact of the NLF (N=92 to 94)



However, the challenge of measuring the scale of these impacts and attributing them to the NLF is illustrated in the following table, which summarises the limitations associated with analysing product safety and compliance-related data; namely, Safety Gate product alerts (see Annex 6 for full analysis) and data on product non-compliance captured by MSA Administrative Cooperation (ADCO) groups.

Data on product safety and compliance: Limitations

The Safety Gate system, formerly known as the Rapid Exchange of Information System (RAPEX), is the EU's **rapid alert system for sharing information between national authorities on dangerous non-food products**. The system is comprised of alerts that contain a wide range of information on non-compliant products identified on the internal market, 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.

An analysis of all Safety Gate data in the period 2005-2021 is presented in Annex 6. However, it provides limited support to the analysis of the impact of the NLF due to the following challenges:

- It is **not clear what proportion of relevant Safety Gate product alerts the analysis has been able to capture** due to the way in which the links between product alerts and non-compliance with specific pieces of legislation is recorded. **More specifically, these links are indicated through one of two open text responses, depending on whether they were submitted before or after 2011. These text responses explain the risk associated with the product alert; however, this text can refer to non-compliance with harmonised standards and/or non-compliance with one or more pieces of specific legislation.** Although an analysis of alerts related to NLF-aligned legislation is possible to some extent, as conducted in Annex 6, its ultimate level of accuracy is unknown as a result of this limitation.
- Safety Gate product alerts are inextricably aligned to the work of market surveillance authorities (MSAs). However, the **practices and priorities of MSAs are different across the EU Member States** and, within Member States, may have changed over the period under examination; this was clearly reported in the impact assessment study of the proposed Goods Package from 2013.[55]

Moreover, a range of ADCO groups supporting different NLF-aligned laws have conducted **campaigns to determine levels of non-compliance for certain products** over the years. For instance, in 2018, the ADCO group on gas appliances conducted a coordinated action to determine levels of non-compliance in parasol patio heaters domestic portable heaters and mobile non-domestic forced convection direct fired air heaters, finding 60.7% non-compliance.[56] Similarly, the 2020 statistics published by the RED ADCO reported a non-compliance rate of 56.18%.[57]

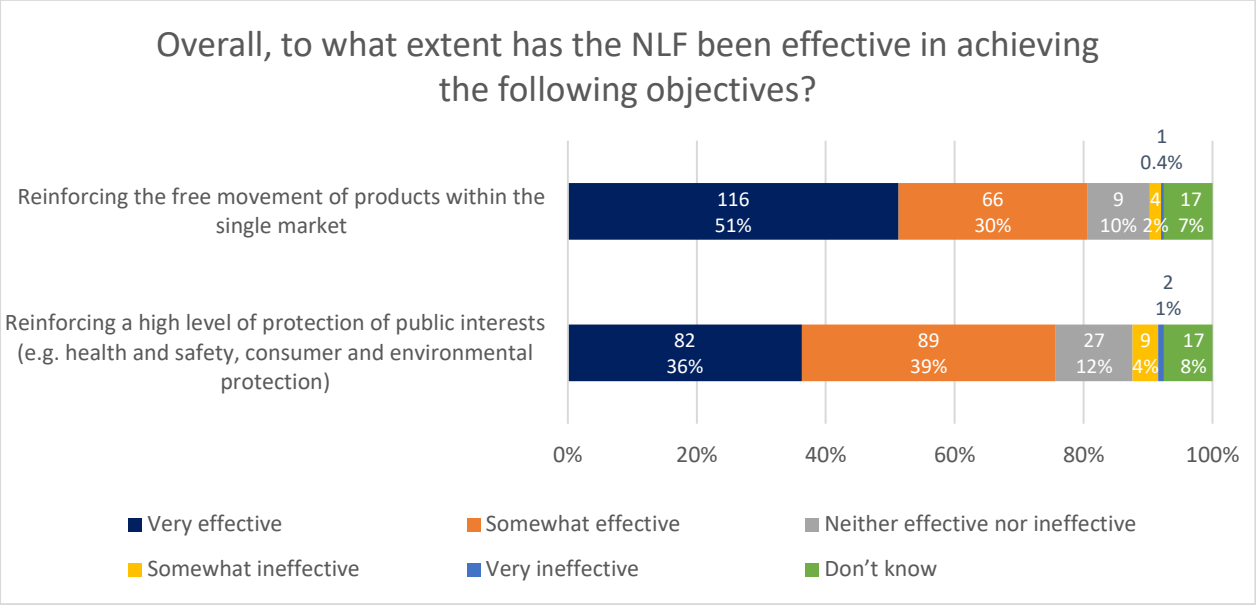
However, these campaigns target products in specific sectors with high non-compliance rates and therefore do not reflect the market as a whole. Furthermore, most are one-off campaigns, meaning that it is not possible to analyse trends over time. Even if time series data were available, other external factors, such as the impact of e-commerce on the sales of non-compliant product types in certain areas, could limit the ability to attribute any trends to the legislative framework.

These factors, as well as others, **significantly restrict the ability of the analysis to attribute or link any product safety or compliance trends identified to the NLF**.

Specifically considering the two general objectives under discussion, the results of the targeted and public consultations provide further validation of the above. As illustrated in Figure 4-8, the vast majority of stakeholders responding to the targeted consultation perceive that the **NLF has been somewhat or very effective in reinforcing the free movement of products within the single market** (80.5%, 182 respondents across the two options) and **reinforcing a high level of protection of public interests** (75.7%, 171 respondents). In the public consultation, these figures were even higher; 90.5% (86 of 95 respondents) for reinforcing the free movement of products and 87.4% (83 respondents) for reinforcing a high level of protection of public interests.

[55] SWD(2013) 33 final of 13.2.2013, Commission staff document on an impact assessment accompanying the document "Product Safety and Market Surveillance Package"
[56] https://ec.europa.eu/docsroom/documents/38401
[57] https://ec.europa.eu/docsroom/documents/47679

Figure 4-8: Overall effectiveness of the NLF in achieving its objectives (Question 10, N=156)



However, as highlighted throughout this chapter, these **positive outcomes are hindered to some extent by a range of current and emerging challenges**: i) the application and implementation issues examined through Chapter 4.1.1.1; ii) the introduction of inconsistent definitions and obligations under legislation that is applicable to many products but not aligned to the NLF; iii) key market developments relating to the digital and circular economies that challenge the fitness for purpose of some aspects of the NLF, as discussed further in Chapter 6 on relevance; and iv) the EU's emerging legislative approach to addressing challenges posed by these market developments, including in recently adopted and proposed laws, such as the RED delegated act on cybersecurity, and proposals for a GPSR, an AI Act and a Machinery Regulation.

4.2 Efficiency

Efficiency considers the **relationship between the effects (i.e. the outputs, results and impacts) achieved by the NLF and the inputs used by the NLF**. In particular, this chapter addresses issues relating to how far the NLF has contributed towards the achievement of its objectives at a proportionate cost, mapping the costs and benefits generated by the NLF and answering the following evaluation questions:

- **EQ2.1:** What are the **regulatory and administrative costs** associated with the NLF and are they affordable for the various stakeholder groups (and SMEs in particular)? Is there evidence that the NLF has cause unnecessary regulatory burden?
- **EQ2.2:** What are the **benefits** and how beneficial are they for the various stakeholder groups (and SMEs in particular)? To what extent has the simplification potential expected at the time of the adoption of the NLF been achieved?
- **EQ2.3:** To what extent **are the costs incurred proportionate to the benefits attained**? What are the factors influencing the proportionality of costs?

This chapter is structured as follows:

- The first sub-section details **methodological considerations** relevant to the assessment of the NLF's efficiency. It summarises the links between the assessment of efficiency and the NLF's intervention logic, before presenting general features of the assessment's approach as well as a four-step process for the evaluation of each cost and benefit (Chapter 4.2.1).

- The second sub-section offers a **review of costs and benefits of NLF-aligned pieces of legislation**, based on previous evaluation studies and impact assessments. This is supported by a case study covering two selected directives, the Electromagnetic Compatibility Directive (EMCD) and the Toy Safety Directive (TSD), which investigates the challenge of attributing observed impacts to the NLF or to the sector-specific legislation (Chapter 4.2.2).
- The third and fourth sub-sections present evidence on the **costs and benefits of the NLF**, gathered through desk research, the interview programme, and the online surveys (Chapters 4.2.3-4.2.4).
- The fifth subsection analyses **opportunities for efficiency improvements within the context of the NLF**, focusing on digital labelling and the use of remote assessment techniques for conformity assessment services, accreditation, and peer evaluation (Chapter 4.2.5).
- The final sub-section provides **concluding remarks** and summary answers to the efficiency-related evaluation questions (Chapter 4.2.6).

To support these sub-sections, an overview of costs and benefits generated by the NLF is presented in table format in Annex 3.

4.2.1 Methodological notes

According to the **intervention logic** previously illustrated (see Chapter 2), inputs and effects can be defined as follows:

- The NLF's **inputs** are the human and financial resources spent by public authorities (European Commission and national authorities), as well as by economic operators to implement and comply with the NLF.
- **Outputs** are the immediate and short-term outcomes (such as the number of NLF-aligned pieces of legislation); **results** are intermediate outcomes (such as the availability of a regulatory toolbox to facilitate the harmonisation of legislation, or the availability of common definitions for sectoral and product legislation); finally, **impacts** correspond to high-level objectives (such as strengthened protection of public interests, or improvements in the effectiveness of the internal market).

Among the three types of effects, the efficiency dimension considers results and impacts especially, as they represent the ultimate effects of the NLF.

Costs of the NLF are represented by its inputs. Benefits of the NLF are its positive results and impacts. In what follows, an analysis based on a triangulation of previous literature (especially evaluations of NLF-aligned pieces of legislation), stakeholder consultations and evaluative judgment offers insights for the assessment of the NLF's efficiency.

For the purposes of this analysis, the **timeframe** considered starts in 2014 and ends in 2020. Despite the NLF being adopted in 2008, it is more appropriate to consider only effects brought about after 2014, as most of the legislation aligned with the NLF to date was recast and aligned in or after 2014[58]. Accordingly, the **baseline scenario** against which each cost and benefit is assessed is the pre-2014 situation.

A crucial question to be addressed in the assessment of the NLF's efficiency is related to **attribution**; namely, the degree to which costs and benefits are the result of the NLF itself or the underlying NLF-aligned legislation. Solving this conundrum is not straightforward due to the interplay of horizontal and sector-specific provisions. Through case studies examining the specific cases of the Electromagnetic Compatibility Directive (EMCD) and the Toy Safety Directive (TSD), the question of

[58] See more information about temporal and geographic scope under 1.2.

attribution is addressed by identifying which provision is the root cause of costs and benefits of NLF-aligned legislation. The case studies are presented in Annex 4 and referred to throughout this section.

The **identification** of the NLF's costs and benefits is performed based on the review of evaluations of NLF-aligned legislation, as well as the NLF's intervention logic and the 2007 NLF impact assessment.

For each cost and benefit of the NLF, the following sequential approach shapes the analysis:

- **Step 1) Definition**. A short description is provided, clarifying the stakeholders affected and the underlying drivers.
- **Step 2) Attribution to the NLF**. The attribution to the NLF is briefly discussed and justified.
- **Step 3) Qualitative assessment**. Stakeholders' feedback, evidence from desk research and contextual considerations are analysed and developed into a narrative leading to an informed judgment.
- **Step 4) Quantitative assessment**. If a quantitative or monetary estimate of the cost or benefit can be provided, this assessment provides an incremental estimate against the baseline scenario. Figures provided in the quantitative assessment should be interpreted as indicative of an order of magnitude, based on the line of reasoning followed.

4.2.2 Costs and benefits of NLF-aligned legislation: a review of previous studies

For those NLF-aligned pieces of legislation evaluated on behalf of the European Commission after 2014, the following table includes information concerning: **costs; benefits; and the proportionality of costs and benefits.** For each piece of legislation, the source of the information included in the table is the respective evaluation study. The table presents this information for the following pieces of legislation[59]:

- Toy Safety Directive 2009/48/EU.
- Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU.
- Electromagnetic Compatibility Directive 2014/30/EU.
- Low Voltage Directive 2014/35/EU.
- Construction Products Regulation 305/2011.

[59] A support study for the evaluation of the Lifts Directive on behalf of the European Commission and the related Commission Staff Working Document were published in 2017 and 2019 respectively. These documents, however, focus on the original Directive (95/16/EC) and not on the new NLF-aligned Lifts Directive (2014/33/EU), which repealed the former in April 2016. For this reason, the evaluation is not included in the following table.

Table 4-5: 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	***For manufacturers:*** • Compliance costs of the RoHS Directive for businesses include collecting and reviewing information, gathering supply chain	• Reduced exposure to restricted substances,	• Benefits driven by the environmental and health **benefits outweigh the**

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
and Electronic Equipment Directive 2011/65/EU **2021 Evaluation**	information, costs related to a dedicated IT system to manage all required pieces of information, costs related to the exemption system. • Technical costs include complying with 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.	leading to environmental and health benefits. • **Economic 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.	**compliance and enforcement 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. EMC-relevant measures).	• **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
	• 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 EU.	• Stakeholders consider that **benefits outweigh costs**.

Legislation and evaluation	Costs	Benefits	Proportionality of costs and benefits
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.

In addition to evaluation studies, impact assessments have also been considered[60], although they in principle primarily assess future alternative options, rather than existing costs and benefits. In particular, in 2011 the Commission published an impact assessment accompanying ten proposals to align product harmonisation directives to Decision No 768/2008/EC[61]. The impact assessment considered the following aspects: i) economic impacts (functioning of the internal market, competitiveness of EU-firms, operating costs and administrative burdens, impacts on public authorities, consumers, households and other users, third countries and international relations); ii) social impacts (public health and safety); iii) environmental impacts (restriction of environmental unfriendly goods and prevention of fire, explosions and accidents leading to environmental risks); and iv) simplification of the regulatory environment. In terms of methodology, it relied to a great extent on the results of a stakeholder consultation. No quantification of the impacts was provided and their assessment was largely of a qualitative nature. The assessment concluded identifying the alignment of the Directives to the NLF via legislative measures as the preferred option.

From a horizontal reading of the evaluations or impact assessments on individual NLF-aligned pieces of legislation, the following main messages can be drawn.

- **The evaluated Directives and Regulations generate benefits that outweigh their costs**. Even though the studies were faced with difficulties in quantifying impacts, qualitative analysis relying on stakeholders' opinions led to a positive assessment on efficiency. Quantification struggles were often related to lack of data (e.g. concerning increased product safety) or incomplete datasets (e.g. in terms of spectrum of product types covered by a legislation; Member States; stakeholders affected by the legislation) but also to the unquantifiable nature of some relevant impacts (e.g. due to the strategic nature of some benefits).
- **The generated costs are mostly borne by manufacturers.** The main costs identified in the case of NLF-aligned legislation are borne upfront by manufacturers and can be grouped as: familiarisation costs (e.g. time spent with identification of and familiarisation with legislative requirements); product development costs (e.g. engineering costs; purchase of standards, design adaptation to related standards); conformity assessment costs (e.g. preparing and updating document required by the conformity assessment procedure; laboratory tests; involvement of a notified body); and production-related costs. The extent to which the costs borne by manufacturers are passed on to end-users and consumers could not be ascertained in the framework of these studies.
- **The generated benefits are typically of technical or strategic in nature**. Technical benefits refer to the correct functioning of products and to their increased safety. Strategic benefits mainly refer to increased health and safety, increased competitiveness, legal certainty, ensuring a level playing field in the internal market, and the high standing of EU legislation in third countries.
- **Impacts affect SMEs differently**. SMEs are reported to have limited staff with specific legal skills and for this reason, identifying obligations and ensuring compliance can represent a hurdle. When faced with new legislative requirements, SMEs tend to turn to external consultants, increasing overall costs. Also, due to the limited capacity of their laboratories – as regards both economic resources and competences – SMEs have to use external testing laboratories or notified bodies to ensure compliance with applicable NLF-aligned legislation. This again increases the costs. Furthermore, SMEs' low production volume fails to reap economies of scale benefits and to

[60] Not all Impact Assessments carried out on NLF-aligned legislation are however relevant for this review. For example, in 2020, an Impact Assessment on specific aspects of the Radio Equipment Directive was published, followed in 2021 by the related Commission Staff Working Document. This Impact Assessment, although it has a part on costs and benefits, does not cover an evaluation of costs and benefits of the Directive as such, as it focuses on changes to specific (cybersecurity-related) parts of the RED. As of Spring 2022, in addition, an Impact Assessment concerning possible revisions to the Toy Safety Directive is ongoing (no deliverable is publicly available yet).

[61] SEC(2011) 1376 final. The ten Directives under scope were: Low Voltage Directive; Electromagnetic Compatibility Directive; ATEX Directive; Lifts Directive; Pressure Equipment Directive; Simple Pressure Vessels Directive; Measuring Instruments Directive; Non-automatic Weighing Instruments Directive; Civil Explosives Directive; Pyrotechnic Articles Directive.

compensate initial investments. The costs in terms of turnover thus might affect SMEs disproportionately.

Drawing a line between NLF-related impacts and impacts that should be attributed only to the individual legislation is not straightforward. Two case studies on recently evaluated directives, the Electromagnetic Compatibility Directive (EMCD) and the Toy Safety Directive (TSD), investigate the issue of attributing effects to the NLF or to the sector-specific legislation. The case studies, presented in Annex 4, aim to schematically review the costs and benefits identified in the two evaluations and offer insights on their relationship with the NLF.

To summarise, **costs of product development or costs of production** deriving from technical requirements in the Directives can be assessed as being not related to the NLF. For example, this is the case for EMC-related engineering costs and production costs (e.g. shielding), which according to the evaluation of the EMCD would likely be borne irrespective of the Directive, to ensure product quality and safety, and therefore represent business-as-usual (BaU) costs. Similarly, under the TSD, some costs were generated by the Directive's requirements on chemicals (e.g. one-off adaptation costs and production costs). These, too, cannot be assessed as NLF-related.

In the case of **costs related to conformity assessment**, the costs can be attributed to some extent to the NLF, as they stem from the integration of NLF rules in the Directives. These costs include, for instance, preparing technical documentation, performing laboratory tests (although they partially represent BaU costs) and potentially using a notified body. However, it is important to note that in a hypothetical scenario without the NLF, the Directives would likely still contain conformity assessment procedures, 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.

Similarly, many of the Directive-specific **benefits** are primarily the result of provisions included in the Directives themselves, such as the technical benefits of reduced incidence of electromagnetic disturbance resulting from the essential requirements (in the case of the EMCD), or increased safety (in the case of the TSD). However, some benefits, such as increased market efficiency, improved industrial competitiveness and reduced legal uncertainty can be attributed to some extent to the NLF. Although the EMCD and TSD costs attributed to some extent to the NLF are more than its benefits, their scale, based on stakeholder feedback, is strongly tending towards benefits, which are more strategic and wide-ranging than costs, which are more often generated upfront.

4.2.3 Costs of the NLF

The costs of the NLF are represented by its **inputs**; namely, the human and financial resources spent by public authorities (European Commission, EA and national authorities), as well as by economic operators to implement and comply with the NLF. This section details these costs following the four-step approach outlined above under Chapter 4.2.1.

4.2.3.1 Costs of the NLF: Resources spent by bodies at European level in relation to NLF implementation

Step 1) Definition. Resources spent by the European Commission's relevant units and the European co-operation for Accreditation (EA) in relation to NLF implementation, compared with pre-2014 scenario.

Step 2) Attribution to the NLF. These resources represent inputs to the NLF's functioning. As such, they are attributed to the NLF, in line with its intervention logic.

Step 3) Qualitative assessment. In the European Commission, most of the resources used across DG GROW and other DGs to implement NLF-aligned legislation relate to the implementation of the

specific product or sectoral Directives and Regulations rather than the NLF[62]. Although there are resources dedicated specifically to the NLF as an overarching framework within DG GROW, it is considered that the resources used by the Commission would have been largely necessary even in the absence of the NLF to ensure some form of coordination across product legislation and can therefore be considered as a business-as-usual (BaU) cost.

The European co-operation for Accreditation (EA) was formally appointed by the European Commission in Regulation (EC) No 765/2008 to develop and maintain a multilateral agreement of mutual recognition, and plays an important role in the implementation of the NLF (as detailed in Chapter 3.1). EA's main mission is to promote a transparent and quality-led system for the evaluation of the competence of conformity assessment bodies throughout Europe and to manage a peer evaluation system among national accreditation bodies. However, its budget cannot be entirely considered as related to the NLF implementation, as defined in the scope of this evaluation. EA's scope in fact extends beyond Europe, including a total of 49 national accreditation bodies. Moreover, even in the absence of the NLF, some form of coordination between accreditation bodies would likely be required. Nevertheless, information about EA's budget provides contextual information instrumental to understanding the NLF's implementation on the ground.

As of 2022, EA has an annual budget of around 1.5 million Euro and 8 staff members. In 2018, the Operating Grant which enables EA's activities was increased by around 130,000 Euro. This increase, according to feedback from EA, was not caused by the alignment of legislation to the NLF. The cause was new EA activities (several of them related to new EU pieces of legislation taking recourse to accreditation and conformity assessment, in non-harmonized sectors), the increased scope (conformity assessment activities) to cover in the EA peer evaluation system, and the strengthening of EA communication activities. Due to these issues, the number of staff members was slightly increased as well.

Step 4) Quantitative assessment. For the European Commission, the costs in managing the NLF and NLF-aligned legislation can be considered BaU costs, and the incremental cost generated since 2014 is nil.

Considering that EA's annual Operating Grant was increased by about 130,000 Euro in 2018, but that EA's scope extends more widely than the geographic scope of this evaluation, the relevant annual increase can be estimated at around 90,000-120,000 Euro. This annual incremental cost, considered for the three years between 2018 and 2020, represents the total incremental cost.

Based on this, in the years between 2014 and 2020, the total incremental cost in the resources spent by bodies at European level in relation to NLF implementation, compared with the pre-2014 situation, can be estimated at **around 270,000-360,000 Euro**.

4.2.3.2 Costs of the NLF: Resources spent by national authorities in relation to NLF implementation

Step 1) Definition. Resources spent by national accreditation bodies and notifying authorities in relation to NLF implementation.

Step 2) Attribution to the NLF. These resources represent inputs to the NLF's functioning; in particular, the work of NABs is heavily linked directly to the NLF. However, the scope of work conducted by NABs goes beyond NLF-aligned legislation. Furthermore, the work of notifying authorities is heavily driven by the provisions within specific sectoral Union harmonisation legislation, some of which is NLF-aligned and follows the reference provisions and rules established with the NLF legal texts, some of which is not. As such, these resources can only be partially attributed to the NLF.

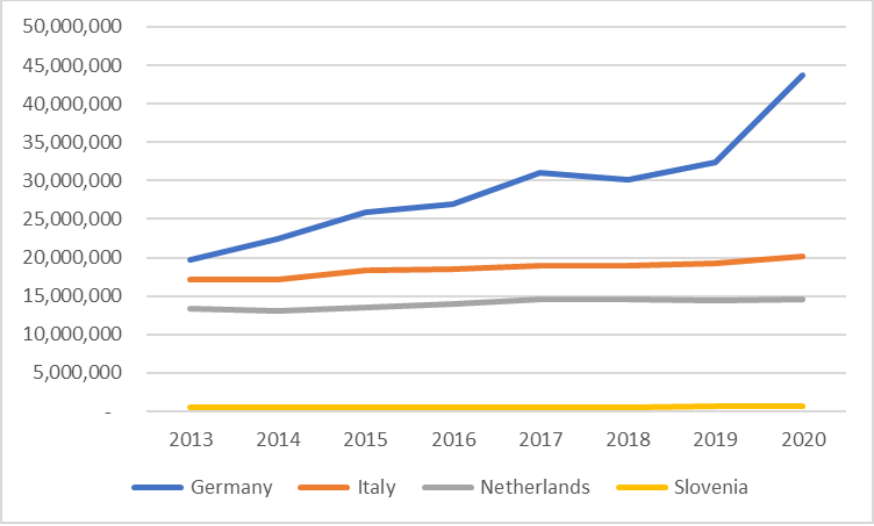
[62] Tracking the resources spent over time to ensure the implementation of the NLF and NLF-aligned legislation is also made complex by significant organisational changes occurred in the timeframe considered (e.g. transformation of DG ENTR into DG GROW and 2021 DG GROW reorganisation).

Step 3) Qualitative assessment. Estimating the resources spent for the implementation of the NLF by accreditation bodies faces certain **conceptual and practical challenges**. First, the budget of accreditation bodies does not represent a cost borne by the bodies themselves (or by public finances), as they are largely funded through the services they sell to conformity assessment bodies (see also below, under Resources spent by economic operators in relation to the accreditation framework) and only to a small extent through public finances. Second, identifying the share of human and financial resources spent solely on ensuring the implementation of NLF-aligned laws, excluding non-aligned laws, is not straightforward. In fact, the evolution in the use of resources does not necessarily strictly reflect NLF-related elements, but can be linked to wider functions. Third, in more practical terms, the different structures and legal status' used by such bodies at national level hamper a cross-country comparison. Datasets on budget and staff size of these authorities are not systematically available. Despite these limitations, selected figures offer insights into the size and activities of these bodies and their evolution in the timeframe considered. For selected NABs, information about their budget and staff size is provided below.

Among **accreditation bodies**, about half are private organisations (operating on a non-profit basis). This is, for instance, the case in Germany, Italy and Spain. ACCREDIA, the Italian accreditation body, receives no public funding. ENAC, the Spanish accreditation body, receives limited public funding (less than 1% of its budget) and its finances are based on selling accreditation services. It has more than 100 employees and deploys over 700 assessors.

The following graph shows the evolution of the annual budget of four national accreditation bodies for which a complete data series between 2013 and 2020 could be provided (Germany, Italy, Netherlands, Slovenia). All four NABs show a budget increase over this period, ranging from the 10% growth of the Dutch NAB to the 122% growth of the German NAB. Cumulatively, the budgets of the four organisations grew from 50.67 to 79.19 million Euro.

Figure 4-9: Annual budget of national accreditation bodies in selected EU Member States (Euro, 2013-2020)



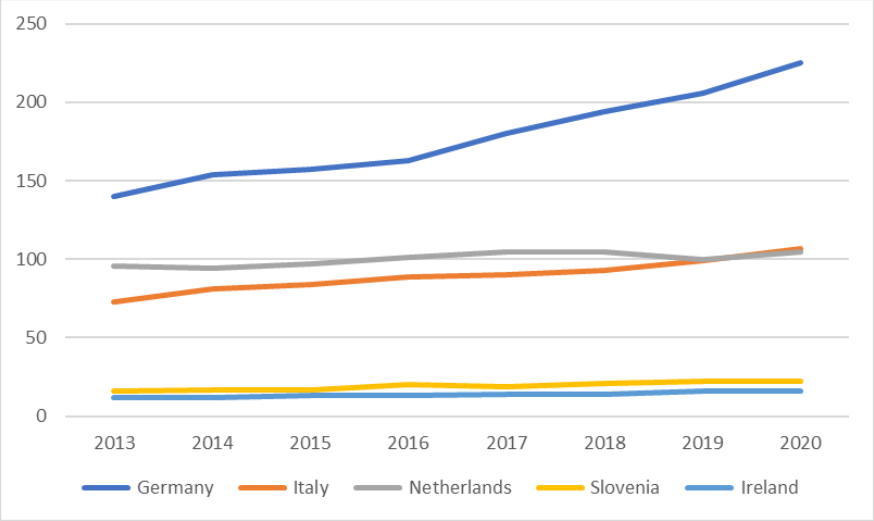
Source: Authors, based on data collected from NABs and NABs websites.

In addition to incomplete datasets, a comparison with the budget evolution of other NABs is hampered by national specificities. For instance, the Swedish accreditation body is only a business unit of a wider organisation; in Latvia and Hungary, the legal status of the body changed in recent years, impacting on the internal organisation and budget. Moreover, while in some EU Member States accreditation is mandatory for all NLF-aligned directives and regulations, this is not the case in all countries, adding a layer of complexity to any cross-country comparison.

Business associations interviewed pointed to the need for additional resources to strengthen some NABs, as their current budgets and staff skills prevent them from being as beneficial as they could be. Moreover, inconsistencies in the activities carried out by different national accreditation bodies are reported (see also below under Resources spent by conformity assessment bodies in relation to the accreditation framework), which could benefit from feeding additional expertise into some of these organisations. Greater harmonisation and a definition of uniform minimum standards would be welcomed by economic operators, even though they stressed the need to do so in a proportionate manner, so as to avoid excessive cost increases or high requirements for the manufacturers.

The evolution of staff size (not including assessors) of NABs reflects the budget trends. All selected accreditation bodies for which data on the staff evolution between 2013 and 2020 was available show an increase in staff members over this period. The degree of the increase varies, ranging from a 9% growth in the Dutch body to a 66% increase in the German body. Under this aspect as well, comparisons with other countries are affected by elements such as different practices of recourse to external consultants, and recruitment difficulties for NABs that are public entities and thus subject to specific limitations. In fact, stakeholder feedback points to the insufficient staff availability in selected accreditation bodies (e.g. Greece), or a significant number of open positions not filled (e.g. Bulgaria), which limits their effectiveness and prevents the generation of additional benefits. This lack of staff, however, is generally due not to limited budget, but rather to legal rules and limitations on the hiring of experts in state-run organisations.

Figure 4-10: Annual staff size (not including assessors) of national accreditation bodies in selected EU Member States (Staff members, 2013-2020)



Source: Authors, based on data collected from NABs and NABs websites.

Typically, the accreditation process foresees lead assessors and technical experts (who are generally freelance staff). In addition to staff size, the extent of audit activities over time therefore also sheds light on the evolution of NLF implementation activities. In this regard, anecdotal data from the Italian accreditation body Accredia point to an increase in this indicator as well: its 560 assessors reached a total of about 16,800 audit days worked in 2020, with an upwards trend compared to 2019 despite the COVID-19 crisis[63].

[63] More in detail, 178 assessors worked about 5,800 days to audit 501 accredited bodies for carrying out certifications, inspections and verifications; 327 assessors worked about 10,000 days verifying 1,272 accredited laboratories for conducting tests, medical analyses and interlaboratory tests; 106 assessors worked about 1,000 days verifying 202 accredited laboratories for conducting calibrations and measurement in the medical field and producing reference materials.

Drawing conclusions on the impact of the NLF on the resources spent by NABs based on budget and staff size would not be correct. According to feedback from NABs, the budget trends also reflect aspects that are not strictly related to the NLF, but to wider functions and organisational elements, such as information security or archive enhancement. Despite these caveats, the available data certainly point to an **overall growth in the NABs' role across Member States**. The accreditation aspect of NLF implementation, as such, appears to require an increasing amount of human and financial resources.

As for accreditation bodies, the **resources used by notifying authorities** greatly varies depending on the national context. In the case of notifying authorities, a further variable is represented by the type and number of pieces of NLF-aligned legislation covered. As an example, the staff size of a Greek notifying authority, responsible for over 15 pieces of product legislation, is 3.5 FTEs (within the Ministry of Development and Investments). Figures on budgets, in the case of notifying authorities, are typically not available, as they are generally part of wider public organisations (ministries, public agencies, other authorities), for which no disaggregation by unit is provided. Based on the Commission's NANDO database, there are 139 notifying authorities covering NLF-aligned legislation in the EU27 and 12 in EEA-EFTA countries.

Step 4) Quantitative assessment. The available data on budget and staff size of selected national bodies provides contextual information that helps forming a qualitative assessment of the NLF implementation cost at national level. Yet, developing a quantitative estimate of the incremental cost in 2014-2020 compared with the pre-2014 situation is challenged by a lack of systematic data and, more importantly, it would require the adoption of excessively strong assumptions on the share of resources specifically attributable to the NLF, as well as strong assumptions enabling the extrapolation of EU-level data from selected countries, despite national specificities.

4.2.3.3 Costs of the NLF: Resources spent by economic operators in relation to NLF implementation

Human and financial resources spent by economic operators in relation to the implementation of the NLF are related to the following main elements: i) the conformity assessment; ii) participation in the development of harmonised standards; iii) the CE-marking; and iv) the accreditation framework.

Resources spent by economic operators in relation to conformity assessment

Step 1) Definition. Resources spent by economic operators in relation to conformity assessment procedures, including laboratory tests, technical documentation and involvement of notified bodies.

Step 2) Attribution to the NLF. These resources represent inputs to the NLF's functioning, as the NLF provides a suite of conformity assessment modules and related rules to be incorporated into specific Union harmonisation legislation. However, the specificities of the conformity assessment procedures are established in the aligned legislation; as such, these costs can only partially be attributed to the NLF.

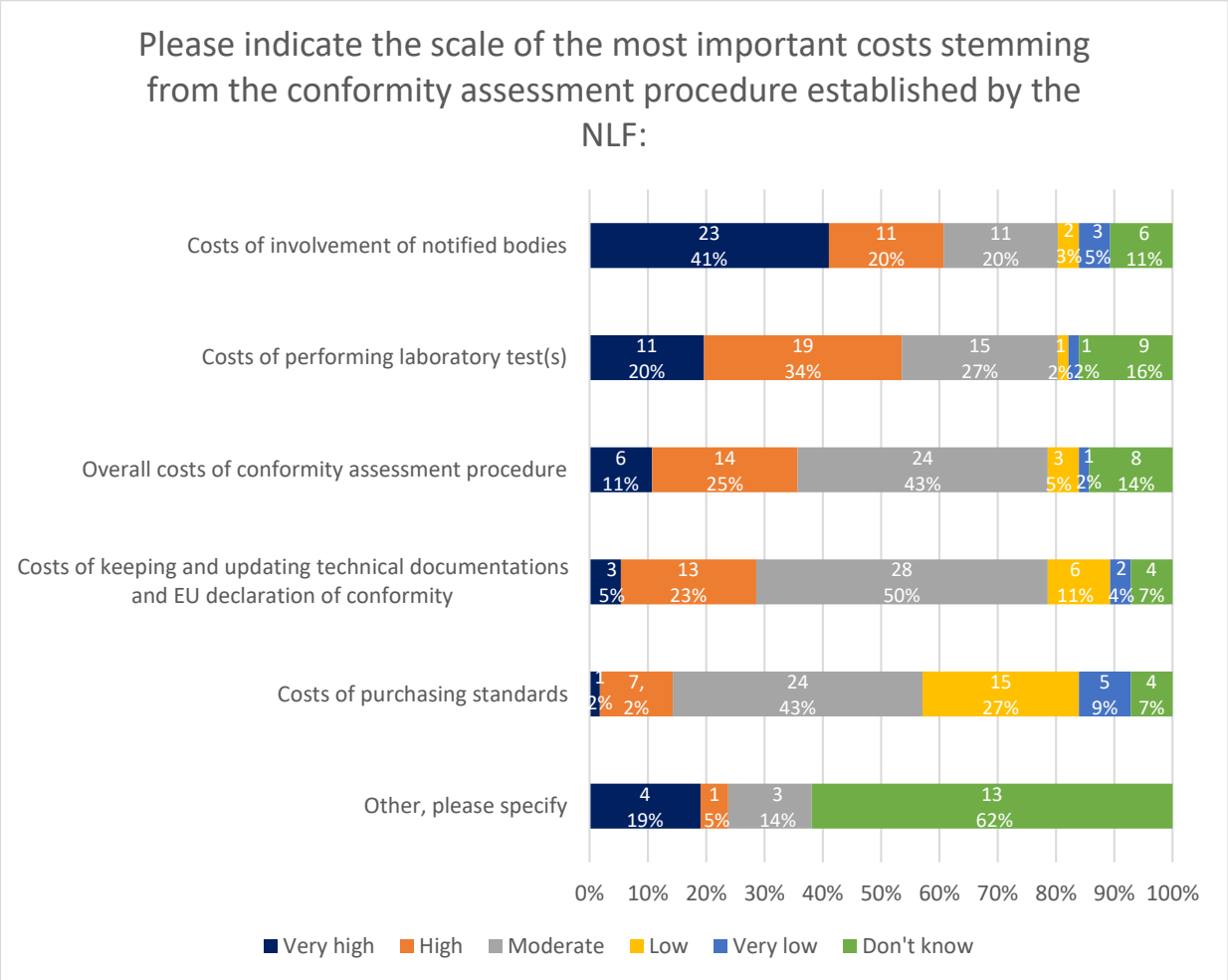
Step 3) Qualitative assessment. Costs for economic operators are generated during **conformity assessment** procedures as a result of different drivers, among which the following stand out: the performance of laboratory tests; developing, keeping and updating technical documentation; and the involvement of a notified body.

While laboratory tests would largely be conducted even in the absence of NLF-aligned legislation, to ensure product quality and safety, the other two costs are more closely NLF-related. In general, based on the interviews conducted for this study, the view of individual companies and business associations concerning conformity assessment procedures is 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 each product (even if they use the models provided by the NLF) are included in NLF-aligned sectoral legislation.

In the targeted consultation, economic operators and industry associations were asked to indicate the scale of the costs stemming from the conformity assessment procedure, 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 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).

Figure 4-11: Scale of the most important costs stemming from the conformity assessment procedure established by the NLF (Question 40, N=56)



Question 40 was asked to: economic operators and industry associations.

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: in many cases, the establishment of a laboratory requires a significant initial capital investment; further laboratory costs include the operation and maintenance of the technical equipment, as well as the cost of specialised staff members. Under the EMCD, for instance, testing chambers typically cost several hundred thousand Euro. A consequence of this, according to the evaluation, is that only large companies have internal laboratories. The daily fees of third-party laboratories in the EU is reported to be in the range 800-1,500 Euro.

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%.

A cost related to conformity assessment procedures is generated also for importers, having to spend time on ensuring that appropriate conformity assessment procedures have been carried out by the manufacturers.

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.

Importantly, while the cost borne in relation to the conformity assessment represents an input for the NLF's functioning, it cannot be identified as an incremental cost generated by the NLF's 2008 legislative package. The principles of conformity assessment have not changed with the introduction of the NLF, as is acknowledged also by evaluations of individual NLF-aligned legislation. For instance, the Lifts Directive evaluation notes that the cost of conformity assessment cannot be attributed to the NLF-aligned Directive, as it was already borne previously[64]. Accordingly, no additional costs can be identified compared to the previous conditions.

Step 4) Quantitative assessment. As the NLF has not brought about significant changes in the field of conformity assessment procedures, and the specificities of conformity assessment procedures are detailed in Union harmonisation legislation, the incremental cost in terms of resources spent by economic operators in relation to conformity assessment is nil.

Resources spent by economic operators in relation to harmonised standards

Step 1) Definition. Resources spent by economic operators in relation to the participation in the development of harmonised standards and the negative outcomes of current procedures in the European standardisation system. The purchase of standards is not included under this cost.

Step 2) Attribution to the NLF. These resources represent inputs to the NLF's functioning: as such, they are attributed to the NLF, in line with its intervention logic.

Step 3) Qualitative assessment. In the framework of the NLF, **harmonised standards** remain an essential conformity assessment tool for economic operators, a legal reference for the European Commission and a technical benchmark for notified bodies. The development of harmonised standards has a cost that is borne by experts of (mostly large) companies, as well as national authorities in some Member States that support their NSB and many other stakeholders, including Regulation 1025/2012 Annex III stakeholders. The cost of the development of standards within the ESOs was approximately 3,000 million Euro in 2009, according to the Commission impact assessment accompanying the Draft Regulation on European Standardisation[65]. The **approximate cost of creating**

[64] The Lifts Directive evaluation could not provide quantifications of the cost of conformity assessments, due to the lack of statistics on the number of conformity assessments and the lack of available cost estimates.

[65] Commission staff working paper - impact assessment accompanying document to the Proposal for a Regulation on European Standardisation – SEC(2011) 671 final (1.6.2011).

one standard was estimated at approximately 1 million Euro. This includes the costs of experts, the organisation of meetings / travel etc. The ESOs pointed out that this cost is financed primarily by industry (93-95%) followed by national governments (around 3-5%) and the European Commission / EFTA contribution (around 2%). The fact that industry bears most of the cost of the system, together with the voluntary character of standards, reflects its high interest in the role of standards, including in support to the application of NLF-aligned legislation. The report implied that the benefits outweigh the cost and that therefore, for society as a whole, the cost of creating standards is minimal compared to the benefit for the economy, even erring on the side of caution regarding the data.

Whereas the cost of participation in the development of harmonised standards represents an input for the NLF's functioning, another standard-related cost is a negative outcome that comes about in the implementation of the NLF. In fact, the role of **standards** is frequently mentioned by economic operators and business associations as a severe issue, generating significant costs for companies beyond the costs associated with the development of standards detailed above. From the interviews with industry stakeholders and ESOs, the question was raised whether the positive balance between the costs and benefits of harmonised standards will be maintained in the future if the current procedures of the European standardisation system are not rapidly streamlined. While standards represent a pillar of the NLF's functioning, companies face difficulties in using new standards, reportedly due to delays in the mandates by the Commission and the citation of harmonised standards at EU level: this ultimately hampers companies' competitiveness, as competitors on the global stage (for instance, in the United States and China) adopt more advanced standards than Europe. In this context, it was further noted that some economic operators may disinvest from the development of European standards. Instead, they may choose to concentrate on investing in the development of international ISO/IEC standards and spend more on third-party compliance services to ensure compliance in the EU.

Step 4) Quantitative assessment. Since no changes concerning standards were introduced with the 2008 NLF, no incremental costs compared to the previous conditions are identified.

Resources spent by economic operators in relation to CE marking

Step 1) Definition. Resources spent by economic operators in identifying how to apply CE marking on the product and affixing it.

Step 2) Attribution to the NLF. These resources represent inputs to the NLF's functioning: as such, they are attributed to the NLF, in line with its intervention logic.

Step 3) Qualitative assessment. **CE marking** is largely considered by economic operators to represent a key driver for the competitiveness of companies on the internal market and not to represent a burden. However, a general consensus is found regarding the possibility to increase efficiency through the introduction of e-labelling (see also below under Potential for efficiency improvement).

In previous evaluations of NLF-aligned directives (e.g. EMCD and Lifts Directive), markings have not emerged as a main source of costs. Similarly, in the evaluation of the Toy Safety Directive, the cost related to CE marking (identifying how to apply it on the product and applying it) is reported to weigh 2% of the total man-hours required for manufacturers to comply with the Directive's requirements.

Step 4) Quantitative assessment. 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[66].

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

Resources spent by conformity assessment bodies in relation to the accreditation framework

Step 1) Definition. Resources spent by conformity assessment bodies in relation to the accreditation framework introduced by the NLF, including examination fees and maintenance fees.

Step 2) Attribution to the NLF. These resources 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, in line with its intervention logic.

Step 3) Qualitative assessment. The innovations concerning the **accreditation framework** represent a key point of the NLF as introduced in 2008.

To obtain an accreditation, conformity assessment bodies face a range of costs, which are presented below. Interviewed notified bodies reported that those conformity assessment bodies that ceased to exist after the introduction of the accreditation system were mainly those that were not active in third countries (e.g. the US) and not accredited under other schemes, and for which fulfilling the accreditation requirements would therefore have represented a big leap.

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.

Table 4-6: Evolution of number of notified bodies over time, by piece of legislation (2008-2020)

Legislation		2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Current NLF-aligned legislation															
2009/48/EC	Toy Safety Directive	0	0	0	1	37	45	46	46	43	42	42	40	41	42
2010/35/EU	Transportable Pressure Equipment Directive	0	0	0	0	79	96	107	122	126	131	138	145	144	144
2013/29/EU	Pyrotechnic Articles Directive	0	0	0	0	0	0	0	0	11	13	13	14	13	12
2013/53/EU	Recreation Craft and Personal Watercraft Directive	0	0	0	0	0	0	0	0	3	21	26	28	32	31
2014/28/EU	Civil Explosives Directive	0	0	0	0	0	0	0	0	0	8	11	10	10	10
2014/29/EU	Simple Pressure Vessels Directive	0	0	0	0	0	0	0	0	3	56	69	72	72	73
2014/30/EU	Electromagnetic Compatibility Directive	0	0	0	0	0	0	0	0	1	81	89	92	95	96
2014/31/EU	Non-automatic Weighing Instrument Directive	0	0	0	0	0	0	0	0	1	65	71	71	71	74
2014/32/EU	Measuring Instruments Directive	0	0	0	0	0	0	0	0	1	86	97	98	96	93
2014/33/EU	Lifts Directive	0	0	0	0	0	0	1	1	14	224	235	231	229	234
2014/34/EU	ATEX Directive	0	0	0	0	0	0	0	0	0	57	63	68	71	75
2014/68/EU	Pressure Equipment Directive	0	0	0	0	0	0	0	0	7	266	298	321	336	336
2014/90/EU	Marine Equipment Directive	0	0	0	0	0	0	0	0	0	22	37	37	40	44
Reg. (EU) 2016/424	Cableway Installations Regulation	0	0	0	0	0	0	0	0	0	0	1	17	18	19
Reg. (EU) 2016/425	Personal Protective Equipment Regulation	0	0	0	0	0	0	0	0	0	0	36	89	101	106
Reg. (EU) 2016/426	Gas Appliances Regulation	0	0	0	0	0	0	0	0	0	0	8	37	47	45
Reg. (EU) 2017/745	Medical Devices Regulation	0	0	0	0	0	0	0	0	0	0	0	0	8	17
Reg. (EU) 2017/746	In Vitro Diagnostic Medical Devices Regulation	0	0	0	0	0	0	0	0	0	0	0	0	2	4
Reg. (EU) 2019/1009	Fertilising Products Regulation	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Predecessor legislation to NLF-aligned laws															
88/378/EEC	Old Toy Safety Directive	59	59	60	57	1	1	1	1	1	1	1	1	1	1
94/25/EC	Old Recreational Craft Directive	29	30	28	31	29	31	34	35	35	27	6	5	5	1
95/16/EC	Old Lifts Directive	234	251	256	253	241	230	238	239	235	0	0	0	0	0
96/98/EC	Old Marine Equipment Directive	30	30	30	30	29	30	31	33	34	1	1	1	1	1
97/23/EC	Old Pressure Equipment Directive	249	254	263	259	254	255	261	270	280	4	4	4	4	4
2004/22/EC	Old Measuring Instruments Directive	53	76	92	94	103	104	104	104	104	0	0	0	0	0
2004/108/EC	Old Electromagnetic Compatibility Directive	119	160	163	165	170	153	153	145	143	0	0	0	0	0
2009/105/EC	Old Simple Pressure Vessels Directive	94	100	103	104	102	103	100	102	98	8	7	6	5	4

***Source**: Authors based on NANDO database.*

Additional costs generated for conformity assessment bodies wanting to become accredited are the following: examination fee to an accreditation body; maintenance fee; cost of developing and maintaining a quality management system; and insurance costs.

- **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[67] 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: the fees of an assessor in one Member State can be significantly higher than in another Member State. 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[68]. Importantly, however, differences in costs across countries are not due solely to daily fees of assessors: examination fees vary across countries due to differences in the duration and frequency of the examination themselves. 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. More generally regarding this cost, a conformity assessment body highlighted that the obligation for to use their country's NAB to be accredited resulted in inefficiencies, since their national body may be slower and more costly than the equivalent bodies in other countries. In this respect, the CAB suggested that providing the opportunity of being accredited by the accreditation body of a different Member State could increase efficiency.

  Anecdotal evidence of examination costs is now 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):** For this cost, differences between accreditation bodies also emerged. The differences in cost of accreditation bodies (borne by accredited bodies) depend (as for examination fees) on the number and type of laws 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

[67] 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).

[68] Calculated dividing the daily fee (770 Euro) by the number of assumed working hours per day (8).

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. 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). 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. 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.

According to other notified bodies interviewed (mainly covering the area of radio equipment), the organisations that ceased to exist after the introduction of the accreditation framework were not using any quality management system at the time. While the accreditation framework can in principle contribute to quality and consistency in procedures, the lack of harmonised accreditation criteria and procedures across Europe is reported to prevent the generation of further benefits.

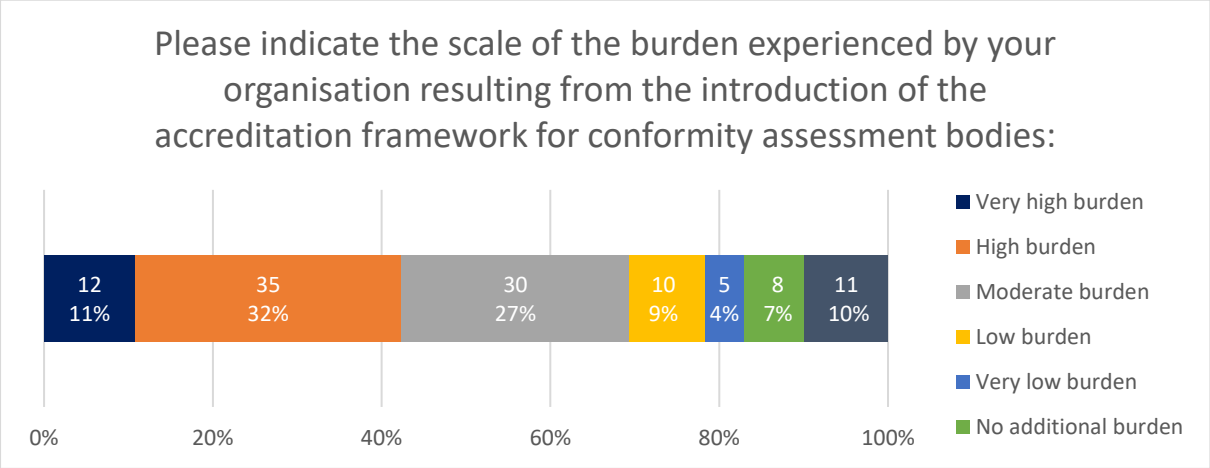
Concerning notified bodies that have not obtained accreditation, interview feedback from accredited notified bodies pointed to the fact that, before the introduction of the 2008 requirements, laboratories were frequently active as notified bodies; however, to avoid the accreditation costs mentioned above, some labs decided to focus on testing as their sole business area. Similarly, consultancies that were active as notified bodies chose to restrict their business to consulting.

In general, an NAB representative consulted for this study 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. In fact, there are accredited laboratories (even bodies with just two employees) in sectors where accreditation is not mandatory. As such, in his opinion, the cost of accreditation should not be seen as a burden.

The costs that notified bodies that have not become accredited face are: Capex, human resources, and opportunity costs. As a result, according to interviewees from the testing, inspection and certification industry, the costs for notification are then higher for such bodies, because they need to provide much more evidence to demonstrate their competence and qualifications (generally, it is however the national notifying authority that decides whether they consider non-accredited organisations to be notified).

As illustrated below, the evidence from the targeted consultation supporting this evaluation, suggesting that, according to most respondents, the introduction of the accreditation framework for CABs has resulted in a moderate, high, or very high burden.

Figure 4-12: Scale of the burden resulting from the introduction of the accreditation framework for conformity assessment bodies (Question 42, N=111)[69]



Understandably, there was some variation between stakeholder types: notified bodies / conformity assessment bodies were most likely to report that the burden was high or very high (57.6%, 34 of 111 responses), as compared with relevant national authorities (25%, 13 responses across national competent authorities, accreditation bodies and notifying authorities).

Step 4) Quantitative assessment. The NLF introduced important innovations in relation to the accreditation framework. Estimating the cumulative size of resources spent by conformity assessment bodies faces the challenge of a strong fragmentation due to the many dimensions that are a cause for variation in accreditation costs (e.g. differences in fees, assessment duration and frequency, presence of maintenance fee, size and number of locations of conformity assessment body, legislative scope and conformity assessment modules etc.) and the lack of systematic and comparable datasets. In principle, however, the accreditation costs (not including the cost to develop and maintain a quality management system and insurance fees) can be seen as corresponding, in terms of order of magnitude, with the cumulative budgets of accreditation bodies (as they fund themselves to a very large extent by selling their accreditation services). Based on the analysis performed under Chapter 4.2.3.2 (Resources spent by national authorities in relation to NLF implementation), these costs can be reliably seen in the **order of magnitude of hundreds of million Euro, with a growing trend between 2014 and 2020**.

4.2.4 Benefits of the NLF

The benefits of the NLF are represented by its **positive results and impacts**. This section first details the positive results achieved, primarily linked to the NLF's specific objectives, including cost savings in administrative and substantive compliance tasks and the prevention of divergence across the legal framework. It then presents the impacts, which are either linked to the high-level general objectives of the NLF (such as strengthened protection of public interests, or improvements in the effectiveness of the internal market) or are strategic benefits, such as facilitating investment in innovation and improving the global standing of EU legislation. This section details these benefits following the four-step approach outlined under Chapter 4.2.1.

[69] Question 42 was only asked to the following stakeholder groups: national accreditation bodies, national competent authorities, national notifying authorities, and notified bodies / conformity assessment bodies.

4.2.4.1 Benefits of the NLF: Results (linked to specific objectives)

Cost savings in administrative tasks

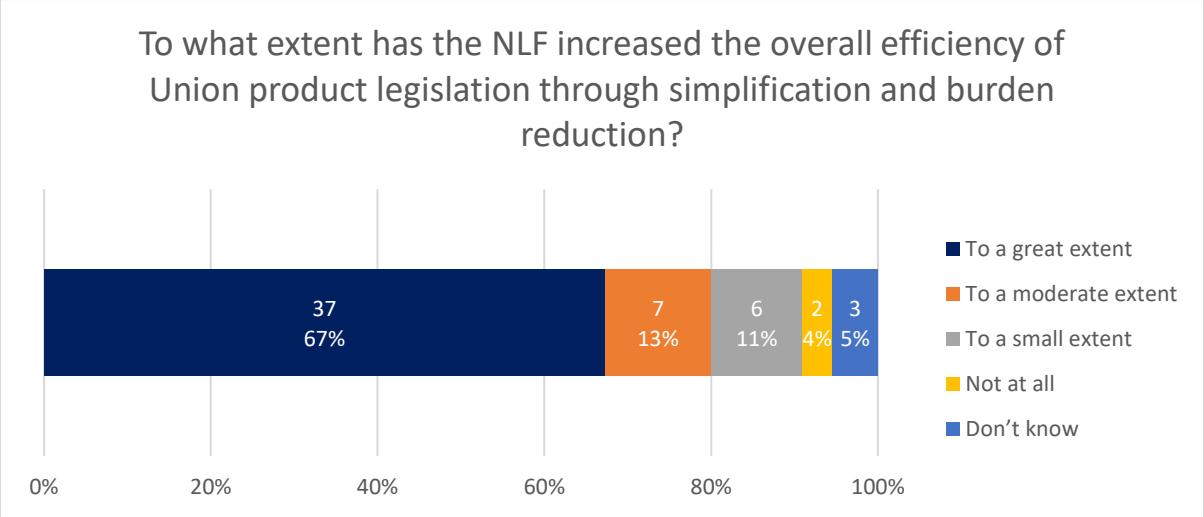
Step 1) Definition. Reduction in costs borne by manufacturers resulting from the introduction of a more common approach across EU harmonisation legislation (e.g. with common definitions, administrative requirements, common suite of conformity assessment modules). These cost savings cover the administrative simplification dimension. They represent direct benefits.

Step 2) Attribution to the NLF. Cost savings in terms of legislative familiarisation and administrative simplification represent positive results of the NLF's functioning, corresponding to one of its specific objectives: as such, they are attributed to the NLF, in line with its intervention logic.

Step 3) Qualitative assessment. The opinions of stakeholders were elicited on the NLF generating cost savings and strategic benefits. A largely positive opinion was reported by economic operators and industry associations on the impact of the NLF on **reducing costs in familiarisation with legislation** thanks to the introduction of common definitions (e.g. consistent definitions of operators), even though some inconsistencies were reported to be still in place, preventing full harmonisation.

Among the economic operators and industry associations surveyed in the targeted consultation, 67.3% of respondents (37 responses) agreed to a great extent that the **NLF increased the overall efficiency of Union product legislation through simplification and burden reduction** (Figure 4-13).

Figure 4-13: Extent to which the NLF increased the overall efficiency of Union product legislation through simplification and burden reduction (Question 46, N=55)



Question 46 was asked to: economic operators and industry associations.

In another more specific question, 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**.

While previous evaluations of individual NLF-aligned pieces of legislation do not strongly focus on overarching cost savings brought about by the NLF's harmonisation effort (as this is typically an aspect for cross-cutting studies), the EMCD evaluation includes some considerations that are relevant in this context. According to the study, many interviewees underlined that the NLF has facilitated coherence between the different Directives. They also explained that the NLF has clarified definitions and has strengthened the coherence of the formal obligations for economic operators. The common horizontal provisions specifically meant, according to the interviewees, that the EMCD, the LVD (when

applied in conjunction with the EMCD) and the RED (applicable if an electrical product integrates radio functionality) became more coherent with one another.

Step 4) Quantitative assessment. Compared to other more strategic benefits, these cost savings are modest and generated upfront at the micro level for economic operators. While no quantitative estimate for this cost saving can be provided, 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.

Cost savings in substantive tasks

Step 1) Definition. Reduction in conformity assessment costs borne by manufacturers due to the increased coherence between laws and the flexibility of the system. These cost savings represent direct benefits.

Step 2) Attribution to the NLF. Resources spent by economic operators in relation to the conformity assessment procedures represent inputs to the NLF's functioning, and therefore costs. Thanks to the NLF's overarching framework, a reduction in these costs is achieved, which represents a direct benefit.

Step 3) Qualitative assessment. As highlighted above, the NLF does not include specific provisions concerning conformity assessment procedures. Yet, by providing a common framework, the NLF brings about savings in the performance of these tasks, thanks to the fact that the different pieces of legislation follow the same logic, and thanks to the flexibility of the system introduced, as far as the suite of conformity assessment modules is concerned. This reasoning was confirmed through the stakeholder consultation performed as part of this study. During the interview programme, a consensus emerged; the NLF generated **cost savings in conformity assessment activities**. The results of the targeted consultation were somewhat more nuanced, but nevertheless of a mostly positive nature: 80% (44 of 55 respondents) of economic operators and industry associations reported that the reduced regulatory divergence achieved by the NLF has led to cost savings in the conformity assessment procedures to a moderate or great extent.

Step 4) Quantitative assessment. Like cost savings in administrative tasks, these savings are generated upfront for economic operators. Considering the different forms conformity assessment procedures can take under different pieces of legislation, despite following the same overarching logic, these savings are not cumulatively quantifiable. Differences in conformity assessment costs are reported also by country and by company size.

In the TSD evaluation, for instance, generating the conformity assessment is reported to cover 6% of the total man-hours needed to comply with the Directive's requirement, but with a discrepancy by company size: 4% for large firms, 7% for SMEs.

It can also be said that, while cost savings are brought about, they 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. 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.

Prevention of divergence and regulatory certainty

Step 1) Definition. Reduced uncertainty over applicable rules, thanks to the common approach brought about by the NLF.

Step 2) Attribution to the NLF. Enhanced regulatory certainty represents a positive result of the NLF's functioning, corresponding to one of its specific objectives: as such, it is a direct benefit attributed to the NLF, in line with its intervention logic.

Step 3) Qualitative assessment. This benefit, to some extent linked to the previously mentioned cost savings, can be singled out separately due to the aspect of reduced uncertainty, significantly bolstered by the introduction of 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 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.

Step 4) Quantitative assessment. 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.

4.2.4.2 Benefits of the NLF: Impacts (linked to general objectives)

Increased safety, health, and reduced environmental damages

Step 1) Definition. Increased level of safety and health for consumers, and reduced environmental damages, deriving from the reduction of differences in the activities carried out by notified bodies (due to the NLF).

Step 2) Attribution to the NLF. In principle, there is a solid link between the NLF's provisions (especially regarding the accreditation framework), the reduction of differences in notified bodies' activities within countries and across Europe, and increased levels of safety and health for end users, as well as reduced environmental damages. Following this line of reasoning underpinning the NLF, an indirect impact in these areas can be attributed to the NLF itself. At the same time, great caution must be adopted in identifying causal links between trends in safety, health, and environment data and the NLF.

Step 3) Qualitative assessment. As suggested by some of the evaluations of individual NLF-aligned pieces of legislation already, interviewed stakeholders also pointed to the NLF generating benefits in terms of **increased safety, health, and reduced environmental damages**, deriving from the reduction of differences in the activities carried out by the notified bodies, thanks to the NLF.

Within previous evaluations, the studies on the TSD and the Lifts Directive faced a lack of data or deemed it impossible to draw unambiguous quantitative conclusions on the extent of this benefit. In the case of the TSD, the opinion of stakeholders supported the idea that the Directive had generated positive impacts in terms of health and safety, enhancing the protection of children. The Lifts Directive evaluation stated instead that no causal link between the legislation and lift safety could be established, despite accidents involving maintenance personnel having decreased. The EMCD, due to the topic covered, did not generate significant impacts in terms of health or safety (strong technical benefits were generated instead, reducing the incidence of electromagnetic disturbance and

preventing the incorrect functioning of electrical equipment, potentially dangerous for health and safety).

A positive opinion from stakeholders on the generation of this benefit was found also within the public consultation performed as part of this study, with **87% of respondents (83) agreeing that the NLF has been effective in its contributions to reinforcing a high level of protection of public interests** (health, safety, consumer protection, environmental protection).

In short, qualitative opinions of stakeholders strongly suggest that the NLF has brought about benefits in the areas of health, safety, and environment. While in principle this widely shared opinion appears well-founded, no concrete evidence or causal link effectively supports it.

An analysis of the data contained in the Safety Gate alerts covering the period 2005-2021 has been conducted as part of this study (see Annex 6), providing contextual descriptive statistics on trends related to the detection of unsafe products that are subject to NLF-aligned legislation across the internal market. Yet, external factors (such as the growth of e-commerce, the increased presence of products from third countries, and the evolving role of market surveillance authorities, as well as others) significantly restrict the ability of the analysis to attribute or link any product safety trends identified to the NLF.

Finally, it can be noted that a study published in 2020 by the Italian accreditation body has estimated the annual social benefits generated by the Italian Quality Infrastructure. These annual benefits, in terms of reduced external costs, amount to 1.28 billion Euro, and are brought about through: i) specific environmental certifications (e.g. ISO 14001), contributing to a 6.9% reduction in CO2 emissions, corresponding to an annual social benefit of 361 million Euro; ii) energy certifications, contributing to a reduction of 6 million tonnes CO2 emissions, corresponding to 170 million Euro; iii) systems to ensure safety at work, reducing injuries in the workplace by 16%, corresponding to a benefit of 301 million Euro; iv) increased food safety, reducing the number of health-years lost by 75%, corresponding to 426 million Euro; and v) selected EU directives, leading to health benefits, monetised at 25 million Euro. While the study scope does not precisely correspond to the NLF, and values are not directly extendible to the European scale, the methodologically strong analysis performed in the study nevertheless provides useful contextual information about orders of magnitude of benefits that can be attached to the field of testing, inspection, and certification.

Step 4) Quantitative assessment. Given the caveats highlighted above, no quantitative estimates or examples could be provided by stakeholders as part of the interview programme.

Prevention of unfair competition

Step 1) Definition. Reduced unfair competition between businesses deriving from the reduction of differences in the activities carried out by notified bodies (due to the NLF).

Step 2) Attribution to the NLF. Similarly to the previous benefit, in principle a link can be identified between the NLF's provisions (especially regarding the accreditation framework), the reduction of differences in notified bodies' activities across Europe, and a better level playing field among businesses. Accordingly, a potential impact in this area could be attributed to the NLF.

Step 3) Qualitative assessment. A low level of agreement was found among interviewed stakeholders about the NLF being able to generate this benefit. In particular, interviewees from individual companies or industry associations were prone to highlighting differences in the activities of conformity assessment / notified bodies and their costs, potentially increasing unfair competition, rather than fighting it. At the same time, a consensus was generally found that, were notified bodies to be equipped with a consistently good level of competencies across countries, and were activities to be more harmonised, the NLF would in principle be able to reduce unfair and promote fair competition. Despite this, it should be noted that, while the NLF implementation may still fall short of

generating this type of benefit, a scenario without the NLF and the continuation of the previous conditions does not reduce unfair competition either.

Step 4) Quantitative assessment. No quantitative assessment of this benefit can be provided, due to both its nature and the mixed feedback gathered from consulted stakeholders.

Single market benefits

Step 1) Definition. Better functioning of the internal market in terms of the free movement of goods thanks to the reduction of market barriers brought about by the NLF.

Step 2) Attribution to the NLF. Reducing market barriers represents a positive outcome of the NLF's functioning, corresponding to one of its general objectives: as such, it is attributed to the NLF, in line with its intervention logic. However, caution must be adopted in establishing strict causal chains.

Step 3) Qualitative assessment. Interviewed economic operators and business associations generally agreed that one of the key benefits of the NLF is its ability to **reduce market barriers** and lead to common market access conditions across Europe. In addition to this barrier reduction, a further positive economic impact should be highlighted. The 2020 study by the Italian accreditation body, mentioned above, found that accredited organisations witness an increase in their turnover (the higher the share of accredited activities, the higher the turnover increase). According to the study's results, 10.8 billion Euro of the growth of cumulated added value between 2013 and 2018 are explained by the impact of testing, inspection, and certification (value related to Italian economy only).

The relevance of economic benefits of the NLF is also underscored by the lack, in an alternative no-NLF scenario, of another system similarly ensuring equal market access conditions across Europe.

Step 4) Quantitative assessment. While no direct extrapolation of Italian-level data to the European scale can be performed[70], it can be inferred that the size of economic benefits from accreditation is, EU-wide, in the **order of magnitude of tens of billions of Euro**.

Global relevance of EU legislation and CE marking

Step 1) Definition. Enhanced standing of the EU in global commerce, thanks to the ability of EU legislation to elevate regulatory standards worldwide and shape international practices.

Step 2) Attribution to the NLF. Due to the highly strategic nature of this benefit, great caution must be used in identifying strict causal chains between the NLF and the benefit. In principle, however, enhanced global relevance of EU product legislation and CE marking can be attributed, at least partially, to the NLF.

Step 3) Qualitative assessment. 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.

The growing ability of the EU to promulgate regulations that become entrenched in the legal frameworks of developed and developing markets alike, leading to a "Europeanization" of some sectors of global economy, is in fact an asset which has been recognised in legal-economic literature (notably by Anu Bradford, the author who coined the 'Brussels effect' phrase). Considerations in the same vein can be found in evaluations of individual NLF-aligned pieces of legislation. For instance, the

[70] The Italian study could rely on extremely rich datasets of certified businesses, not available in other national contexts.

Lifts Directive evaluation notes, drawing on first-hand input from consulted stakeholders, that 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.

At the same time, qualitative feedback suggests that in recent years, since the change in the EU approach to standardisation following the James Elliott legal case, EN standards are slower to be developed and cited in the *OJEU* and international standards may be used by manufacturers instead of EN standards, as the latter are experiencing bottlenecks; this may threaten the global relevance of the EU approach to product legislation and safety.

Step 4) Quantitative assessment. Global relevance of legislation represents a typically qualitative benefit, notably due to its highly strategic nature.

Investment in innovation

Step 1) Definition. Extent to which the NLF has stimulated innovation and risk-taking by industry.

Step 2) Attribution to the NLF. NLF provisions and increased investment in innovation can in principle be linked to the NLF-related simplification, improved clarity, legal certainty and enhanced quality. Accordingly, a potential impact in this area could in part be attributed to the NLF. Clearly, no causal link in this area can be ascertained with certainty, due to the number of possible external factors and complex interplay of socio-economic forces driving innovation investment and output.

Step 3) Qualitative assessment. Compared to other benefits previously mentioned, a significantly lower level of agreement was found among interviewed stakeholders concerning the NLF's impact on innovation investment. In general, no strong link between the NLF and innovation investments could be identified by interviewees.

Within the public consultation, respondents were asked for their views on **the extent to which the NLF had a positive impact** on product innovation: 48% of respondents (44) took this view, the lowest share among the different benefits respondents were asked about. Some economic operators taking part in the consultation however took care to underline that an important benefit of the NLF lies in the fact that it strengthens innovation across the EU. Industry-driven hENs developed in ESOs are, in this opinion, an essential tool to support innovation.

Step 4) Quantitative assessment. No quantitative assessment of this benefit can be provided, due to both its nature and the mixed feedback gathered from consulted stakeholders

4.2.5 Potential for future administrative simplification and burden reduction

This section examines, based on feedback received through the stakeholder consultations, evidence on the opportunities for future administrative simplification and burden reduction resulting from digitalisation. Following the same analysis structure, this section first examines the possible benefits of digital or e-labelling practices, before discussing the use of remote assessment techniques for conformity assessment, accreditation, and peer evaluation activities.

4.2.5.1 Digital labelling

Step 1) Definition. Digitalisation of compliance and consumer information considers the potential for the CE marking and other traceability information, the EU declaration of conformity, technical product information, the technical file, and end-user targeted product information (e.g. safety documentation, instruction manuals, guidance on reasonably foreseeable use) to be provided digitally instead of with or on the product.

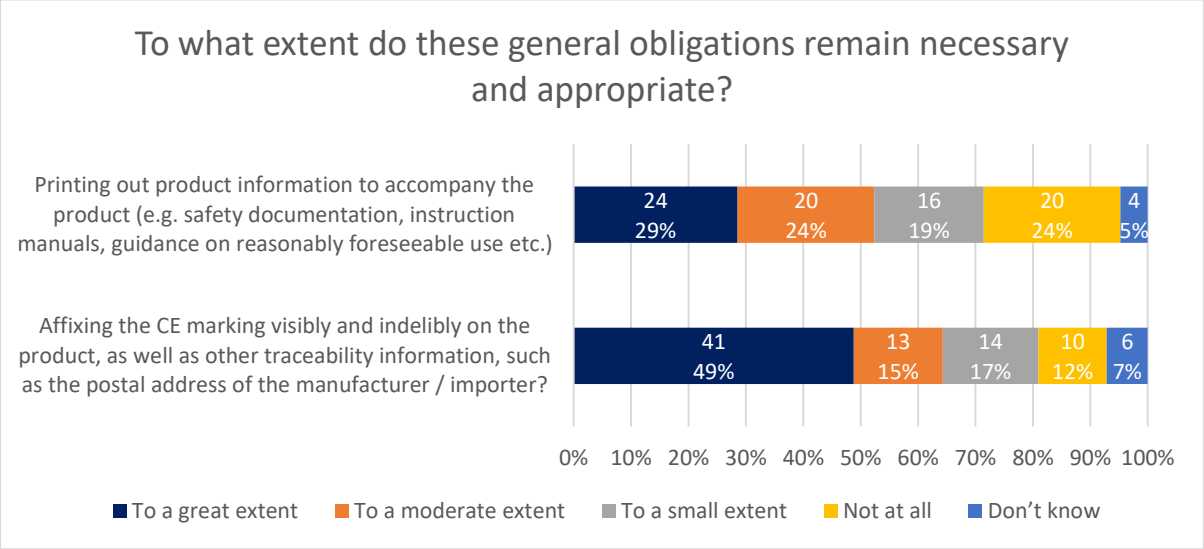
Step 2) Attribution to the NLF. Regulation (EC) No 765/2008 lays down the general principles of CE marking.

Step 3) Qualitative assessment. The targeted consultation explored this issue in detail, first examining the extent to which stakeholders consider certain general information obligations to be necessary and appropriate, before exploring the scale of the burden deriving from those obligations, the extent to which digitalisation could support the simplification of meeting these obligations and the potential impact on the consumer's right to be duly informed. This evidence is supported by feedback gathered through the interview programme.

As illustrated below, the **results were mixed regarding the necessity and appropriateness of the general information obligations stemming from the NLF**. 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 (48.8%, 41 responses), compared to printing out information to accompany the product (28.6%, 24 responses). However, 28.6% (on CE marking) and 42.9% (on printing product information) of respondents perceived these obligations to have either limited or no ongoing relevance.

Considering responses by stakeholder type, no notable trends were identified in relation to the CE marking obligations; however, economic operators and industry associations comprise 31 of the 36 respondents that selected 'To a small extent' or 'Not at all' in relation to the printing obligations.

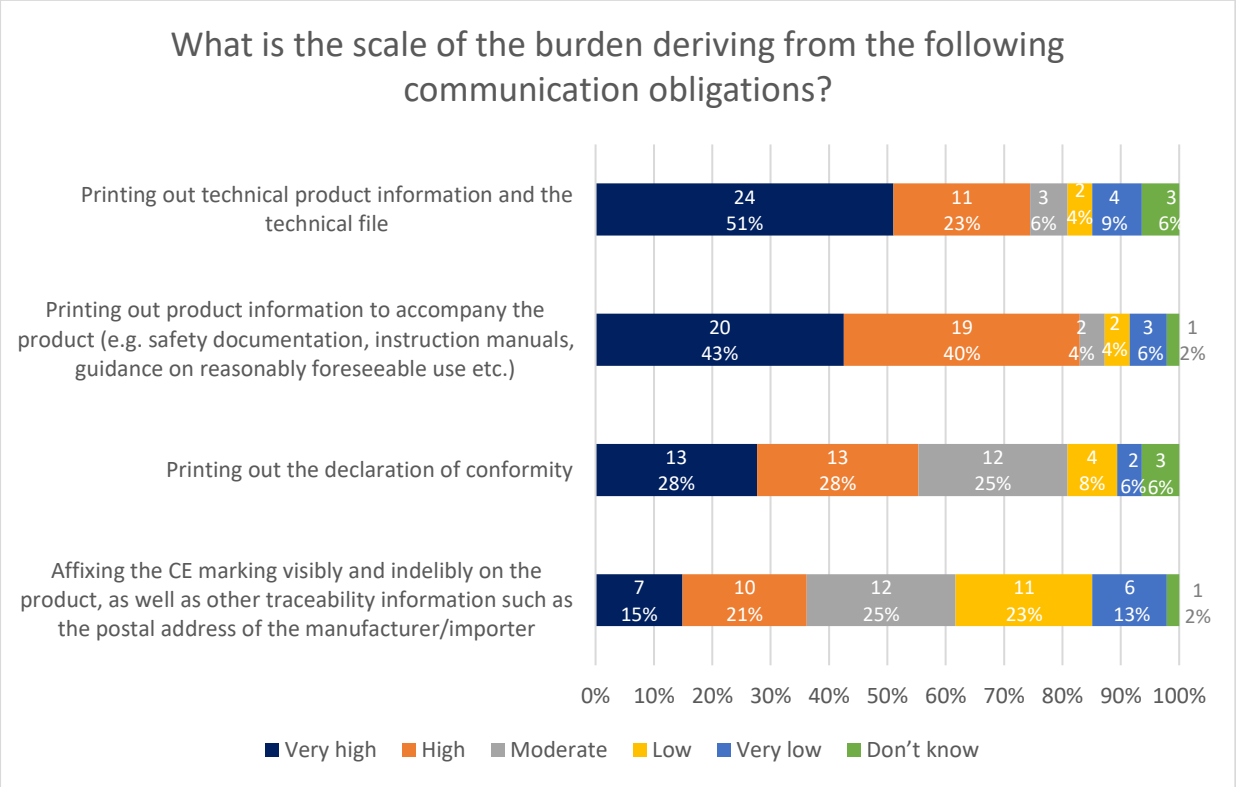
Figure 4-14: Necessity and appropriateness of NLF general information obligations addressed to consumers (Question 33, N=84)



Question 33 was asked to: economic operators, industry associations, consumer associations, MSAs and national competent authorities.

The following figure shows industry perceptions on the **scale of the burden** they face in relation to different communication obligations. Printing out product information to accompany the product was deemed most burdensome: 83% (39 of 47 responses) rated it high or very high. 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 least burdensome: only 36.2% (17 responses) rated it as high or very high. Furthermore, the combined high and very high responses were much higher for the options related to printing than the combined low and very low responses.

Figure 4-15: Scale of the burden deriving from communication obligations (Question 35, N=47)



Question 35 was asked to: economic operators and industry associations.

In light of this evidence, industry stakeholders were asked about the potential for efficiency improvements related to these obligations. Nearly 87.2% of these stakeholders (41 of 47) responded that the digitalisation of these communication obligations would improve the efficiency of conformity assessment without hindering market surveillance to a great or moderate extent.

This view is strongly confirmed by a study conducted for DigitalEurope and the Mobile & Wireless Forum, which examined the costs and benefits associated with digitalising certain compliance information in the consumer electronics sector. The study found significant practical benefits, including direct cost-savings for industry in product design, manufacturing and updating compliance information; indirect market benefits related to increased trade and tackling counterfeit products; improved access to up-to-date information (for the end-user); and positive environmental impacts. In addition, the study argued that e-labelling does not have adverse impacts on other types of stakeholders, noting that it is already used in the majority of consumer electronics products across certain third countries, including the US, Australia and Singapore.[71]

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**. Views on digitalisation of the CE marking, however, were more mixed.

The **primary challenge** for the digitalisation of these obligations is the potential impact on users that are less digitally adept. In this respect, the targeted consultation asked economic operators, industry associations, consumer associations, MSAs and national competent authorities about the extent to which the **digitalisation of CE marking / traceability / product information would jeopardise the right of consumers** to be duly informed (Figure 4-16). While 28.9% thought this right would be jeopardised

[71] VVA. (2018). Study for the introduction of an e-labelling scheme in Europe, June 2018, conducted for DigitalEurope and the Mobile & Wireless Forum.

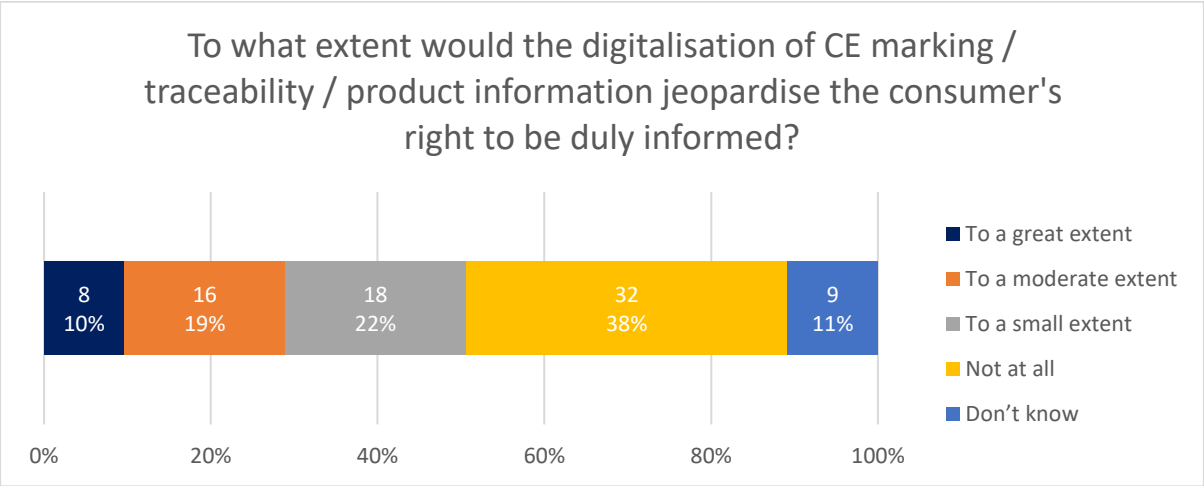
to a moderate or great extent (24 responses), 21.7% thought this would only be to a small extent (18 responses), while 38.6% (32 responses) thought it would not be jeopardised at all.

However, there was **some divergence in the responses of the different stakeholder types**. Industry associations (71%, 22 of 31 responses) and economic operators (43.8%, 7 of 16 responses) were most likely to answer that digitalisation would 'not at all' jeopardise the consumer's right to be informed. They pointed out that digitalisation will enable fast and easy access to information when relevant and any time after receipt of a product. Most EU consumers now have digital tools and information can be stored on retailers' or manufacturers' websites. However, none of the 18 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.

The public consultation was able to put a similar question to citizens (EU or non-EU). Citizens' views were strongly neutral regarding the digitalisation of CE marking and other traceability information. But, in contrast to the above concerns, there was a strong perception across the 30 responding citizens that **digital provision of product information would have positive (33%, 10) or very positive (40%, 12) impacts** on consumers.

One potential solution to this challenge proposed by an interviewed industry stakeholder is providing the information digitally as standard, with the option for printed information upon request.

Figure 4-16: Extent to which the digitalisation of CE marking / traceability / product information would jeopardise the right of consumers to be duly informed (Question 37, N=83)



Question 37 was asked to: economic operators, industry associations, consumer associations, MSAs and national competent authorities.

In previous evaluations, too, some feedback from industry associations was reported (the reference is to the EMCD evaluation) pointing to appreciation for the idea of electronic labelling being introduced within the NLF, as is the case in other jurisdictions.

Step 4) Quantitative assessment. Quantitative estimates on e-labelling were provided in a 2018 study[72] focusing on three segments of the European consumer electronics market: telephony, computing, and TV, radio and multimedia[73]. According to the study, under the current system the total

[72] VVA. (2018). Study for the introduction of an e-labelling scheme in Europe, June 2018, conducted for DigitalEurope and the Mobile & Wireless Forum.
[73] 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.

annual costs of indicating compliance in these three fields are about 800 million Euro[74]. 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 Euro 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**[75].

4.2.5.2 Remote assessment of conformity assessment, accreditation, and peer evaluation services

Step 1) Definition. As documented in an EA communication published on 23rd March 2020, the outbreak of the COVID-19 pandemic and the related travel restrictions implemented by governments across the EU forced conformity assessment (CAB) and national accreditation bodies (NAB), in the first instance, to "**cancel or postpone most of their 'in situ' activities such as on-site assessments, audits, witnessing visits and inspections**"[76]. Furthermore, CAB and NAB workforces across the EU were required to work remotely.

In response, **EA suggested the "use of remote assessment techniques** whenever needed to substitute or complement on-site assessments"[77], even if these techniques were not recognised within the applicable standards. EA was also forced to start conducting remote peer evaluations of NABs.

EA clearly noted that CABs and NABs may have to stop the provision of certain services or deviate from certain requirements in the relevant standards and accreditation rules. Considering such difficult situations, the communication noted that: "both EA members and accredited CABs are required to act responsibly, to analyse the risk of providing services with deviations from the requirements and not to provide them if such deviations jeopardise the technical validity of that specific activity. EA also expects EA NABs and accredited CABs to act with full transparency, informing affected clients of any change in the procedures and keeping records justifying the decisions taken". This EA communication was supported by additional information at the global level by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

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[74] 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).

[75] 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, 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.

[76] https://european-accreditation.org/ea-communication-to-the-impact-of-the-covid-19-outbreak/

[77] https://european-accreditation.org/ea-communication-to-the-impact-of-the-covid-19-outbreak/

On this basis, CABs, NABs and EA began **using remote techniques for the delivery of conformity assessment services, accreditation services and peer evaluations.**

This section presents stakeholder feedback on the experience of using remote techniques for these services and analyses the resulting potential for administrative simplification and burden reduction. In addition to feedback received through the stakeholder consultation activities, this analysis uses the results of a survey on remote techniques (possibly) used by notified conformity assessment bodies for the assessment of conformity of products against EU legislation.

Step 2) Attribution to the NLF. Annex II to Decision No 768/2008/EC provides a suite of conformity assessment modules to be incorporated into NLF-aligned legislation and is supported by Articles 4 and 6 of the Decision, in particular. However, the NLF does not make any mention of use of remote assessment techniques.

Step 3) Qualitative assessment. Given the importance of on-site activities across these areas, a representative of an NAB noted a **reluctance within the accreditation industry to conduct remote assessment activities prior to the COVID-19 pandemic**. However, as detailed above, the COVID-19 pandemic forced all conformity assessment and accreditation stakeholders 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.[78] This finding is supported by the survey of notified conformity assessment bodies, as illustrated in the below table.

Table 4-7: Summary of results from the survey on the use of remote assessment techniques

Summary: Survey results on the use of remote assessment techniques for conformity assessment services

Conducted in early 2022 by DG GROW, the survey was targeted solely at Notified Bodies (NBs). Of the 1,536 NBs contacted, 142 (9%) responded to the survey. The main results were:

- **Frequency of use:** Of the 142 NBs that responded, nearly two thirds have made use of remote assessment techniques (91, 64%).
- **Sectors of use**: For those NBs that have used remote assessment techniques, the majority performed them on construction products (51, 56%). The other areas with strong representation were pressure equipment (14, 15%) and personal protective equipment (PPE) (12, 13%). In addition, the following areas subject to NLF-aligned laws were represented at a low level: electromagnetic compatibility, lifts, and EU fertilising products.
- **Modules and systems covered by remote techniques:** The survey identified at least a low level of use across all conformity assessment modules and CPR systems. Furthermore, 58% of respondents that have used remote assessment techniques had done so in relation to more than one module/system.

  The modules focused on production process analysis are most commonly the subject of remote assessment techniques: 41% of NBs reported using such techniques for Module D activities (conformity to type based on quality assurance of the production process), and 20% for Module D1 activities (quality assurance of the production process). Common use was also reported in relation to Module H (conformity based on full quality assurance) – 14% of respondents – and Module H1 (conformity based on full quality assurance plus design examination) – 18% of respondents.

  For CPR Systems, relatively high use was reported for System 2+ (24%), System 1 (16%) and System 1+ (12%).

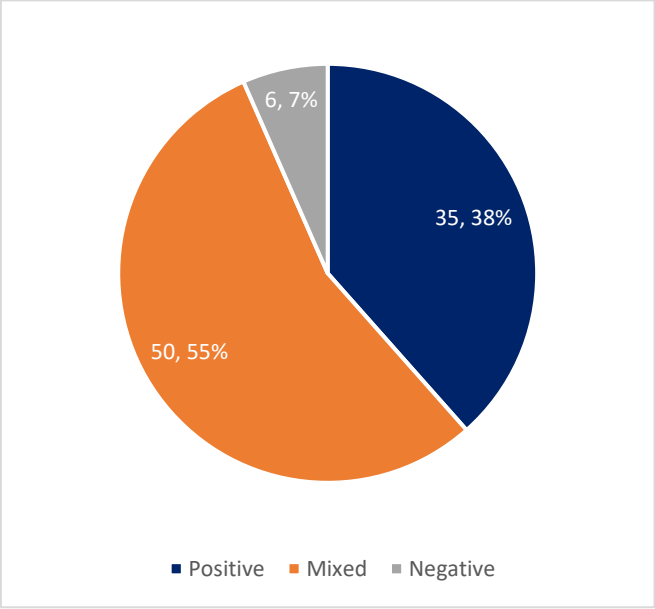
[78] https://european-accreditation.org/remote-peer-evaluation-feedback-from-mija-renko-sa-slovenia/

- **Reasons for not using remote techniques:** For those who have not used such techniques, the most often cited reason for not engaging in remote assessment techniques was the complexity of products and other specificities of their sector (12, 24%). Closely related to this reason, two respondents (4%) stated that 'the relevant Harmonised Standards do not provide explicitly for remote assessment techniques' and a further three NBs that responded 'Other' noted that relevant authorities, such as the European Commission, accreditation bodies and notifying authorities, had either not permitted the use of remote assessment techniques or had not provided a binding opinion on the suitability of using such techniques.

  Other commonly cited reasons were: 'we have not actively considered the use of remote assessments' (9, 18%), and 'it is not the policy of our NB to make use of remote assessment techniques' (8, 16%).

Views on the success of this shift to remote activities were sought through interviews with relevant stakeholders and open-ended questions in the targeted consultation supporting this evaluation and the Commission's survey on remote assessment techniques. In this respect, **notified bodies and NABs considered the experience to have been generally successful**. In fact, in response to the Commission's survey, only six NBs that had used remote assessment techniques reported negative experiences. As illustrated in the below figure, the majority of respondents (55%) had mixed experiences with the use of such techniques, while 38% had only positive experiences. Similarly, respondents to a global survey of 4,350 conformity assessment stakeholders conducted by IAF/ILAC/ISO in 2021 found that 71% of respondents were satisfied with their remote experience, while only 4% reported dissatisfaction.[79]

Figure 4-17: Responses to the question: How do you rate your overall experience with remote assessment techniques? (N=91)



Source: *Author adapted from DG GROW Survey on Remote Techniques (Possibly) Used by Notified Conformity Assessment Bodies for the Assessment of Conformity of Products against EU Legislation.*

Digging deeper into these experiences, a respondent to the targeted consultation praised the speed with which EA responded to the emerging COVID situation in March 2020, while other stakeholders highlighted the following **benefits of remote assessments**:

[79] IAF, (2021), IAF/ILAC/ISO Survey Shows Significant Benefits of 'Remote Techniques' and Tangible Desire for the Adoption of Remote and New Technologies.

- Ability to continue conformity assessment and accreditation activities through the COVID lockdowns implemented across Europe, thereby enabling the functioning of the conformity assessment and accreditation systems that underpin NLF-aligned legislation. In this respect, stakeholders also highlighted that the use of remote assessment techniques also protected the health and wellbeing of inspectors.
- Increased efficiency of assessment and accreditation activities due to reduced travel, as well as easier access to and management of documents.
- Reduced environmental impacts, also due to reduced travel and decreasing use of paper documents.
- Increased accessibility for people with disabilities.

The IAF/ILAC/ISO survey results support these findings, as respondents highlighted a wide range of benefits, including: reduced travel time and costs (96% of respondents); reduced travel risk (95%); reduced environmental footprint (95%); efficient use of personnel being audited/assessed/evaluation (87%); and keeping to strict time/schedule of the audit/assessment/evaluation plan (82%).[80]

In addition, in terms of **opportunity costs**, industry and NB stakeholders noted that the inability to use remote assessment techniques in the fields of medical devices and PPE (at least in the initial stages of the pandemic) contributed to the significant challenges industry faced bringing products instrumental in the fight against COVID-19 to market in 2020. Although remote assessment techniques are now permitted in relation to PPE, these stakeholders highlighted that such remote techniques are still not permissible in relation to medical devices. Further detail on the impacts of COVID-19 and the role of the NLF is presented in Chapter 6.4.

However, stakeholders highlighted a few **disadvantages** to remote assessments. 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.[81] NBs echoed this point, noting the lack of interpersonal connection and communication with auditees as a key disadvantage, alongside the inability to check various spaces / rooms and the inability to conduct simultaneous inspections of complex products or systems. NBs noted that these challenges can be further exacerbated by lack of training and technical capacity or issues with the technology being used to conduct the remote assessment.

In addition, a recurring concern amongst NBs was that clients could more easily hide certain aspects of their production or product during a remote inspection.

Although some respondents to the Commission's survey intend to return to normal in-person processes where possible, most stakeholders consulted believe that remote assessment techniques will become an **important assessment tool in future**. However, across all groups, stakeholders stressed that the use of **remote assessment techniques should not fully replace in-person activities**. For instance, an accreditation stakeholder highlighted the importance of conducting witnessing visits 'in situ', while NBs highlighted the limitations of conducting initial audits remotely, without established rapport, or performing detailed and tactile inspections and verifications remotely (e.g. for welds on pressure equipment).

This finding is supported by the IAF/ILAC/ISO survey referenced above, which found that 60% of respondents would prefer a "blended audit/assessment/evaluation", while "19% prefer fully remote and 21% prefer on-site"[82]. Considering the nature of blended assessments, NBs noted that the use of

[80] IAF, (2021), IAF/ILAC/ISO Survey Shows Significant Benefits of 'Remote Techniques' and Tangible Desire for the Adoption of Remote and New Technologies.
[81] https://european-accreditation.org/remote-peer-evaluation-feedback-from-mija-renko-sa-slovenia/
[82] IAF, (2021), IAF/ILAC/ISO Survey Shows Significant Benefits of 'Remote Techniques' and Tangible Desire for the Adoption of Remote and New Technologies.

remote assessment techniques is more appropriate in relation to particular activities. Respondents to the Commission's survey of NBs stated that certain conformity assessment modules (e.g. Module B) could be targeted for the use of remote assessment techniques, and a differentiation could be made between new and repeat clients. NBs noted that, while they may not feel comfortable assessing a new client remotely, these techniques can be more suitably used with existing clients. The findings of the IAF/ILAC/ISO survey supported this finding – 98% of respondents noted that remote activities are beneficial or somewhat beneficial was in 'Keeping certificate/accreditation/recognition status'.[83]

Overall, 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.

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.

Step 4) Quantitative assessment. As highlighted above, the NLF has not brought about significant changes in the field of conformity assessment procedures. In this respect, the incremental cost in terms of resources spent by economic operators in relation to conformity assessment is nil when comparing to the baseline. The benefits of remote assessment would therefore accrue at the level of individual Union harmonisation legislation.

4.2.6 Conclusive remarks and summary answers evaluation questions

EQ2.1 – What are the regulatory and administrative costs associated with the NLF and are they affordable for the various stakeholder groups?

Costs associated with the NLF refer to human and financial resources spent by EU and national authorities, and by economic operators, to ensure the implementation of the NLF.

Costs borne by economic operators, in particular, are brought about during the conformity assessment procedures (especially in terms of testing, preparing and updating technical documentation and, when applicable, the involvement of a notified body) and through the innovations introduced in 2008 concerning the accreditation framework. On the latter point, notified bodies wanting to become accredited face costs due mainly to examination fees and the payment of an annual fee to the accreditation body (where applicable), as well as the development and maintenance of a quality management system (if not already in place), and an insurance fee.

EQ2.2 – What are the benefits and how beneficial are they for the various stakeholder groups?

The benefits generated by the NLF can be structured by stakeholder group as follows:

- **Cost savings for economic operators:**
  - Reduced costs in familiarising with the legislative requirements and the definitions in place (administrative tasks).
  - Reduced costs in conformity assessment activities (substantive tasks).
- **Benefits for economic operators:**
  - Enhanced legal certainty.

[83] IAF, (2021), IAF/ILAC/ISO Survey Shows Significant Benefits of 'Remote Techniques' and Tangible Desire for the Adoption of Remote and New Technologies.

- Reduction of intra-EU market barriers.
- Enhanced industrial competitiveness.

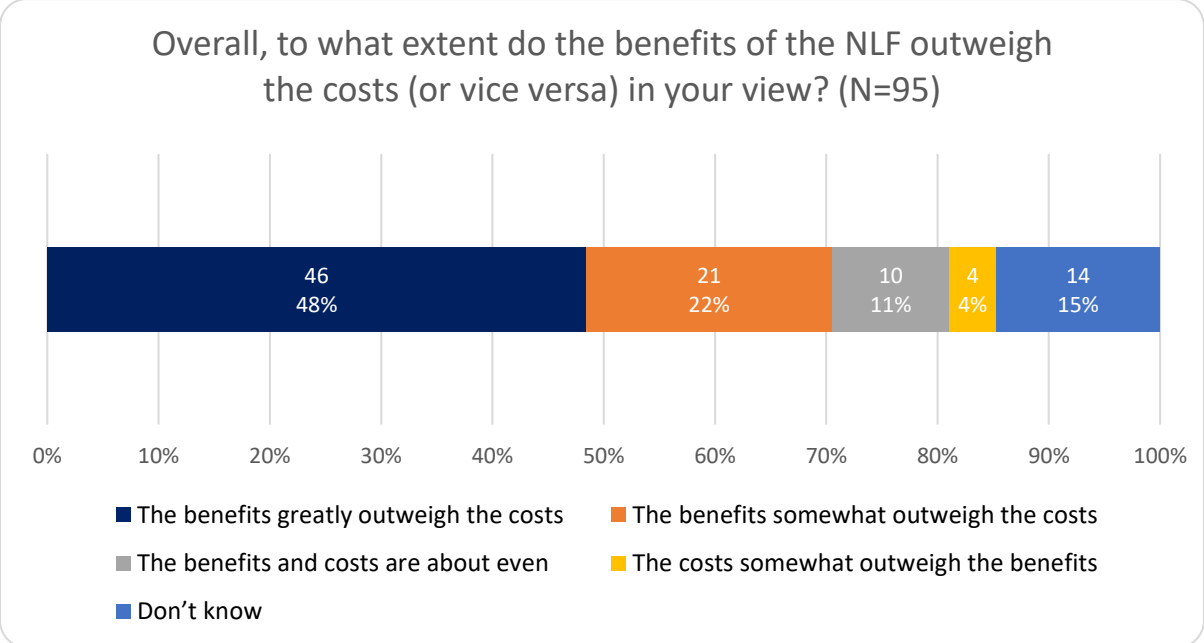
- **Benefits for end users and the society as a whole:**
  - Increased safety, health and reduced environmental damages.
  - Cost savings, as the development of standards is essentially borne by industry.
- **Wider strategic benefits:**
  - Increased global relevance of EU regulations and conformity assessment procedures.

While cost savings for economic operators are generated upfront at the micro level, other benefits (legal certainty, reduction of barriers to market access, enhanced competitiveness) are more related to the macroeconomic scale. Wider societal benefits, such as increased safety, health and reduced environmental damages are directly linked with the NLF's general objectives and have a strategic nature, as does increased global relevance of EU product legislation.

EQ2.3 – Are the costs proportionate to the benefits attained?

Whereas it does not appear possible to quantify all costs and benefits of the NLF, the opinions of interviewed stakeholders point to the benefits of the NLF strongly outweighing its costs. In the public consultation, respondents were also positive about the **net benefits of the NLF** in relation to its costs. As illustrated below, 48% suggested that the benefits greatly outweigh the costs (46 responses), while a further 22% (21 responses) consider that the benefits somewhat outweigh the costs.

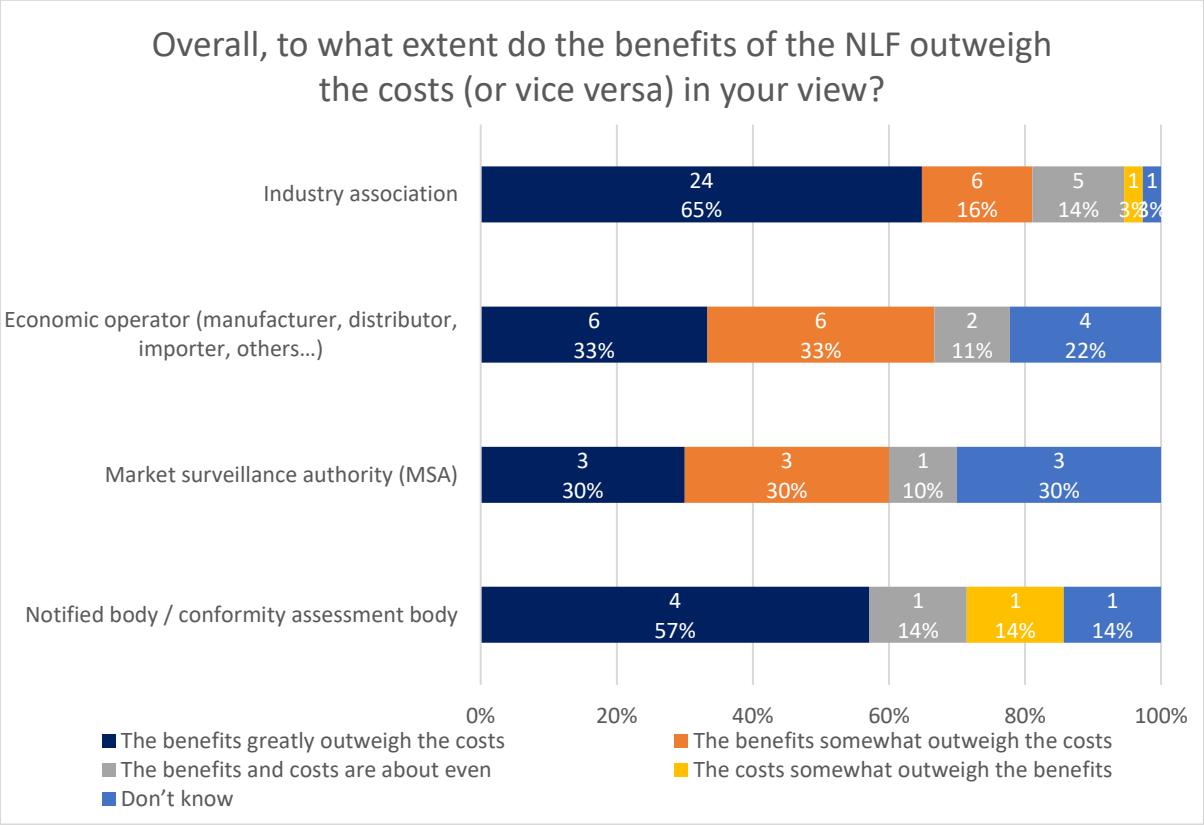
Figure 4-18: Overall balance of NLF benefits and costs – Public consultation (N=95)



Question asked to all respondents except citizens

While there was some divergence between stakeholders of different types (among the larger groups of stakeholders, industry associations and notified bodies were most likely to agree that the NLF's benefits greatly outweigh its costs), **more than 60% of respondents of each stakeholder type agreed that benefits of the NLF greatly or somewhat outweigh costs**.

Figure 4-19: Overall balance of NLF benefits and costs (disaggregated by stakeholder type, N=95)



4.3 Coherence

The assessment of the coherence criterion examines the following dimensions:

- **Internal coherence** considers the extent to which the two legal texts of the NLF are internally coherent, including whether any inconsistencies or duplications exist. It also considers 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 appropriate.
- **External coherence** considers the extent to which there any gaps, loopholes, inconsistencies, or duplication in relation to the NLF and its interaction with other EU legislation. Issues relating to the alignment of Union harmonisation legislation with the NLF's reference provisions are analysed in Chapter 4.1.1.1, under the assessment of effectiveness. This is because supporting the consistency and coherence of this legislation is a specific objective of the NLF. This section considers the coherence of the NLF and its aligned legislation with a wide range of existing and proposed EU legislation:
  - **Sectoral and product-specific legislation** – e.g. the proposal for a Machinery Regulation and the proposal for a Regulation concerning batteries and waste batteries.
  - **Horizontal legislation** – e.g. the GPSD, which sets out provisions on product safety for products not covered under sectoral legislation, as well as requirements for all products, the proposal for a General Product Safety Regulation (GPSR) revising the GPSD, the Product Liability Directive (PLD) in the area of liability for defective products, and the proposal for an AI Act.
  - **Environmental legislation –** e.g. the WEEE Directive, the Ecodesign Directive and the

Sustainable Products Initiative.

- **Other relevant legislation** – e.g. the GDPR, the Services Directive.

This chapter first focuses on an analysis of internal coherence, before examining external coherence, with an extensive analysis of definitions under the NLF and related legislation.

4.3.1 Internal coherence

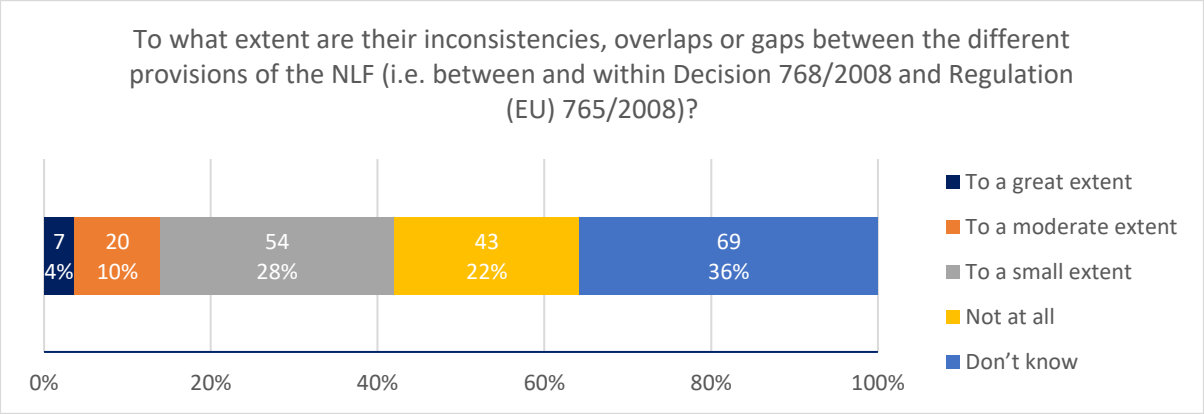
The assessment of internal coherence addresses the following question:

EQ3.1 – Are there any inconsistencies, overlaps or gaps within the different provisions of Decision 768/2008 and Regulation (EU) No 765/2008)?

There is the potential for inconsistencies and overlaps to occur 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 CE marking are stipulated in Article 30 of Regulation (EC) No 765/2008, supported by Annex II to the Regulation, Decision No 768/2008/EC provides reference provisions for inclusion in specific Union harmonisation legislation that cover the general principles of the CE marking (Article R11) and the rules and conditions for affixing the CE marking (Article R12). Similarly, the reference provisions detailed in Annex I to Decision No 768/2008/EC incorporate the concepts and reflect the rules on accreditation provided or by Chapter II of Regulation (EC) No 765/2008.

However, **no issues have been raised** by interviewed stakeholders regarding the coherence and consistency of these 'internal' provisions. The findings of the targeted consultation further reflect this finding to some extent. As illustrated below, the majority of respondents (35.8%, 69 responses) reported that they **did not know** whether inconsistencies, overlaps or gaps exist between the different provisions of the NLF (Figure 4-20). Of those who felt able to judge, 28% (54 responses) considered that such inconsistencies, overlaps, or gaps exist to a small extent, while 22.3% (43 responses) saw no inconsistencies, overlaps or gaps at all.

Figure 4-20: Extent to which there are inconsistencies, overlaps or gaps between the different provisions of the NLF (Question 59, N=193)



The views of those that reported inconsistencies, overlaps or gaps were explored through an open-ended follow-up question. However, the rationales provided in that question were either not relevant to internal coherence issues or highlighted challenges with the Market Surveillance Regulation 2019/1020, which, although part of the NLF, is out of scope of this evaluation. For instance, one stakeholder noted that the NLF should be aligned to the Market Surveillance Regulation with regard to the new definition of fulfilment service providers.

4.3.2 External coherence

Feedback on the NLF's internal coherence was limited as the legal texts were considered to be coherent. In contrast, stakeholders provided extensive feedback on issues relating to external coherence. This is due to various factors, including: i) the significant number of different pieces of NLF-aligned legislation (23 directives and regulations); and ii) the need to update some of this body of sectoral legislation to reflect developments and trends relating to the digital and circular economy, as documented in Chapter 3.3; and iii) the fact that wider legislation necessarily interacts at least to some extent with the NLF, including horizontal and some environmental legislation.

The analysis has considered how far the NLF's core reference provisions and general principles are being adhered to. The extent to which the provisions of the NLF and definitions are consistent and coherent with the wider EU legal framework is also examined.

4.3.2.1 Analysis of coherence between the NLF and other EU legislation.

The assessment of external coherence addresses the following study question:

EQ3.2 – To what extent is the NLF still consistent with other EU legislation, including new proposed legislation (e.g. the GPSR proposal, Machinery Regulation proposal and the AI Act)?

Degree of alignment vs. divergence with NLF-aligned legislation

As the NLF's core aim is to ensure a common approach to NLF-aligned legislation through common reference provisions, an assessment of the extent of alignment – and its impact – across the body of 23 different regulations and directives was provided earlier under 'effectiveness'. Divergence between different pieces of NLF-aligned legislation was also considered in the earlier section. The analysis showed that broadly, such legislation is based on common provisions, and is therefore largely coherent and consistent. However, there is a need to consider how far new legislative proposals – including proposed recasts of existing legislation such as the Machinery Regulation proposal are consistent with the NLF's general principles.

Alignment of new legislative proposals with the NLF principles

A key issue analysed was how far the NLF remains coherent with other EU legislation, in particular new proposed legislation. This encompasses sectoral legislation that is in the process of being fully NLF-aligned (e.g. the Machinery Regulation proposal as the Machinery Directive from 2006 was only partially aligned) and wider horizontal and technology-specific legislation, such as the GPSR proposal and the proposal for an AI Act.

An overview of selected examples of new legislative proposals and of how far these are coherent with the NLF is provided in the table below. Examples of how far the new legislative proposals are coherent with the NLF, and illustrations of areas where there may be divergence with the NLF as the NLF does not tackle some regulatory issues is considered in the final column.

Table 4-8: Coherence of the NLF with new legislative proposals

Legislation	Type of legislation	Status	Examples of NLF alignment	New areas addressed (going beyond elements covered by the NLF)
Machinery Regulation proposal **COM/2021/202 final**	Sectoral	Proposal published April 2021 [84]	• Broadly aligned with the NLF. • Integrates the NLF Decision 768/2008/EC provisions.	• Software and cybersecurity updates explicitly mentioned. Concerning cybersecurity, does not aim to include general cybersecurity requirements but only ensure 'cyber-safety' – i.e. that a machine remains safe in case of a cyberattack. • Some technology-specific requirements: ○ Risk assessment required to take into account potential changes to products post-market placement due to AI and machine learning. ○ Third party conformity assessment for high-risk AI. • Clarifies the safeguard close procedure.
Batteries Directive **2006/66/EC**	Sectoral	2019 proposed Directive[85] EC intends to revise Batteries Directive to better factor in circularity, improve sustainability and keep pace with technological developments.	• Batteries Directive pre-dates the NLF so currently applicable legislation is not NLF-aligned.	• Perceived deviation from a technology-neutral approach through inclusion of detailed technical specifications within product legislation rather than in harmonised standards. • Product lifecycle approach. All batteries placed on EU market should become sustainable, high-performing and safe along the entire lifecycle.
GPSR proposal[86]	Horizontal	Proposal published June 2021	• Incorporates core NLF principles but also additional elements.	• Some stakeholders perceive that these additional elements go beyond the NLF's common reference provisions. • In particular, GPSR emphasises new aspects in the risk assessment of products (e.g. if a product has "appropriate cybersecurity features necessary to protect the product", and to reflect a product's "evolving, learning, or predictive functionalities.") • Places new obligations on manufacturers to 'take account' of connectivity/IoT risks when assessing a product's safety. • Addresses security updates, software, changes to products post market placement. • The GPSR also introduces obligations for online marketplaces and traceability obligations for distance sales for all products, including those subject to Union harmonisation legislation,

[84] Proposal for a Machinery Regulation published April 21st, 2021 - https://ec.europa.eu/docsroom/documents/45508
[85] Proposal for a Regulation concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020.
[86] Proposal for a Regulation on general product safety, Brussels, 30.6.2021, COM(2021) 346 final
https://ec.europa.eu/info/sites/default/files/proposal_for_a_regulation_on_general_product_safety.pdf

Legislation	Type of legislation	Status	Examples of NLF alignment	New areas addressed (going beyond elements covered by the NLF)
				since these aspect are currently not covered by the NLF. The aim is to ensure equal conditions between offline and online sales and to address the safety of products sold on online marketplaces. • GPSR includes accident reporting for all products, including those subject to Union harmonisation legislation, since these aspect are not currently covered by the NLF. • GPSR proposal requires importers to retain technical documentation, which goes beyond the NLF. • Under the NLF, obligation on importers to ensure that technical documentation can be made available to MSAs on request. Importers can meet obligation through contractual arrangements with manufacturers as technical documentation may include confidential and commercially sensitive information which the manufacturer would not normally distribute to 3rd parties. • GPSR proposal requires manufacturers to display certain contact information, including both postal and electronic addresses. NLF does not have a mandatory requirement beyond a postal address. • The proposed GPSR expands the application of the Responsible Person from Article 4 of Regulation (EU) 2019/1020 on market surveillance and compliance of products to all non-harmonised products and adds responsibilities such as sample testing.
Product Liability Directive (PLD) **Council Directive 85/374/EEC**	Horizontal	Impact assessment being completed April 2022. Draft legislative proposal in 2022	• 1985 Directive (civil law), so non-aligned with NLF (criminal law) • However, legislative proposal in 2022 will need to align with NLF as far as possible.	• Non-alignment under current PLD with definitions of economic operators in the NLF (e.g. term 'producer' and not 'manufacturer' or 'economic operators'). • Problem that some economic operators that are strictly liable (e.g. producers of raw materials, refurbishers, remanufacturers and software developers) are not defined as economic operators in the NLF. • A future revised PLD may need to include additional EOs that are not yet mentioned in the NLF but which are defined in at least some underlying product legislation (e.g. refurbishers, remanufacturers and software developers are mentioned in the MDR). • Concept of substantial modification constituting a new product is not defined in common definitions in the NLF, but concept needed for PLD revision. Therefore, the definition in Blue Guide (or that in the GPSR or Machinery Regulations proposals) could be used.
Cyber Resilience Act (CRA)	Horizontal	Preparatory study to support impact assessment being undertaken in Q1/ Q2 2022.	• CRA intended to build on voluntary CSA. • Effort being made to ensure NLF-alignment	• To cover digital products (and ancillary data and services) • Could have implications for the NLF as the NLF would need to refer to the horizontal provisions in the CRA and also, the common menu of conformity assessment modules could need to be updated to incorporate validation of cybersecurity of products in use through new conformity assessment procedures assessed against new harmonised standards.

Legislation	Type of legislation	Status	Examples of NLF alignment	New areas addressed (going beyond elements covered by the NLF)
The AI Act[87]	Technological	Proposal published Feb 2021	• Definitions taken from the NLF (although some additional concepts and definitions)	• Technology-specific requirements • High-risk AI subject to greater requirements e.g. disclosure rules for high-risk AI/ logging. • Additional concepts and definitions
Sustainable Product Initiative – proposed legislation to expand Ecodesign requirements	Environmental and sectoral	Proposal published March 30th 2022	• Technology-neutral (as technical requirements are developed through implementing regulations and not specified in overarching legislation)	• Product lifecycle approach embedded • Traceability in value chain enhanced through inclusion of digital product passports.

[87] COM/2021/206 final, Proposal for an AI Act - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206

Conclusions – assessment of the alignment of new legislative proposals with the NLF principles

The desk research and analysis of stakeholder feedback regarding the coherence between the NLF and recent legislative proposals identified a number of interesting findings.

Firstly, a **technology-neutral approach** has been embedded in Union harmonisation legislation since the New Approach was adopted, which has been continued as a core NLF principle since 2008. Nevertheless, there is an ongoing policy debate between stakeholders such as EU industry and consumer associations and EU regulators regarding **how detailed and technical EU harmonisation legislation (and any subsequent implementing regulations, for instance through delegated acts), should be**.

Industry associations, individual manufacturers and ESOs interviewed and responding to the public and targeted consultations perceive the NLF's technology-neutral approach to defining essential requirements, with detailed technical specifications being left to the ESOs to develop through harmonised standards (or being alternatively documented in the manufacturer's technical file where no standards exist) as being an important core NLF principle. This was seen as ensuring coherence across NLF-aligned legislation. However, in recent EU regulatory proposals, there is evidence of divergence from the notion of technology-neutrality. Several new legislative proposals were regarded by industry as not fully respecting a technology-neutral approach, and/ or being too technically-detailed. Examples are:

- **The inclusion of a series of Delegated Acts within the Radio Equipment Directive (2014/53/EU)** – several of these have subsequently been adopted covering software updates, data protection and privacy through the publication of a DA in October 2021 – Art. 3(3(d), (e) and (f);
- **The proposal for an AI Act (Feb 2021) –** includes stricter rules for high-risk AI systems. Some industry stakeholders are not in favour of regulating AI separately from other digital technologies already covered by NLF-aligned sectoral legislation;
- **The proposal for a Machinery Regulation (April 2021) -** which would - if adopted - require a risk assessment to be undertaken at pre-marketing stage when placing products that incorporate AI and machine learning capabilities.

ESOs expressed concern about the inclusion in recent Union harmonisation legislation and in draft legislative proposals of the ability for the Commission to follow-up subsequently on secondary sectoral legislation with additional implementing acts (such as the delegated acts under the RED). These legal instruments allow the Commission to develop more detailed technical requirements further down the line following the initial adoption of legislation. According to a major EU standardisation organisation, there is a risk of a blurring of lines regarding responsibilities and competences if the EC is also involved in developing technical requirements to implement legislation through the adoption of implementing regulations or delegated acts. Technical specifications according to essential legal requirements should in their view be dealt with by relevant actors according to their respective competences, and therefore continue to be part of the standardisation mandates issued from the Commission to the ESOs.

A key message from interviews was that industry and the ESOs would prefer EU regulators to focus on setting the high-level strategic objectives, whilst leaving detailed technical implementation aspects to standardisation bodies. However, the Commission's desk officers responsible for particular pieces of legislation made clear during the evaluation that the inclusion of the possibility to develop further implementing acts is a measure of last resort under which the Commission would have to step in to draft technical requirements, e.g. in the absence of suitable harmonised standards from the ESOs. Harmonised standards would therefore remain the default rule.

Secondly, regarding the extent to which there is any evidence of gaps, inconsistences or duplication between different pieces of EU legislation, a key finding is that more recent legislative proposals build

on the NLF's core principles and are therefore broadly coherent, but sometimes go beyond the NLF's common reference provisions requirements. However, the extent to which this is a problem from a coherence perspective is contested among stakeholders. On the one hand, many EU industry associations would prefer all new legislative proposals to retain their focus on the NLF's core principles and to avoid any requirements not already included in the NLF. However, on the other hand, it was recognised among some industry associations and all consumer associations taking part in the stakeholder consultations that as the NLF was adopted in 2008, it has become outdated in certain areas in particular due to **growing digitalisation and the development of the circular economy**, requiring new legislative proposals to consider today's product market realities and conditions of use rather than the situation 15 years ago when the NLF was being drafted. Recent legislative proposals have had to take as a starting point the NLF's common reference provisions, but there are elements outside these that constitute regulatory gaps which may undermine the coherence between the NLF and sectoral Union harmonisation legislation, as well as between the NLF and horizontal pieces of law.

Taking a simple example pertaining to administrative requirements to provide contact information, the NLF only mandates that a postal address should be provided on the product (or its packaging) whereas the 2021 GPSR proposal mandates both a postal and electronic contact information. Whilst this means minor incoherence and inconsistency between the obligations for economic operators between NLF-aligned sectoral legislation and the GPSR covering all products not already covered in sectoral legislation, in a digital age, electronic contact information is necessary.

Given considerable developments in product markets driven by the advent of new technologies and digitalisation, and the development of the circular economy, recent legislative proposals address issues and include some requirements that were not addressed when the NLF legal framework was adopted in 2008. Examples are:

- **Referring to additional economic operators in modern value chains not mentioned in the NLF common definitions of economic operators** e.g. EU responsible persons, such as Fulfilment Service Providers, refurbishers and remanufacturers, software developers.
- **The importance of a lifecycle approach to products, rather than solely being focused on the moment of market placement.**
    - **Addressing changes to products post market placement, which have become much more frequent.** Software updates and upgrades, changes due to predictive and learning technologies, such as AI and machine learning, as well as refurbishing and remanufacturing activities mean that products change more frequently post market placement, under the responsibility of a growing range of economic operators, whereas the NLF focuses on the placing on the market and the pre-marketing phase under the responsibility of the manufacturer and sometimes the installer.
    - **Addressing the link between product safety and cybersecurity**, which was not previously addressed in the NLF. Cybersecurity is an increasingly important issue.

Given the various market-related developments relating to technological, digitalisation and the growth in the circular economy, the NLF was perceived by consumer associations and also by a minority of industry stakeholders as having become outdated. However, it should be noted that the majority of industry stakeholders perceived the NLF as remaining fit for purpose given the inherent flexibility of a technology-neutral approach (as harmonised standards can accommodate technological developments and reflect state of the art).

Although this primarily affects relevance and ongoing fitness for purpose, **differing views on the NLF's ongoing fitness for purpose also impact on external coherence** as it has become progressively more difficult over time for EU regulators required to follow the NLF's regulatory toolbox and common reference provisions to ensure full consistency between the NLF and requirements set out in sectoral

and horizontal legislative proposals. It was argued by some EU regulators responsible for particular pieces of sectoral legislation that whilst the NLF principles and common reference provisions provide the starting point and basic building block for designing NLF-aligned legislation, there is often a need for EU legislators to add incremental elements to accommodate the digital and circular economies, as new issues have emerged that were not addressed at the time the NLF was drafted.

Some stakeholders participating in the NLF workshop in March 2022 viewed this challenge as being a chicken and egg situation as **until the NLF is updated, its coherence with other pieces of Union harmonisation legislation, as well as horizontal legislation risks being undermined.** A majority of industry associations considers that the NLF remains fit for purpose for the design of products under the responsibility of the manufacturer; in their view, what needs to be improved is how to interface this NLF key feature with the responsibility and corresponding legal obligations of all other actors down the distribution-and-use chain, after the placing of the product on the market. If the NLF were to be updated, they admit that some missing definitions and concepts could be included. However, they insist on the need to first maintain consistency between the NLF and other pieces of Union legislation that apply to the product life-cycle and its various levels of involvement from third-parties to the manufacturer.

Thirdly, an issue was raised that in the views of some industry stakeholders, inadequate attention is being paid by some regulators to ensuring NLF alignment. This was perceived as being more a problem in relation to other Directorate Generals and not legislation falling under DG GROW, the lead on the NLF.

The perception was that whilst the NLF regulatory toolbox is taken into consideration by EU regulators as the starting point and a reference in terms of its general principles, other factors have influenced the shape of the final draft of legislative proposals, such as sector-specific considerations. The concern was that some legislative proposals went beyond the NLF's general principles and introduced more specific additional requirements which were not seen by industry as being sufficiently technology-neutral.

However, it is important to point out that DG GROW is involved in all Steering Committees on the ISSG and its role is to ensure that an NLF perspective is considered. Therefore, the need to align with the NLF is always discussed and commented on. The practical challenge however is that some issues, such as cybersecurity, changes to products post market placement due to AI / machine learning/ software updates etc. were not included in the NLF as it dates from 2008. Therefore, some aspects of proposed legislation may appear to go beyond the NLF but in practice, a compromise has to be found when legislators need to accommodate digitalisation and the circular economy, which the NLF does not explicitly address.

External coherence is now considered from different perspectives in further detail. This includes:

- Coherence – integration of digital technologies into products;
- Coherence – the circular economy;
- Evolution of trade and new roles in the distribution chain;
- Presumption of conformity; and
- Coherence of definitions included in the NLF compared with the evolution of NLF-aligned and other EU legislation.

4.3.2.2 Coherence – the integration of digital technologies into products

Regarding further aspects of external coherence, an important issue is how far the NLF is **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 economic operators in the value chain.

Under the NLF, manufacturers are required to undertake a risk assessment as part of conformity assessment procedures prior to placing a product on the market. In addition, risks should be adequately considered in technical documentation (i.e. in the technical file to support the DoC). Furthermore, under Articles 19 and 20 of Regulation (EC) No 765/2008, accident reporting is required. Although outside the scope of the present study, the NLF also strengthened risk assessment as regards products presenting a serious risk through the market surveillance mechanisms.

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 for a Machinery Regulation[88], as well as the proposal for an AI Act, manufacturers or providers placing respectively AI-embedded machinery or high-risk AI systems on the market will be required to perform a risk assessment of potential risks associated with AI that may emerge post-market placement (given the autonomous learning capabilities of AI) before they place a product on the market.

These are examples of regulatory developments that aim to improve the robustness of risk assessment if increased risks are identified linked to particular new technologies. In this respect, they aim to tackle market challenges that did not exist when the NLF was adopted and, as such, are not covered by the NLF. However, most industry associations and large manufacturers interviewed expressed concerns about the concept of introducing risk-based assessment requirements linked to the use of specific new technologies, especially AI. The main concern is that this in their view **diverges from the technology-neutrality principle** of the NLF . However, the Commission regulators responsible mentioned that they have only set essential requirements for AI-driven products and high-risk AI products One of the European Standardisation Organisations interviewed expressed the view that there were concerns about the Commission having regulatory powers in some pieces of legislation to introduce more technical rules once legislation has already been adopted, such as through delegated acts, for instance under the RED. In their view, the Commission's role as regulator should focus more on setting high-level essential requirements leaving detailed technical implementation to the ESOs through development of harmonised standards with industry.

A further question raised in relation to coherence is **whether the new AI proposal provides regulatory clarity for the NLF**. It was mentioned that the AI proposal was developed in a way that was aligned with the NLF. However, some industry stakeholders perceive that the final regulatory proposal moves beyond the NLF's principles, especially that of technology-neutrality. However, the AI Act was intended to deal with a specific technology, hence a technology-specific approach is part of its inherent nature. It must be also noted that, within the field of AI, the AI Act is AI technique/approach neutral. A further comment is that the proposal for an AI Act targets new economic operators that are not always within the scope of the NLF about the current definitions of economic operators, such as software providers or users.

In this regard, Digital Europe pointed out that the *"NLF legislation guarantees the safety of ICT products, correctly implemented through either third-party conformity assessments or self-assessments, with the use of harmonised standards. The AI Act, through its 'AI system' definition, extends this approach to embedded software as well as standalone AI software – this is a novelty for most NLF legislation"*, although such an approach is present in the Medical Devices Regulation.[89]

Overall, whilst the AI Act is built on the NLF as a basic building block, it also introduces new elements that go beyond the NLF. According to some industry associations, consumer associations and ESOs interviewed , there are several examples of Commission regulatory proposals that have arguably

[88] https://ec.europa.eu/docsroom/documents/45508
[89] https://www.digitaleurope.org/resources/digitaleuropes-initial-findings-on-the-proposed-ai-act/

incorporated the core NLF framework's general principles, but have gone beyond these and also incorporated further elements.

Whilst this was criticised as being contrary to the spirit of the NLF by some stakeholders, a counterpoint is that it can be pointed out that some of these new additional elements refect the fact that the NLF was developed in a way that did not explicitly accommodate digitalisation (including cybersecurity) or address the circular economy at all as these aspects were less prominentin 2007 when the impact assessment was being done. Therefore, reflecting the imperative for EU regulators to modernise and update the legal framework, they have necessarily had to go beyond the NLF's minimum common elements in some draft laws. Examples of areas where draft proposals appear to build on, but go beyond the NLF as it currently stands are:

- **Proposal for a Regulation on machinery products (Machinery Regulation, COM(2021) 202)** proposes to take back or modernise four definitions from the existing Machinery Directive 2006/42/EC and proposes to add two definitions of generic concepts ('substantial modification' and 'instructions for use'), which are included in the Blue Guide and in some other legislation (e.g. the MDR 2017), but were not defined in the NLF. A risk assessment for machinery including high-risk AI (as defined in the AI Act) is also required by manufacturers and software developers if it affects machinery safety. Changes to products post-market placement are not addressed in the NLF which focuses on the point of placement on the market. This raises a chicken and egg issue as to whether the proposal goes beyond the NLF, or simply reflects today's market and regulatory realities, implying that the NLF has become out of date.
- **Proposal for a Regulation on Artificial Intelligence (AI Act, COM(2021) 206)** has added 24 definitions that are new or partly diverge from the NLF. However, on closer inspection, there is evidence of alignment for some of these definitions as these are commonly used concepts in the NLF that were never legally defined, such as: intended purpose, reasonably foreseeable misuse, safety component of a product or system, instructions for use, substantial modification. Other proposed new definitions could become part of the NLF if the "artificial intelligence system (AI system)" becomes a ubiquitous feature of any product or system in our modern life, such as: "small-scale provider", "user", "operator", "performance of an AI system", "post-market monitoring", "common specifications", "publicly accessible space", "law", "enforcement authority", "law enforcement", "national supervisory authority", "national competent authority", "serious incident". Although these definitions are new or differ from those in the horizontal NLF legislative instruments, many are aligned with definitions stipulated in individual pieces of NLF-aligned legislation (such as the Medical Devices Regulation and the Lifts Directive) or terminology explained in the 'Blue Guide'.
    - In both the proposed Machinery Regulation and in the AI Act, software, an intangible product, must be CE-marked. Although this is also the case in the Medical Devices Regulation, this approach diverges from current requirements in other NLF legal texts.
    - The professional user is subject to specific obligations, which do not exist in the New Approach and the NLF, whose primary objective is to regulate the placing on the market of products, not their use.
- **Proposal for a Regulation on general product safety (COM(2021) 346)** has five concepts and definitions that are not included in the NLF legal texts, but can be considered as generic or partly generic when viewing safety as a horizontal concept across EU product legislation. Three of these definitions existed in some form in the GPSD ("product", "safe product" and "dangerous product"), while two are new to the GPSR proposal ("online marketplace" and "substantial modification"). In addition, the concept of "presumption of safety" is considered to be more demanding than the equivalent concept in the NLF and NLF-aligned legislation (i.e. "presumption of conformity").

4.3.2.3 Coherence – the circular economy

Regarding gaps relating to the circular economy, an example is the concept of a **substantial modification of a product**. The concept can be used to determine whether a product has been modified to the extent where it can be considered as new and therefore should be subject to conformity assessment procedures prior to being placed on the market again. Presently, there is no definition of a 'substantial modification' in the NLF, yet there are related explanations in the 'Blue Guide' on the implementation of EU products rules[90], which is non-binding. The 'Blue Guide' states that a product involving "*changes or overhauls aiming to modify its original performance, purpose or type*" should be considered as a new product and therefore require the refurbisher or remanufacturer to ensure that all legal obligations for placing this product again on the market are met.

This concept is relevant to economic operators that are not currently defined within the NLF, but which are increasingly important within modern industrial value chains, namely remanufacturers and refurbishers. As the concept of a substantial modification is not defined in the NLF, and is missing in those pieces of legislation where business models relating to refurbishing and remanufacturing are most prevalent, such as the Machinery Directive and Medical Device Regulations (but also the GPSD), most industry stakeholders interviewed consider this to be a **prominent legal gap**.

However, three recent EU legislative proposals (i.e. the proposal for a Machinery Regulation[91], the Regulation on General Product Safety (GPSR)[92], and the Artificial Intelligence Act[93]) all contain different proposed definitions as to what constitutes a substantial modification, while building in the concept of a change not foreseen or intended by the original manufacturer. In the Medical Device Regulation (EU) 2017/745, the issue of new economic operators that refurbish products is addressed, but there is no mention of a substantial modification. The terminology differs and instead the concept of a partial and a full refurbishment is established.

The increased complexity of value chains is also inherent to circular economy business models. However, the NLF pre-dates the significant increase in refurbishing and remanufacturing. Therefore, the NLF does not include any definitions of economic operators, such as repairers, refurbishers and remanufacturers and does not explain their role in the value chain or stipulate any obligations.

A French trade association believes 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. As an example, industry stakeholders highlighted the unsuccessful attempt to clarify the definition of **remanufacturing** in the 'Blue Guide'. These considerations have been brought to the attention of the EU legislator, which has included a definition of substantial modification in three of its recent proposals (as discussed above).

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"*.[94] 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

[90] Commission Notice — The 'Blue Guide' on the implementation of EU products rules 2016 (Text with EEA relevance): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.272.01.0001.01.ENG
[91] https://ec.europa.eu/docsroom/documents/45508
[92] https://ec.europa.eu/info/sites/default/files/proposal_for_a_regulation_on_general_product_safety.pdf
[93] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206
[94] Hojnik, J. (2016) The servitization of industry: EU law implications and challenges.

but especially post market placement, as services are typically provided once the product is in operation.

When achieving the objective of high levels of product safety or other EU policy objectives is not only dependent on manufacturers, the legislator has introduced new definitions referring to the specific roles of other economic operators in relation to achieving the policy objective, after first placing of a product on the market or its first use. Examples are the following definitions of **roles in the distribution chain**, which have been introduced in different pieces of legislation, such as the **Ecodesign Directive, the Lifts Directive** and the proposal for an **AI Act**. These go beyond the original definitions in the NLF, which mean that the NLF will have to be reviewed and potentially revised in future to remain up-to-date with individual pieces of legislation:

- '**Recycling'** and **'reuse**' in Directive 2009/125/EC on ecodesign of energy-related products. These definitions describe the process, after the placing on the market and the "first use" of the product, in which economic operators are involved:
  - for 'recycling', in the "reprocessing in a production process of waste materials for the original purpose or for other purposes but excluding energy recovery"; and
  - for 'reuse', "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".
- **'Installer**' in the Lifts Directive 2014/33/EU, which goes beyond the "the design, manufacture and placing on the market of the lift" as it extends the responsibility to the "installation" of the lift.
- **'Provider**' in Proposal COM(2021) 206 for an AI Act, which intends to correspond to the NLF definition of 'manufacturer', has a specific meaning in relation to taking the responsibility for the development of an AI system and, as such, diverges from the definition of 'provider' in Directive 2006/123/EC on services in the internal market.

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'.**

4.3.2.4 Evolution of trade and new roles in the distribution chain – the impact of the Market Surveillance Regulation

Some stakeholders welcomed the recent revision of Regulation (EU) No 765/2008 through Regulation 2019/1020, which has added the new definitions of '**fulfilment service provider**', '**information society service provider**', '**distance sales**' and '**online interface**' that attempt to capture the new roles associated with the emergence of online marketplaces. They 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 strengthening the overall coherence of the NLF model.

A European consumer association, however, expressed the view that the **definitions of 'making available on the market', 'placing on the market'** and **'conformity assessment'** have some weaknesses as they are static concepts, which would make market surveillance 'conservative' in taking into consideration online trade or the life cycle of products.[95]

[95] More than a third also considered the rules not to be adapted to new technologies (36%) and perceived legal **definitions** as **not sufficiently clear or outdated** (35%). Slightly less than a third of respondents (30%) reported that roles and obligations of different economic operators were **not appropriately defined** and that there were difficulties for consumers to report unsafe products. When asked whether the definition of a product in the GPSD should specifically encompass software

4.3.2.5 Presumption of conformity

While the GPSD has a definition of 'presumption of safety', some stakeholders regret that the NLF does not provide a definition of '**presumption of conformity**'. Both Regulation (EC) No 765/2008 and Decision No 768/2008/EC refer to the definitions of 'European standards' and 'harmonised standards' whose use is deemed to facilitate the free circulation of goods across the EU territory. This was seen as undermining coherence between the NLF, which provides a common framework for NLF-aligned sectoral legislation, and the GPSD, which provides a common framework wherever sectoral legislation for specific products is not present.

The presumption of conformity is a concept that is widely used in the context of the European "New Approach" better regulation model, which for over three decades has efficiently served the needs of manufacturers as regards the lawful placing of products on the EU single market. It has recently gained increased attention following the adoption of Regulation (EU) No 1025/2012 on European Standardisation. This Regulation codifies the main avenue for manufacturers to benefit from the presumption of conformity: namely, that the design and manufacturing of their products complies with what are termed 'harmonised standards', the titles of which have been cited in the Official Journal of the *European Union* (OJEU) to confer presumption of conformity with the legal requirements the standard aims to cover.

However, the concept of presumption of conformity has become a source of conflicting views on the role and use of harmonised standards in facilitating the demonstration of conformity for the free circulation of products across the Member States' territories.

Almost all industry stakeholders and several Member States see the presumption of conformity as a legal benefit and a key feature of the NLF, which stems from the citation of harmonised standards in the OJEU, but which has no effect if manufacturers do not activate it on a voluntary basis: in claiming the use of harmonised standards for the design and manufacturing of a product, they benefit from a free circulation of their products on the territory of all Member States. On the contrary, further to several CJEU court cases, harmonised standards are considered as "part of the EU law", because their use grants a "presumption of conformity" with NLF-aligned legislation.

4.3.3 Coherence of NLF definitions and alignment with non-NLF-aligned sectoral legislation

The coherence of definitions included in the NLF is now considered. This analysis is based on the set of definitions provided in Regulation (EC) No 765/2008 and Decision No 768/2008/EC. Where relevant, this chapter refers to Regulation (EU) 1025/2012 on European standardisation, which has codified more specifically the NLF concept of a "harmonised standard". This term has been further used as a reference in legislative work on sectoral product legislation aligned with the NLF over the past decade. This analysis examines the relevance of the NLF definitions with definitions set out in several pieces of Union harmonisation legislation.

As detailed in Chapter 4.1.1.1, the set of definitions in the NLF reflects the legislator's main concerns in 2008; namely, to improve the free circulation of goods within the single market. However, key developments in the market, such as the globalisation of trade and the growth of the digital and circular economies, have led to a gradual shift in the priorities of EU legislators. More and more, EU legislators are focused on reinforcing the level of confidence in the market in relation to core EU policy objectives (e.g. on environmental protection).

incorporated into the product, the majority of respondents agreed, even in case the software is downloaded after the product has been sold (56%). Source: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=PI_COM:Ares(2020)6973501

Within this changing context, the NLF (specifically Regulation (EC) No 765/2008 and Decision No 768/2008/EC) has provided a **satisfactory benchmark for sectoral legislation overall**, both in relation to the revision of existing EU legislation and the development of new legislation. The current set of 22 definitions was considered to be sufficiently clear and fit for purpose by most stakeholders interviewed, with some exceptions which are detailed below.

The NLF definitions have generally been satisfactorily used by the legislator over the past decade. **Industry stakeholders** are keen to stress that the development and implementation of the Alignment Package has brought greater coherence to the application of legislation and/ or in its interpretation when enforced by Member State authorities. This positive assessment of coherence between the NLF reference provisions and NLF-aligned legislation is detailed further in Chapter 4.1.1.1.

However, as highlighted in previous chapters, a **wide range of Union harmonisation laws that are applicable to products has not been aligned to the NLF**. These include 'New Approach' directives that have not been updated since the adoption of the NLF (e.g. Council Directive 92/42/EEC on hot water boilers), as well 'New Approach' directives that have been revised or repealed (e.g. Directive 2009/125/EC on ecodesign requirements). These also include other UHL, such as the WEEE Directive.

In this context, **industry associations** highlighted examples of divergence between the NLF and EU environmental legislation, in particular, during the interview programme. This was viewed as causing uncertainty and divergences in legal interpretation thereby undermining coherence, especially when such legislation is applicable alongside NLF-aligned legislation. More specifically, the following examples were provided:

- Approach to defining economic operators and, in particular, the definition of '**manufacturer**' in Directive 2009/125/EC on ecodesign of energy-related products significantly diverges from the NLF definition. The Directive does not include a definition of an 'economic operator' and the definition of a manufacturer has been extended to essentially cover any 'economic operators'. This is a source of confusion and application problems, as the ecodesign framework applies to many products covered by NLF-aligned legislation (e.g. electrical products) where the role of the manufacturer is distinct from that of the importer and distributor.
- Definitions of '**placing on the market**' and '**making available on the market**' in Directive (EU) 2019/904 on the Single Use of Plastics (SUP) diverge from the NLF, as they relate to the making available of a product "on the market of a Member State" rather than "on the Community market", which causes application problems. The impact of this divergence is explored in the box below.

Impact of divergence in definitions in Directive (EU) 2019/904 on the Single Use of Plastics.

According to the non-binding guidance in the EU's 'Blue Guide' on the implementation of EU product rules, a product is considered as having been placed on the market when it is **made available for the first time on the EU market**.

According to the narrow interpretation of the definitions of 'placing on the market' and 'making available on the market', which are set out in Article 3 of the SUP Directive, existing stocks without the relevant marking **would only be compliant if the products remain in the same Member State where they were already placed on the market** prior to the 3 July 2021.

This could result in a ban on making these products available for final distribution in another Member State after 3 July 2021. In this respect, a major European employers' federation warned that such a narrow interpretation could have a significant impact on industry and on distribution value chains, stating that it would prohibit the making available of these products for final distribution in another Member State and impose disproportionate limits on their free movement within the EU, further fragmenting the single market and the cross-border provision of goods / services.

In addition, the following considerations were raised by other stakeholders:

- **Certification bodies** consider that new economic roles, such as **online marketplaces,** are increasing, but the role of marketplaces was not defined in the NLF (at least until Regulation EU 2019/1020 was adopted, which only came into effect in July 2021).
- **Trade associations** insist that the NLF definitions should be adhered to, and that existing inconsistencies in horizontal definitions should be removed. This was also supported by at least one consumer organisation.

The multiplication of new legislative proposals that present new or amended definitions that diverge from those included in the NLF was highlighted as a significant challenge by **trade associations**. As demonstrated in the following box, this is particularly true for the concept of '**instruction for use**', which is included with slightly different definitions in COM(2021) 206 and COM(2021) 202.

'New' definitions and the fitness for purpose of the NLF: Example of 'Instructions for use'

The NLF provides common reference provisions related to the concept of instructions for use. More specifically, economic operators have an obligation to ensure that instructions and safety information are provided alongside the product in a language that can be easily understood by consumers and other end-users, considering the Member State concerned – see Article R2(7), R4(4), R5(2) of Decision 768/2008. However, no terms related to this obligation are legally defined.

The proposal for a Machinery Regulation and the proposal for an AI Act both take the step of legally defining the concept of 'instructions for use'; however, as can be seen below, the definitions differ slightly. For instance, the Machinery Regulation proposal specifies the time at which the information is provided ('when the machinery product is placed on the market or put into service'); the AI Act contains no such specification. Furthermore, the Machinery Regulation refers specifically to manufacturers, whereas the AI Act refers to a newly defined economic operator, the 'provider'. These differences, as well as others, will impact the legal certainty of all stakeholders, and particularly economic operators, as regards the provision of instructions for use if: i) a product is subject to both pieces of legislation; or ii) a product is subject to one of these laws alongside one or more NLF-aligned laws.

***Article 3(18) of the proposed Machinery Regulation**: 'Instructions for use' means the information provided by the manufacturer when the machinery product is placed on the market or put into service to inform the user of the machinery product of the intended purpose and the proper use of that machinery product as well as information on any precautions to be taken when using or installing the machinery product, including information on the safety aspects.*

***Article 3(15) of the proposed AI Act**: 'Instructions for use' means the information provided by the provider to inform the user of in particular an AI system's intended purpose and proper use, inclusive of the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.*

Lastly, reference should be made to Chapter 6. 2 – Review of whether there are any definitions missing in the NLF. In this regard, there is a close inter-relationship between the assessment of external coherence and relevance as if there are gaps in definitions within the NLF that are already addressed through other EU legislation, this may undermine the NLF's relevance and ongoing fitness for purpose.

4.4 Conclusions

Considering the overarching question guiding this Chapter – **To what extent was the NLF successful and why?** – the research findings indicate the following conclusions.

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. The impact of the NLF in relation to the first two objectives has primarily been achieved indirectly through the effective application of NLF-aligned Union harmonisation legislation. It is not possible to assess the direct impacts of the NLF towards the achievement of these objectives, as there are attribution challenges, namely that most impacts stem from the application of the underlying sectoral legislation, with the NLF playing a supportive, enabling role that underpins the body of Union harmonisation legislation and ensures that there is a maximum commonality where possible. The legal framework provided by the NLF therefore makes the application of underlying sectoral legislation smoother, and more coherent and consistent than it would otherwise be.

However, whilst the NLF has contributed towards these objectives, there remain challenges in optimising the free movement of goods, due to the many changes that have taken place in product markets in the past 15 years and the significant evolution in EU legislation to reflect these developments, notably the impact of digitalisation, new technologies and the circular economy. For example, the NLF does not yet accommodate the circular economy, although underlying sectoral and horizontal legislation is already addressing at least in part these aspects. Looking ahead, the lack of modernisation of the NLF since 2008 may make it more difficult for the NLF to continue contributing to providing a high level of protection of public interests and fostering the free movement of products.

Progress towards the achievement of the third general objective of establishing a common harmonisation framework has been significant. More specifically, alignment with the NLF's reference legal provisions and use of the NLF's common implementation mechanisms has been ensured across 16 directives and 7 regulations to date, with further alignment expected through the proposal for a Machinery Regulation.

Positive progress has also been made across the NLF's specific objectives relevant to this evaluation. However, certain implementation challenges were highlighted in many cases. More specifically:

- **Reinforcing the New Approach** (in particular, the principle of technology-neutral essential requirements). The commitment to expressing essential requirements that avoid going into technical detail has been clearly implemented across NLF-aligned legislation.
- **Supporting the consistency and coherence of EU harmonisation legislation**. Tied strongly to the third general objective, the process of aligning 23 pieces of EU legislation to the NLF has heavily strengthened the consistency and coherence of these laws. As mostly minor challenges and examples of divergence exist across the wide body of NLF-aligned legislation, it remains important to consider the cumulative impact of these minor challenges and divergences.
- **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 real 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. As such, the overall experience of the conformity assessment system, considering the performance of these aspects in combination, has been positive, with stakeholders highlighting benefits of greater simplification of compliance activities and increased fair competition between businesses. However, many stakeholders remain convinced 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.
- **Enhancing the clarity and credibility of the CE marking**. Although the CE marking regime was well established prior to 2008, the NLF's rules on the issue were considered to be clear and thus contributed to increasing industry attention on CE marking requirements, strengthening the visibility of CE marking, and ironing out minor inconsistencies between different pieces of legislation.

- 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.

Furthermore, 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.

Although the effectiveness and efficiency of the NLF are viewed positively, the performance of the NLF should not be viewed in a vacuum. As such, assessing the **NLF's coherence with the wider EU regulatory framework** is important, particularly given the significant market and regulatory developments that have occurred since the adoption of the NLF.

In this respect, although there are many pieces of legislation applicable to products that are not aligned to the NLF, 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. For instance, as highlighted in Chapter 4.3, the definition of a 'manufacturer' in Directive 2009/125/EC on ecodesign of energy-related products, and the definitions of 'placing on the market' and 'making available on the market' in Directive (EU) 2019/904 on the Single Use of Plastics.

However, in response to prominent market developments related to the digital and circular economies, **notable coherence-related challenges have emerged in the last few years**. These relate to both (prospective) NLF-aligned and non-aligned laws. More specifically, these challenges can be categorised in three groups:

- **Inclusion of more extensive conformity assessment procedures** within product legislation. Industry stakeholders, in particular, highlighted the risk of movement towards generalised third-party conformity assessment, citing the example of the proposal for a Machinery Regulation, where the updated list of high-risk machinery products includes general coverage of software and AI systems ensuring safety functions.
- **Inclusion of detailed technical specifications within product legislation**. In opposition to the principle of technological neutrality enshrined in the New Approach and the NLF, industry stakeholders highlighted examples of non-NLF-aligned product legislation that include significant technical detail in the legal text. A key example noted was the proposal for a Regulation concerning batteries and waste batteries.
- **Addition of new rules to tackle emerging challenges.** The ever-increasing digitalisation of the European market, as well as the drive for a more circular economy have brought a wide range of challenges related to, amongst others, cybersecurity, remanufacturing, servitisation, and AI. These are issues that did not exist when the NLF was adopted. As such, over the last few years, EU legislators have been developing approaches to tackle these challenges, both within the context of existing legislative provisions (e.g. in the case of the RED Delegated Acts on cybersecurity and the proposals for a Machinery Regulation and a GPSR) and in completely new areas (e.g. the proposal for an AI Act).

  Although in many cases these initiatives build on the NLF or its aligned legislation, they inevitably go beyond the rules established in the NLF, thus highlighting potential gaps in the NLF's coverage.

Furthermore, in some cases, this results in inconsistencies and incoherencies between the legal texts. A key example is the approach to defining the concept of a 'substantial modification'.

Although stakeholders generally recognised the need to tackle the emerging challenges related to the digital and circular economies, measures need to be proportionate and coherent. Moreover, a lack of coherence on these issues could lead to reduced flexibility of the legal framework to deal with market changes, increased burden and costs of compliance for industry, erosion of the principle of technological neutrality and reduced innovation and competitiveness.

5. How did the NLF make a difference?

This chapter first examines the **extent to which the NLF has added value at EU level**, before considering the extent to which the effects (i.e. outputs, results, impacts) achieved through the NLF **could have been achieved using alternative means**. More specifically, the latter point requires an assessment of: i) the situation at EU level had there not been a horizontal umbrella legal framework to ensure greater consistency and coherence across the body of Union harmonisation legislation and ii) the application of NLF-aligned sectoral legislation at the national level.

General stakeholder feedback on EU added value

Regarding perceptions of the NLF's added value, **all categories of stakeholders interviewed were positive about the NLF's role** in having strengthened coherence across the body of EU sectoral legislation for products and in avoiding unnecessary regulatory divergence.

As detailed throughout Chapter 4.1 (effectiveness and impacts), stakeholders perceive the NLF to have had a positive impact across its key objectives. More specifically, the NLF has added value through:

- The development of a **regulatory toolbox for EU regulators setting out common reference provisions** for drawing up EU legislation designed to prevent regulatory divergence, and to ensure consistency and coherence between different pieces of sectoral legislation
- **Reinforcing and building on the principles embedded in the New Approach** through the setting of general principles through the NLF applicable to the underlying body of EU sectoral legislation to ensure that the legal framework remains flexible and adaptable, namely:
  - **Technology-neutrality,** setting non-technical essential requirements, whilst leaving the detailed specifications to harmonised standards.
  - Ensuring **flexibility for manufacturers** by putting in place a common suite of conformity assessment modules and allowing conformity assessment to be based on a risk-based approach.
- **Implementation of the conformity assessment system**, the accreditation framework for CABs and the rules on the notification of CABs.
- **Strengthening the visibility of CE marking**, thereby heightening its role and importance.[96]
- **Eradicating administrative inconsistencies and minor incoherence in legislative requirements for economic operators.** For example, different sectoral legislation had slightly differing requirements and definitions in different pieces of legislation before the NLF was introduced and the process of legislative alignment through the NLF framework took place.

Through these different key features, the NLF has **contributed positively to supporting the free movement of products within the internal market** and to providing a **high level of protection of public interests**, especially in respect of product health and safety, for both workers and consumers. Although industry stakeholders in particular viewed the NLF's added value as being significant, it was acknowledged that the impacts have largely been indirect, as the NLF's impacts stem from the application of individual pieces of NLF-aligned legislation. Nonetheless, the NLF provides the common

[96] 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).

backbone to support the development of new, and revision of existing legislation, and as such, has generated significant added value.

However, a challenge in assessing the NLF's added value is that **many of its most important features were already embedded in EU legislation through the New Approach** and only some elements of the NLF were new in 2008, such as the accreditation system for notified bodies. For instance, a technology-neutral approach with harmonised standards being developed to enable manufacturers to meet the essential requirements to achieve presumption of conformity with these requirements has been in place for several decades. The core CE marking requirements already existed as these were gradually introduced in product specific legislation starting with the Low Voltage Directive in 1973[97]. However, the NLF was seen as having reinforced general principles under the New Approach, and in some cases, through the process of legislative alignment with the NLF (especially in 2014) having drawn manufacturers' attention to key requirements. For example, NLF alignment was viewed as having added value by strengthening the visibility of common CE marking arrangements across different pieces of sectoral legislation, thereby boosting awareness about the CE mark.

The **regulatory toolbox and common reference provisions** under the NLF were seen positively in the stakeholder feedback gathered through interviews, and in the responses to the targeted and public consultations. The overall feedback on the NLF's role is that EU regulators responsible for sectoral legislation have generally followed the toolbox in the NLF's first 10 years. However, concern was expressed that whilst the NLF continues to provide the basic building block for the development of Union harmonisation legislation, in recent regulatory proposals, such as the Machinery Regulation proposal, GPSR proposal and AI Act proposal, there are examples of EU regulators increasingly going beyond the key elements of the regulatory toolbox and introducing further requirements. Detailed examples in this regard are provided in Chapter 4.3.2 on external coherence.

The recent adoption of a number of regulatory proposals that go beyond the minimum core elements included in the NLF has raised questions as to whether the NLF can continue to add value to the same extent without it being **updated to reflect developments in product markets linked to digitalisation** (e.g. increased use of new technologies, cybersecurity considerations) and the **circular economy** (e.g. refurbishing and remanufacturing becoming major market segments in sectors such as machinery and medical devices). The fact that changes to products post market placement are becoming more frequent is relevant to both of these twin drivers.

Some industry stakeholders expressed 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 importance of adhering to the NLF's general principles. They pointed to some regulatory proposals as representing a perceived departure from the NLF's general principles. Examples cited were the GPSR proposal and various pieces of environmental legislation applicable to products.

A European consumer association stated that whilst the NLF has added value during the first decade of its implementation, there is a perceived question mark over its ongoing added value due to the updating and modernisation of other EU legislation that accommodates digitalisation and the circular economy. The same consumer association noted that digitalisation has had a significant impact on product markets, as connected products such as smart toys, voice assistants, thermometers, security cameras etc. have evolved from being emerging parts of the market to mainstream in the space of a few years. In the view of consumer associations, the accelerated pace of technological development has undermined the NLF's added value as it has meant the overarching framework underpinning product legislation has not kept pace and other EU sectoral and horizontal legislation has already been, or is in the process of being updated in the meantime. However, this view was not shared by industry stakeholders who were much more positive about the NLF's added value and did not view

[97] 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.

the NLF as being undermined by recent legislative developments. Rather, many industry associations interviewed expressed the view that by dint of the inherent flexibility in the regulatory toolbox, and through its technology-neutral approach, the NLF framework can already enable individual pieces of legislation to accommodate new technologies. Therefore, the NLF was seen as having continued strong added value.

A further consumer association and some industry associations interviewed commented that a distinction needs to be made between the NLF's added value in theory and practice. The NLF as a legal framework was widely viewed by stakeholders as having added value and was seen as being well-designed and underpinned by pragmatic and industry-friendly principles, which were supported by a broad spectrum of stakeholders.

However, there were some concerns that the NLF's added value has not been as great in practice at implementation level due to certain challenges. For instance, changes over time in the interpretation of the rules and procedures relating to European standardisation, a key pillar of the NLF, were seen as posing obstacles to the NLF achieving it maximum potential added value. Since the NLF was adopted in 2008, there have been both legislative developments (e.g. the adoption of Regulation 1025/2012 on European standardisation) and judicial developments (the CJEU taking jurisdiction to judge the content of harmonised standards). These in turn led to problems in the NLF's smooth and effective functioning, for instance due to the more legalistic approach to the finalisation in the development and citation of harmonised standards following the James Elliot ruling[98]. These have arguably lessened the NLF's added value in practice in recent years, since bottlenecks have emerged in the timely adoption of harmonised standards despite them being crucial to the NLF as they are the primary means by which manufacturers achieve compliance with the essential requirements and also the main benchmarks used to assess compliance by notified bodies and MSAs.

Across the body of NLF-aligned legislation, it has proven increasingly difficult to ensure that harmonised standards are cited in the OJEU on a timely basis, and therefore to keep pace with technological and scientific state-of-the-art. This was mentioned as undermining value added in practice, given that there have been particular challenges under several NLF-aligned Directives and Regulations, such as the RED, EMCD and the CPR.

There have also been challenges in ensuring adequate market surveillance, according to many stakeholders across all key groups. Whilst the latter is out of scope, given that market surveillance aspects of the 2008 legal framework have already been evaluated and the 2019 Market Surveillance Regulation only came into effect in 2022, nonetheless, as surveillance is an essential part of the NLF, it can be noted that standardisation and surveillance were the two areas where stakeholders viewed implementation as being more challenging, and therefore being obstacles to realising the NLF's full added value.

This was also commented on by a major player in the provision of conformity assessment services, who remarked that "a uniform set of rules is a prerequisite for the NLF to add value, but a uniform manner of implementation of these rules is still missing".

In contrast, industry associations stated that the problem is less that the NLF is out of date, and more that there has been a cultural shift in attitudes towards the setting of regulatory objectives and demand for more technical, risk-based assessment requirements for industry. EU regulators, under pressure from MEPs and consumer associations, have moved in the direction of a more technical, detailed approach to revising legislation. This is a delicate balancing act for EU legislators.

Further stakeholder feedback regarding how far the NLF continues to add value was that a number of stakeholders representing notified bodies in Germany pointed out that whilst the NLF is useful,

[98] Case C-613/14. The case concerned whether Harmonised Standards, which were always considered to be voluntary, have legal character.

awareness about its existence needs to be strengthened, especially among co-legislators. This would avoid amendments of a general nature being suggested and / or introduced in sectoral legislation. Whilst such amendments intend to strengthen the effectiveness of individual pieces of product legislation, these notified bodies perceived they may contribute to greater regulatory divergence, and risk undermining the NLF's added value.

Overall, the **new accreditation framework was perceived by notified bodies and national notifying authorities as having added value**. Challenges were also identified related to the implementation of the new accreditation framework for notified bodies. There were question marks as to whether even after the introduction of this framework, the services provided by notified bodies are sufficiently uniform and consistent. There also appears to be a continuing problem regarding being able to ensure that national notifying authorities can monitor and scrutinise the quality of services being offered in third countries in instances when notified bodies located within the EU-27 delegate work to subsidiaries or to third-parties located outside the EU. The trend that the 2007 impact assessment noted has increased, as notified body services sometimes need to be in physical proximity to the manufacturers, who are often located in China and elsewhere in Asia. Moreover, the fact that the accreditation framework remains non-mandatory was viewed as potentially undermining the added value, as not all notified bodies are accredited and national notification procedures for the latter are not transparent and are uneven.

EQ4.1 – What is the added value of the NLF compared to alternative options?

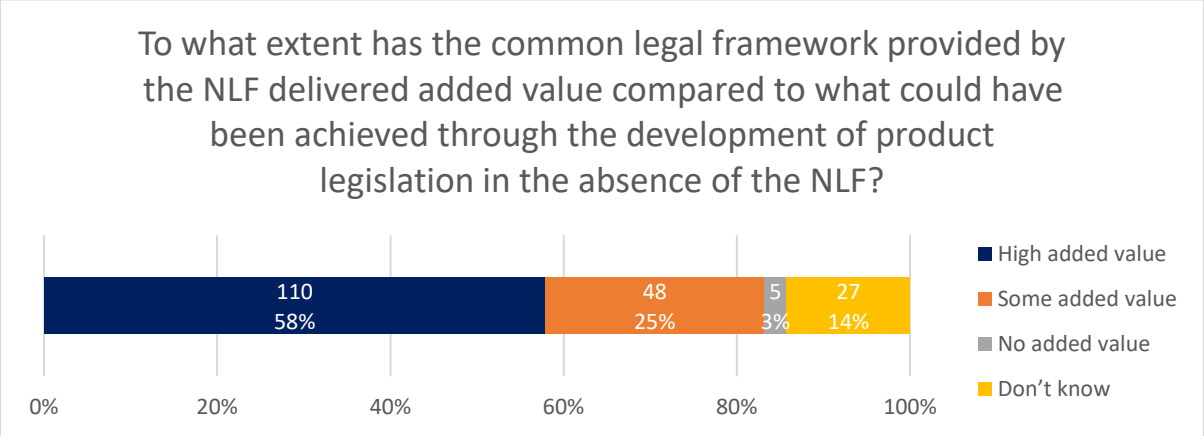
Regarding the **overall EU added value of the NLF compared to alternatives**, this can conceptually be examined in two ways through a **counterfactual assessment**:

- **At EU level,** a situation in which there was no horizontal legal framework to ensure consistency and coherence across the body of Union harmonisation legislation.
- **At national level**, a situation in which there was no horizontal approach terms of differences in the application of sectoral legislation through national transposition processes (Directives) and in the application of EU regulations.

The question as to what would have happened in **the absence of the NLF's existence at EU level** is now analysed. First, if there were no common reference provisions or regulatory toolbox available, then EU legislators would have developed more divergent legislation than has otherwise been the case. Many industry associations and individual manufacturers interviewed expressed the view that without the NLF, EU regulators would have introduced divergent requirements across sectoral legislation more commonly.

A prominent EU industry association commented that the NLF has provided common definitions and requirements for economic operators, and this has provided **stability and predictability in the regulatory regime.** This finding is validated by both the targeted and public consultation results. As illustrated below, 57.9% of respondents to the targeted consultation (110 responses out of 190) 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.

Figure 5-1: Added value of the NLF's common legal framework compared to what could have been achieved through the development of product legislation in the absence of the NLF (Question 63, N=190)



Second, regarding how individual pieces of EU product legislation would have evolved without the NLF, there are unlikely to have been major differences in requirements, as some form of coordination across the body of Union harmonisation legislation would still have been necessary. An example of this is the inclusion of some common definitions in the Blue Guide, although the latter is non-binding. However, regulatory divergence would be greater in the absence of the NLF than it would otherwise have been.

As shown in the legal mapping to assess the "before" and "after" situation in respect of NLF-aligned legislation, there would have remained minor differences and inconsistencies in the administrative requirements for economic operators, and more anomalies and a lack of full coherence in different pieces of applicable sectoral legislation. Although some of these were relatively minor, they nonetheless undermined the overall coherence of the body of EU sectoral legislation applicable to products that manufacturers and other economic operators are required to follow. The NLF has therefore prevented regulatory divergence and inconsistency in the requirements for economic operators which has added value by helping to reduce the cumulative impacts of applicable Union harmonisation legislation for products.

Turning to the second half of this evaluation question – namely, **what would be the most likely consequences of regulating products at national rather than EU level** – this is less meaningful in the case of the NLF than for individual pieces of NLF-aligned legislation. The reason for this is that, by definition, the NLF's regulatory toolbox can only be applied by EU regulators. Nevertheless, as Union harmonisation legislation is applied at Member State level, we have instead mainly considered what difference the NLF framework has made to the overall smoothness of application and the avoidance of misinterpretation of sectoral legislation.

Consideration was also given to what would have been the situation were there not a common approach to the development of Union harmonisation legislation. Stakeholders responded that were single market legislation applicable to products not developed at EU level, this would have resulted in many divergent country-specific requirements and significant market fragmentation. A French industry association gave an example in this regard that in the post-Brexit era: there are likely to be some divergent regulatory requirements in future between the EU and the UK, and "this will remind industry stakeholders what the internal market would be like without the NLF".

In terms of the situation at national level, the NLF's existence was seen as having considerably reduced national "red tape" measures, although not managing to completely eliminate them. For instance, the French regulations require that the Specific Absorption Rate (SAR) of electromagnetic fields does not

exceed 2 W/kg for placing mobile telephones on the market, which is not a requirement in the corresponding EU legislation.

EQ4.2 – What would be the most likely consequences of repealing the NLF?

No stakeholders interviewed were in favour of repealing the NLF. The majority were either in favour of retaining the NLF as it currently stands (e.g. most industry associations) or suggested that it could be made even more relevant, coherent and capable of delivering added value if it were to be modernised and updated to reflect the digital and circular economies. However, even stakeholders that expressed the view that the NLF had become outdated, such as some consumer associations, were against repealing it.

A major EU industry association commented that if the NLF were to be repealed, this would be a disaster for industry as over time, there would likely be increased divergence in the requirements for economic operators in EU sectoral legislation, with a lack of clear and common requirements for economic operators in industrial value chains.

If the NLF were to be repealed, it was seen by industry stakeholders as having adverse impacts on coherence not only in sectoral harmonisation legislation applicable to products, but also in the ability to ensure coherence in the development of horizontal legislation, as the NLF principles form an initial building block upon which legislative proposals impacting on products can be based. Reverting back to a situation prior to the NLF would be akin to the old approach, which was seen as a burdensome regulatory system with detailed legislation including the necessary technical and administrative provisions.

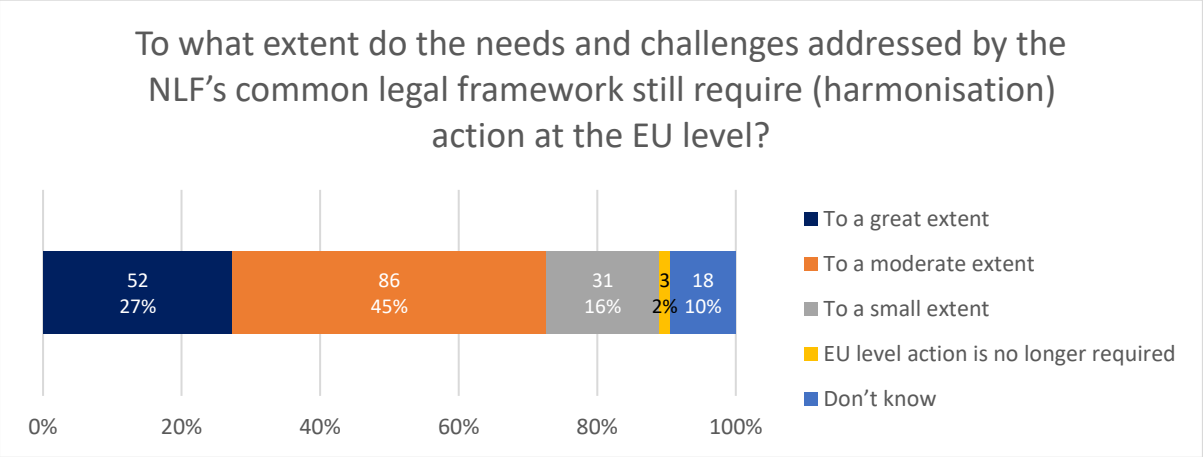
Some industry stakeholders – especially in remanufacturing and the digital sectors – expressed the view that whilst the NLF has added value, some aspects could be dealt with in alternative ways, such as including common definitions in the Blue Guide rather than changing the NLF itself. They were not in favour of repealing the NLF, however.

A major group of notified bodies in Germany stated that if the NLF were to be repealed, then there would be the absence of harmonised EU product legislation. This would lead to "regulatory chaos" and ultimately no internal market in products. In turn, this would result in higher costs for economic operators, an increase in lawsuits and a reduction in the EU's reputation as a global regulatory leader able to ensure product safety globally. Each Member State would have to develop its own national conformity assessment procedures and different legal requirements for economic operators. There would be significant costs to economic operators from having to meet regulatory requirements in 27 different MS rather than at EU level. Such a situation would considerably damage the added value stemming from Union harmonisation legislation in general and the NLF in particular since 2008.

EQ4.3 – Do the needs and challenges addressed by the NLF continue to require (harmonisation) action at EU level?

In terms of whether the **needs and challenges addressed by the NLF continue to require (harmonisation) action at EU level**, interviewed stakeholders universally agreed that, insofar as possible, the NLF should continue to provide a harmonised approach across the body of EU legislation applicable to products to prevent EU regulators from diverging in the revision of existing, and the development of new sectoral legislation. This finding was validated by the results of the targeted consultation. As illustrated below, 27.4% of stakeholders (52 of 190 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 3 respondents (1.6%) perceive that EU level action is no longer required.

Figure 5-2: Extent to which the needs and challenges addressed by the NLF's common legal framework still require (harmonisation) action at the EU level (Question 64, N=190)



Even if the NLF needs to be updated, the notion of having common definitions, common requirements for economic operators, a common suite of conformity assessment modules, etc. was strongly welcomed by industry. They argued that the **NLF needs to be reinforced, modernised and strengthened rather than repealed** in light of developments in product markets and in underlying legislation due to digitalisation and the circular economy.

5.1 Conclusions – added value

Considering the overarching question guiding this Chapter – **How did the NLF make a difference?** – the research findings indicate the following conclusions.

All stakeholders perceived the NLF to have had significant added value in preventing regulatory divergence and in providing stability and certainty. Especially appreciated by stakeholders were the common regulatory toolbox for EU regulators - which was seen as preventing regulatory divergence, a common set of definitions and common requirements for economic operators, which has added value by ensuring consistency and coherence, a technology-neutral approach to developing new, and revising existing EU regulations, which has enabled industry to retain industrial competitiveness.

In addition, the flexibility integrated into the design of a menu of different conformity assessment modules for regulators to select from, and the ability for manufacturers to then select the most appropriate conformity assessment procedure, and to use Module A (internal production control) should they so wish was perceived as adding value. This was also seen by international manufacturers as being a key competitive advantage of the European regulatory system for products.

However, whilst recognising the significant added value having been generated through the NLF, there was also a recognition that some aspects of the NLF may need to be updated in future to ensure their ongoing relevance, and in turn added value. Stakeholders across all categories perceived the NLF as having already added significant value, but recognised the need to improve its implementation so that the theory matches the practice.

There were however some differences between stakeholder categories regarding how best to ensure that the NLF's added value can be maintained and enhanced. For instance, whereas consumer associations and some industry associations advocated that the NLF needs to be modernised for it to continue to add as much value as it has during the early years of its implementation through the process of legislative alignment, many industry associations viewed the NLF as adding considerable value in its current form, without any further changes, given the inherent adaptability and flexibility through its technology-neutral approach.

However, in order to ensure that the NLF continues to generate added value, all industry stakeholders would appreciate more timely availability of harmonised standards, as these underpin the regulatory regime by 1) helping manufacturers to achieve presumption of conformity with the essential requirements in individual pieces of legislation 2) ensuring that hEN standards remain globally-leading and in keeping with international good practice in standards and 3) providing a benchmark for notified bodies and MSAs through which conformity and legal compliance can be assessed.

6. Is the NLF still relevant?

The assessment of relevance is required to consider the extent to which the general and specific objectives of the NLF, as well as its provisions, are clear to all relevant stakeholders and meet their ongoing needs. This requires not only a focus on the needs and problems as they were characterised in 2008, but also the extent to which the NLF remains fit for purpose given the significant developments in design, production, and marketing of product in the subsequent years.

The needs and problems which the NLF aimed to solve at its outset in 2008 are detailed as part of the intervention logic (Chapter 2). Here, we present an assessment of the extent to which those needs remain relevant, before examining the impact of the market developments detailed in Chapter 3 on the NLF's ongoing fitness for purpose. The relevance of definitions within the NLF is also considered.

6.1 Relevance of the original needs, objectives and provisions of the NLF

This section first analyses the ongoing relevance of the NLF's objectives through an examination of the evaluation question **'To what extent are the objectives of the NLF still appropriate today?' (EQ5.1)**. Considering the needs of the EU in 2008, it is important to consider the implementation of the New Approach. Established in 1985, the **New Approach established four fundamental principles:**[99]

i. Legislative harmonisation should be "limited to essential safety requirements (or other requirements in the general interest) with which products put on the market must conform"[100].

ii. Organisations competent in industrial standardisation should be tasked with drawing up technical product specifications.

iii. Technical specifications are not mandatory.

iv. Products manufactured in conformity with harmonised standards are presumed to conform to the essential requirements established in a law.

In this respect, the New Approach aimed to move away from prescribing detailed technical requirements in legislation and towards a technology-neutral legal framework.[101]

Although the New Approach was credited with eliminating some barriers to trade, the Commission, in its impact assessment accompanying the proposal for the NLF[102], identified certain weaknesses in the implementation of the New Approach. The requirements in sectoral legislation were criticised as divergent, burdensome, and confusing, leading to reduced credibility and confidence in the system. More specifically, the **needs and problems the NLF sought to address** included: addressing inconsistencies between different pieces of legislation; strengthening the visibility and use of the CE marking system; improving the quality and consistency of conformity assessment services provided by notified bodies; and ensuring the free movement of goods within the single market.

In general, as illustrated below, most respondents to both the targeted and public consultations **perceive that these needs and the related objectives continue to remain relevant**. The remainder of this chapter considers each need and the related NLF objectives in turn.

[99] Council Resolution 85/C 136/01 of 7 May 1985 on a new approach to technical harmonisation.
[100] A new approach to technical harmonisation, EUR-Lex summary of EU legislation.
[101] Commission Staff Working Document, Accompanying document to 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. Impact Assessment, {COM(2007) 37 final SEC(2007) 174}
[102] Commission Staff Working Document, Impact Assessment for the NLF, {COM(2007) 37 final SEC(2007) 174}

Figure 6-1: Extent to which the needs and problems that the NLF was originally designed to address remain relevant (Question 51, N=200)

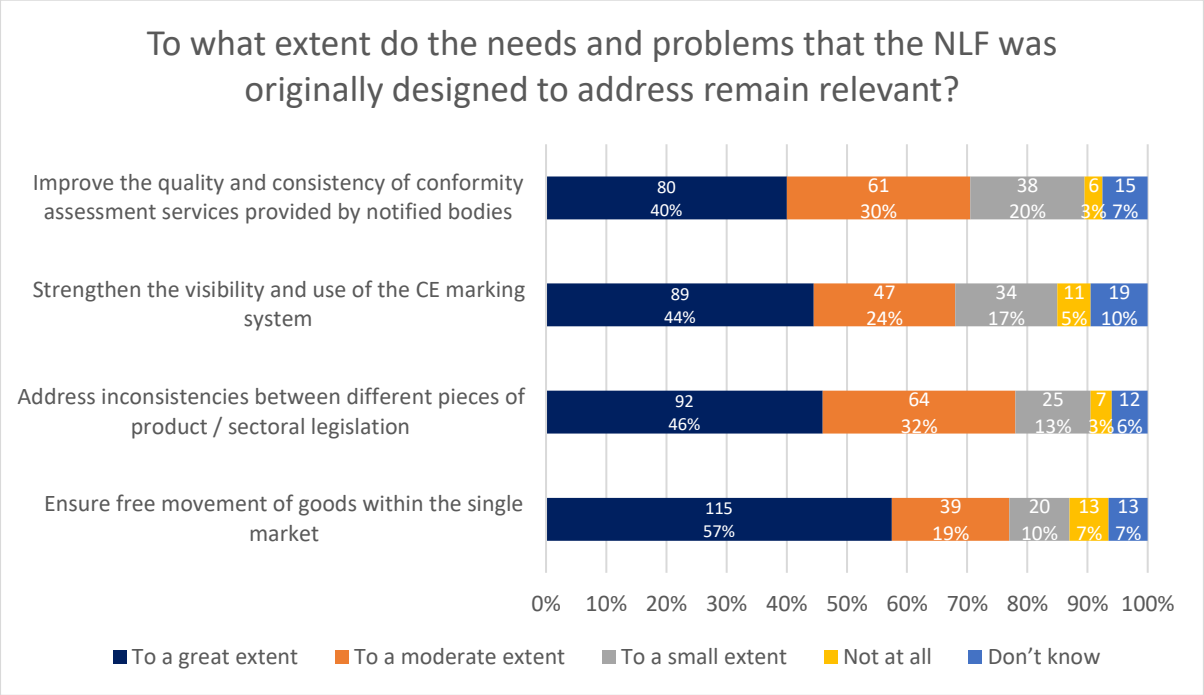
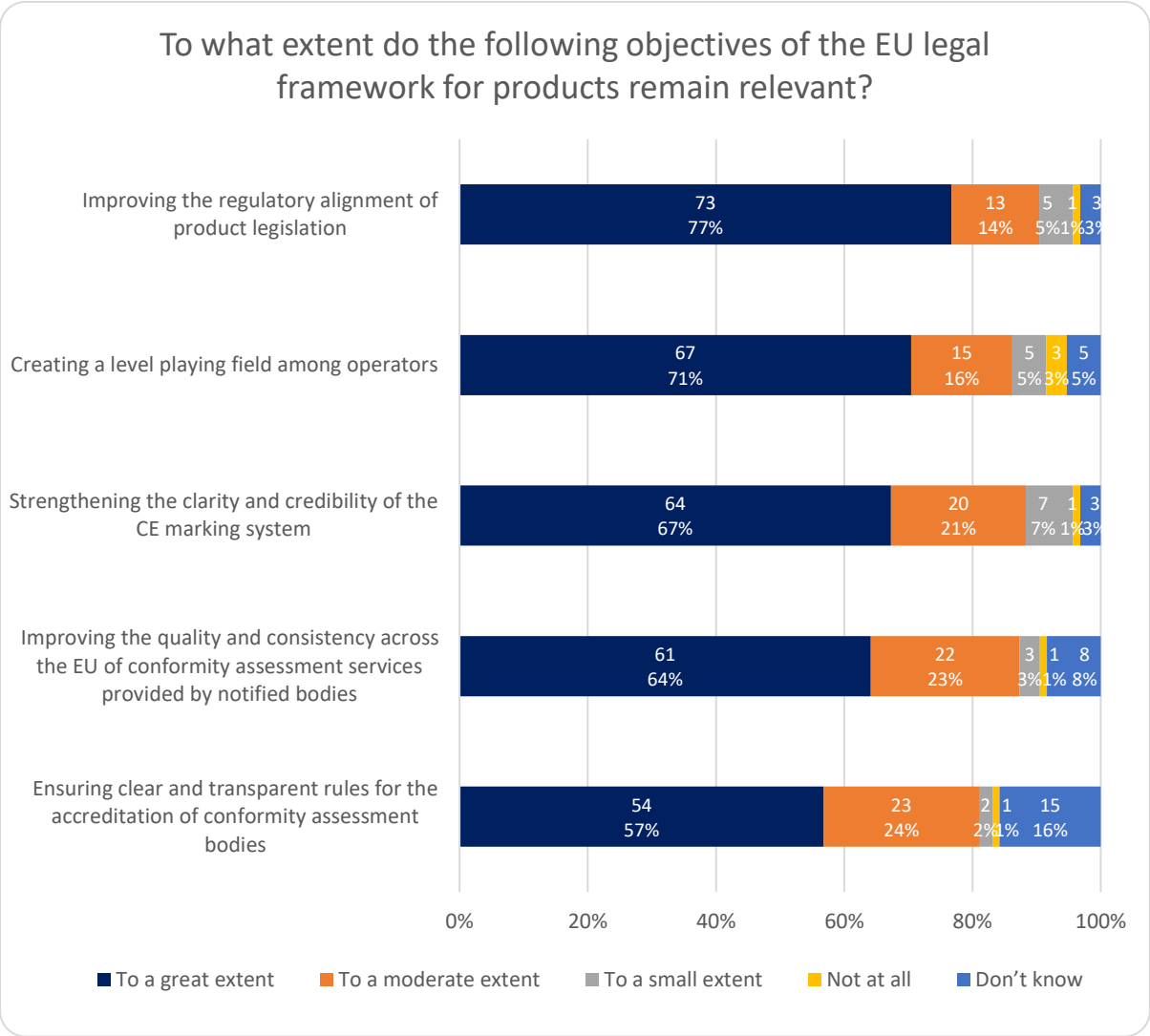


Figure 6-2: Ongoing relevance of the objectives of the EU legal framework for products (N=95)



Question asked to all respondents except citizens.

Legal inconsistency and incoherence

The first need relates to **inconsistencies between the different directives developed in the New Approach model and the related objective**. The following table provides more detail on the nature of this need.

Table 6-1: Overview of needs related to legal inconsistency and incoherence

Inconsistencies between different directives
Under the New Approach, inconsistencies and legal uncertainties increased within the legal framework as the number of applicable laws increased. For instance, different or a lack of definitions, divergent interpretations of definitions, and different procedures for demonstrating conformity led to incompatibilities, difficulties in practical application, legal uncertainty, and duplications. This impacted industry in terms of increased costs related to understanding the complex legal framework, as well as compliance and certification. It was also found to impact the ability of national authorities to implement and enforce the law, which resulted in undermining the free movement of goods.

As illustrated through the analysis of the intervention logic and the effectiveness assessment, the NLF has, both in theory and in practice, contributed to significant improvements in the consistency and harmonisation of provisions across product legislation. This has been supported by all stakeholder groups who have highlighted the value of these common requirements. However, this report also demonstrates that **inconsistencies and legal uncertainties exist** within the context of the alignment of product and sectoral legislation to the NLF (Chapter 4.1.1.1), as well as between NLF-aligned and other legislation applicable to products (i.e. non-NLF-aligned) (Chapter 4.3).

Furthermore, the **existence of such inconsistencies is only set to increase**. Current legislative proposals, as well as the anticipated impact of market and production trends on supply and value chains, will introduce new legal definitions and obligations that are relevant across multiple (if not all) Union product and sectoral legislation. The assessment of the new needs facing the Union legal framework for products and their implications are examined below.

On this basis, **all relevant stakeholders consider the need to pursue the removal of inconsistencies and legal uncertainties as still valid to the NLF**. This is particularly true considering all three general objectives, as well as the specific objective of supporting the consistency and coherence of EU harmonisation legislation.

Challenges relating to the conformity assessment process and rules related to notified bodies

The second need identified prior to the adoption of the NLF relates to a **lack of confidence in the quality and competence of notified bodies and challenges related to the process of notification**. The following table provides more detail on the components of this need.

Table 6-2: Overview of needs related to conformity assessment and notified bodies

Lack of confidence in notified bodies and in the whole notification process
Uneven level of conformity assessment services provided by notified bodies. Different approaches existed within a single piece of legislation to assessing conformity, as well as interpreting essential product and procedural requirements. This resulted in forum shopping for conformity assessment bodies based, for instance, on low prices or less rigorous services. The assessed impacts of this were unfair competition across notified bodies, downward market pressures on price and quality of services provided by notified bodies, and unfair competition between economic operators. Thus, confidence in the sector was undermined. Further potential indirect impacts related to reduced consumer and environmental protection were raised.
Lack of transparency and different approaches in the competence assessment and monitoring of notified bodies. The approaches to assessing and monitoring notified bodies, as well as the relationship between accreditation and notification, differed across Member States. Furthermore, limited information sharing and coordination practices existed between Member States, as well as with the Commission, on these issues. This impacted the competence of notified bodies and undermined the system.
Unnecessary burdensome requirements in the notification procedure. Notification procedures were time-consuming and burdensome under the New Approach due to the need for complicated bureaucratic paper processes. In addition, the Commission were required to publish a list of notified bodies in the OJEU once a year; this list quickly became outdated. Limited non-legal solutions were implemented but they did not fully address the challenges (e.g. establishment of EA and NANDO-Input).

Similarly to the inconsistency challenges discussed above, the NLF has positively impacted the implementation of the conformity assessment system and the process for notification of conformity

assessment bodies. From a logical perspective, 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.

This is confirmed in practice, as detailed further in Chapter 4.1.1.2. Overall, **stakeholders from all relevant groups have noted that the accreditation system functions well and ensures the competence of the notified bodies**. In particular, these stakeholders highlighted improved mutual confidence in test reports and certificates of conformity for cross-border trade, as well as simplifications in the process for notification and designation. Moreover, the transparency of Member State approaches to accreditation and monitoring have improved, including through the provision of legal standing to EA.

However, **stakeholders representing industry and consumer associations, as well as conformity assessment stakeholders have highlighted a few persisting challenges**. For example, as a result of subsidiarity considerations, the NLF did not include a requirement for all notified bodies to be accredited. As a result, consumer associations noted that this negatively impacts trust in the competence of notified bodies, while industry stakeholders believe this continues to permit uneven quality of conformity assessment services across the EU.

Although the situation has undoubtedly improved, **all stakeholder groups believe aspects of this need still remain relevant**. This is particularly true considering the vital role the conformity assessment process plays across the whole legal framework and thus all three general objectives, as well the specific objective on strengthening the quality of conformity assessment services through improved accreditation of notified bodies remain relevant.

Challenges to CE marking

The third need covered **CE marking-related challenges**; more specifically, considerations of its purpose, interpretation, and credibility. The following table provides more detail on the components of this need at the time of the NLF's adoption and the continuing relevance of the related general and specific objectives.

Table 6-3: Overview of needs related to the CE marking

Misunderstanding of the value and role of CE marking
Misunderstanding of CE marking. Although CE marking was not designed to provide information to consumers, its visibility increased to the extent that its purpose was misunderstood. Stakeholders, particularly consumers, were found to have a poor understanding of the role of CE marking (e.g. considering it as an indicator of origin or of third-party testing and approval). In addition, it was placed alongside other marks, which could have similar meanings, and were also unclear to consumers. Overall, this could impact consumer purchasing decisions; consumers may buy non-compliant and potentially dangerous products, or purchase products based on incorrect perceptions. **Lack of credibility of CE marking**. Although positively perceived internationally, internal confidence in CE marking was found to be lower. Weaknesses in CE marking undermined the whole system of product conformity. As such, the existence of products bearing CE marking that were found to be non-compliant impacts confidence in industry more widely. Furthermore, CE marking was used for other purposes related to non-compliant products with impunity (e.g. commercial purposes without being linked to a specific product).

To clarify the purpose of the CE marking and enhance its credibility, the NLF included specific provisions on the principles of CE marking in Regulation (EC) No 765/2008, as well as reference provisions on the principles and the rules and conditions for affixing the CE marking within Annex I to Decision No 768/2008/EC, to be incorporated into specific Union harmonisation legislation. As a result, **stakeholders across all groups consider that the CE marking continues to have a strong reputation globally and delivers significant value as an attestation of conformity**. Moreover, the legal mapping indicates that, with a few exceptions, the reference provisions on CE marking have been incorporated into specific product laws with minimal changes.

However, consumer representatives and other stakeholders have highlighted that, to some extent, the **marking continues to be misleading and confused as a quality or certification marking by consumers**, rather than a compliance marking. Furthermore, industry stakeholders, particularly in the ICT sectors, noted that there is an ongoing global regulatory trend of affixing marks or information on products, which is resulting in costs for economic operators, as detailed further in Chapter 4.1.1.3. As discussed in Chapter 4.2.5.1, stakeholders across all groups have highlighted the opportunities afforded by digitalisation in this respect; namely, the possibility of providing the CE marking and / or other relevant product compliance or user information digitally rather than physically on or with the product.

As the CE marking continues to be a vital component of the NLF, as well as a strong indicator of EU competitiveness globally, industry stakeholders have highlighted the **continuing importance of ensuring its reputation is maintained and its meaning is clear**. This is particularly true considering its role in achieving the general objective of fostering the free movement of products within the single market and the specific objective of ensuring a clear meaning and enhanced credibility of the CE marking.

6.2 Review of whether there are any definitions missing in the NLF

Regarding the question as to **whether there are any definitions missing in the NLF,** the NLF's ongoing fitness for purpose was examined. There are arguably definitions missing if the NLF is to remain up-to-date and to accommodate more recent market developments driven by digitalisation, technological changes, and the circular economy. For instance:

- Stakeholders interviewed pointed to the fact that whilst the NLF provides a definition of the different economic operators within its scope, the 2008 legal framework is **restricted to manufacturers, importers, distributors, and authorised representatives.**
- In contrast, modern value chains are characterised by an increasing number of different types of economic operators, such as **software and AI developers, ancillary digital service and data providers, repairers, refurbishers, and remanufacturers**, etc. Moreover, through the 2019 Market Surveillance Regulation, as explained below, there are a series of different economic operators in the online space, an increasing conduit for product distribution, that now have regulatory responsibilities, which was not the case in the 2008 NLF.
- Linked to the circular economy, and the role of repairers, refurbishers, and remanufacturers mentioned above, **the concept of a substantial modification of a product is a gap in the NLF** (a detailed assessment was provided in Chapter 4.3.2.3 as this also affects external coherence as other EU legislation has already been updated).
- This raises the question as to whether additional definitions are needed to address this perceived weakness in the regulatory framework and reflect the involvement in modern value chains of a broad variety of economic operators.
- Some stakeholders believe that a weakness in the current NLF is that it **does not take into account the product lifecycle and product use**, whereas existing definitions in other EU legislation

sometimes do, notably those on the **use of products** in the workplace, the provision of services, or environmental legislation concerning the use of products and their recycling. For instance:

- The concept of the "**lifecycle**" of a product is defined in the Ecodesign 2009/125 Directive, but with the bias of a use that has an "environmental aspect" and could cause an "environmental impact". The same applies to the generic concepts of "**product design**", "**material**", and "**recycling**".
- Another example is the concept of a "**service**", which is defined in Directive 2006/123/EC on services in the internal market. It is defined in relation to the **"provider"** and "**recipient",** but without connection to responsibilities for the product that the provision of such a service may involve.

Future definitions may also clarify the thin borderline between what is public and private, what is professional, commercial or for own use, depending on the degree of involvement of the end-user in the achievement of the policy objective. This has been either deliberately ignored under the motto that safety is for all (but not of responsibility to the end-user), or combined with the restricted scope of the specific legislation. For instance, neither the GPSD nor the proposal for the GPSR provide a definition of "**consumer**", although it is referred to in the definition of a "safe product", the main purpose of the draft Regulation.

- Similarly, the definition of a "**product**" in the GPSR proposal is compatible with Regulation (EC) No 765/2008 of the NLF, but somehow more restrictive, as it excludes B2B products (if the product is not used by consumers).
- The Directive on safety of workers at work defines "**exposed worker**" and **"operator"** of a machine, under the responsibility of the employer, another indirect end-user.

6.3 Impact of technological, scientific, environmental, and social developments on the relevance of the NLF

Building on the information presented in Chapter 3.2, this section presents a response to the evaluation question **'To what extent has the NLF followed / allowed for technological, scientific, environmental, and social development?' (EQ5.2)**. To achieve this, it examines the impact of recent market and industry developments related to the digital and circular economies on the NLF's provisions and ongoing relevance.

6.3.1 Impact of digitalisation and new technologies

The ever-increasing digitalisation of the European market has brought a wide range of challenges related to, amongst other issues, cybersecurity, servitisation, and AI. As these issues did not exist when the NLF was adopted, many of them bring additional challenges for the NLF. This chapter examines the impact of these challenges on the NLF's ongoing fitness for purpose.

The NLF is currently based on a **'static' notion of a product,** which means that product legislation applies to products at the moment they are placed on the European market. The legislation is therefore applicable at the point of placement on the market, and relates to the first use of the product by its intended end-user. However, this makes it more difficult to address the fact that an increasing share of products may be subject to changes during their lifecycle (i.e. after their introduction into the market).

It has therefore been argued that a more **'dynamic notion' of a product** is needed to reflect the changing reality in terms of how products evolve post-market placement, for example due to software updates and upgrades, and products where additional standalone software may be uploaded which could change their characteristics, capabilities, and potential usage. Further complexity is added where: i) this software is provided by an economic operator not working in conjunction with the final

manufacturer of the product; and ii) this software implements Artificial Intelligence (AI), which can, in the case of machine learning applications, change the nature and actions of a product based on inputs and data collected after being placed on the market.

In this respect, the targeted consultation provided mixed feedback, with 46% of respondents (92 of 200) stating that the notions of 'making available on the market' and 'placing on the market' remain fully clear and appropriate in this context; in response to the same question, 29% of respondents (78) found these notions to only be partially clear and appropriate.

Consequently, recent technological developments have also brought the definition of what is a 'product' into question. There is an increasing blurring between the physical characteristics of products and hardware, and the fact software and applications are increasingly embedded within products.

There is also a debate as to the **extent of responsibilities of different economic operators within the value chain** and the nature of these obligations and responsibilities. In response to the targeted consultation, 51.5% (103 of 200 respondents) reported that the definitions of different economic operators were only partially clear and appropriate when considering new models of production and value chain complexity.

The question as to who is responsible for legal compliance relating to the updating and upgrading of the final product through software and firmware updates post-market placement is under consideration. There remain ambiguities in terms of whether responsibility lies with the manufacturer of the final physical product after the re-use of previous product components, for example, or whether the software provider is responsible for maintaining smart products and keeping these secure and well-functioning. This raises issues as to how the NLF should be adapted in future to reflect the fact that, for a product to remain compliant with the essential requirements, regular updates to software are needed. The extent to which the NLF is sufficiently flexible to make these adaptations is a key question. The proposed regulatory changes outlined in the proposal for a Machinery Regulation provide a good example as to the need to review whether changes are necessary not only in individual pieces of Union harmonisation legislation but in the common horizontal framework provided by the NLF.

Moreover, on occasions, the effective functioning of products, including their ability to protect the health and safety of consumers, may increasingly be **dependent on the provision and implementation of regular software updates**. The connectivity of new products may make software updates more relevant given increased cybersecurity issues and the increasing difficulties to establish the source of damages, with the EU Mid-Term Review stating that "faulty sensors, vulnerable software or unstable connectivity may make it difficult to determine who is technically and legally responsible for any ensuing damage".[103,104]

This added complexity raises issues relating to the **challenges of the identification of safety risks across the product lifecycle,** and whether the responsibility for product safety is limited to a product's placement on the European market or into service, or whether this should extend beyond the traditional lifecycle of a product. It also raises an issue as to how much responsibility different economic operators in the value chain should assume, and for what duration. The question as to how long final manufacturers should be responsible post-market placement in terms of ensuring regular software and firmware updates being provided to the end user could be explored. This issue can be complicated by: i) the fact that software updates may be developed by third parties rather than the manufacturer; and ii) differing intended product lifetimes across product categories (e.g. literature has placed user's expected product lifetimes for computers at 2-5 years[105], whereas research on the

[103] González Fuster, G. & Jasmontaite, L. (2020). Cybersecurity Regulation in the European Union: The Digital, the Critical and Fundamental Rights. 10.1007/978-3-030-29053-5_5.
[104] National Cyber Security Centre. (2019). Smart devices: Using them safely in your home.
[105] DEFRA. (2011). Public understanding of product lifetimes and durability.

EMCD and RED found that test and measurement equipment has much longer intended lifetimes of at least 10 years[106]).

Beyond issues related to **product modifications following placement on the market**, a range of challenges relating to the **inter-relationship between product safety and security** are being posed by the adoption of AI technologies and the Internet of Things (IoT). AI is currently being used in multiple fields, ranging from industrial applications to health applications to tackling the environmental crisis, as well as to addressing cybersecurity concerns. Moreover, the industrial and consumer IoT has driven the take-up of these new technologies, which are becoming smarter through the increasing integration of such technologies within hardware, software, systems and applications.

Although these applications are, and will continue to, bring significant benefits across these areas and to product safety more generally, they can also introduce new product safety risks and enhance existing risks. These risks can, among other issues, be the result of: using biased, poor quality data; insufficient availability of good data; flaws in system design; poor training and testing of algorithms and models; or specific characteristics of AI applications, such as the ability to continue learning while in use. These risks can subsequently result in material and / or non-material harm. Considering material harm, for instance, an AI-driven robotic application could malfunction, causing physical injury. Furthermore, smart products have been shown to facilitate domestic abuse.[107] Non-material risks and harm could include: loss of privacy or other fundamental right limitations; mental health impacts; or discrimination in access to products and services. For instance, individuals with speech impairments have faced issues using voice assistants built into smart speakers.[108]

Even though the approach to the NLF and product legislation is **technology-neutral, these technological developments bring regulatory challenges relevant to this framework**. These challenges can materialise across all elements of the regulatory regime, including product safety and liability-related legislation, market surveillance regimes, standardisation, accreditation, and conformity assessment. More specifically, challenges exist in relation to: the current definition of products; the notion of placing products on the market; and who is liable when harm occurs. Amongst other things, this raises questions of how the regulatory regime considers: i) the extent to which products include software; ii) whether software is sold with the product or downloaded at a later date; iii) changes in products linked to software updates and the maintenance of AI systems; iv) how liability is determined when AI is involved in an incident; and v) transparency of data and explainability of algorithms.

Furthermore, other stakeholders are negatively impacted by these challenges. Industry and conformity assessment bodies lack legal certainty on the application of legislation to AI-driven consumer products and significant challenges exist for MSAs, as they often lack specific knowledge and authority to test and challenge AI systems in consumer products. Moreover, although the growth of e-commerce and online marketplaces is driving growth in consumer product sales, it is also facilitating the prevalence of non-compliant (and unsafe) products on the market.[109]

In response, the **Commission has started implementing measures in specific product legislation and other legislative proposals designed to tackle some of these issues**. For instance, considering specific product legislation, following a 2019 impact assessment on the topic, the Commission published a Delegated Act on cybersecurity within the context of the Radio Equipment Directive;[110] and the

[106] Study supporting the evaluation of the EMCD for DG GROW, and an impact assessment on Increased Protection of Internet-Connected Radio Equipment and Wearable Radio Equipment for DG GROW.
[107] CSES, (2020), Framing the Nature and Scale of Cyber Security Vulnerabilities within the Current consumer Internet of Things (IoT) Landscape, study for DCMS – included a case study on ICT-facilitated abuse.
[108] https://www.voicesummit.ai/blog/how-voice-tech-is-slowly-including-people-with-speech-impediments
[109] European Commission, (2020), Combined Evaluation Roadmap/Inception Impact Assessment: GPSD and AI.
[110] https://ec.europa.eu/growth/system/files/2021-10/C_2021_7672_F1_COMMISSION_DELEGATED_REGULATION_EN_V10_P1_1428769.PDF

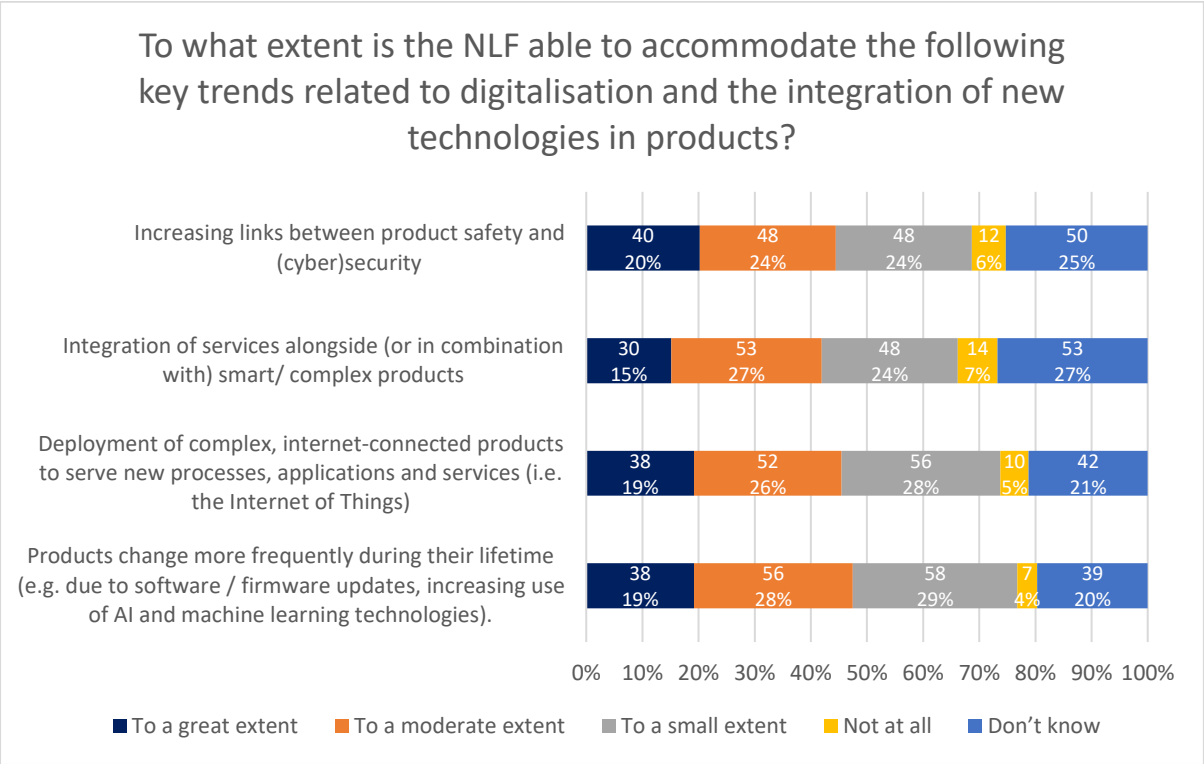
proposal for a Machinery Regulation includes provisions related to ensuring the safety of emerging technologies. In addition, the proposal for an AI Act explicitly focuses on addressing the legal and ethical challenges posed by AI and heavily references the NLF model.

Stakeholder perceptions on fitness for purpose issues related to the digital economy

First and foremost, the majority of stakeholders interviewed consider these **market trends to be relevant to the ongoing fitness for purpose of the NLF**. For instance, on the issue of changes post market placement, 60% of respondents to the evaluation roadmap acknowledged in some manner that products "*are increasingly digital and being frequently updated or upgraded after they have been put into service, or potentially further changing when AI-enabled*".

However, **mixed views on whether the NLF is able to fully accommodate these digital developments have been put forward**. This is illustrated by the results of the targeted consultation. Relatively few stakeholders (between 15.2% and 20.2%, depending on the trend in question) 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 (Figure 6-3). Stakeholders were most likely to consider the NLF able to accommodate the key trends identified to a small or moderate extent, or to answer that they don't know.

Figure 6-3: Extent to which the NLF is able to accommodate key trends related to digitalisation and the integration of new technologies in products (Question 53, N=198)



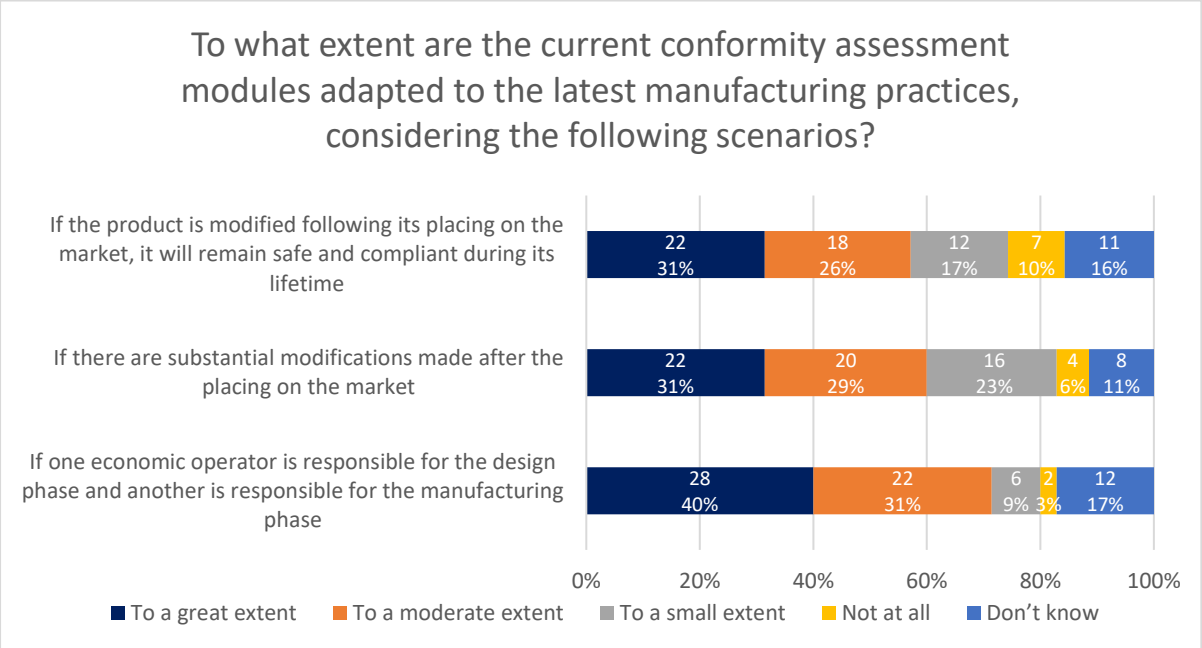
From the interviews with stakeholders, it is clear that the views on whether the NLF is able to accommodate digital economy trends generally fall into three groups: i) certain stakeholders believe the framework remains sufficient, citing the technological neutrality of the NLF as an enabler of this; ii) certain stakeholders agree that legal framework remains sufficient in its current form, but would welcome additional clarification; and iii) certain stakeholders argue that the NLF is not sufficient in its current form to accommodate the digital transition.

In particular, 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.

As detailed in Chapter 4.1.1.2, the current suite of conformity assessment modules and the conformity assessment procedures are generally considered by many stakeholders to be functioning well. However, through the targeted consultation, economic operators, industry associations and national competent authorities reported **mixed views on the extent to which the current conformity assessment modules were appropriate in light of modern manufacturing practices**. While most respondents perceive the modules to be adapted to a great or moderate extent for scenarios where one economic operator is responsible for the design phase and another is responsible for the manufacturing phase (71.4%, 50 of 70 responses), the balance between positive and negative responses were more even for the other two scenarios:

- **Substantial modifications:** When there are substantial modifications made to a product after its placement on the market, 28.6% of stakeholders (20 responses) considered the NLF to be either not at all adapted or only adapted to a small extent to this scenario. However, 60% (42 responses) perceived the NLF to be adapted to either a great or moderate extent.
- **Product changes post-market placement:** 57.1% of stakeholders (40 responses) considered that the conformity assessment modules were adapted to a great or moderate extent to ensure the safety and compliance of a product that is modified following its placement on the market. However, 27.1% (19 responses) perceived there to be significant issues in this regard, reporting either no or limited coverage of this scenario in the current modules.

Figure 6-4: Extent to which the current conformity assessment modules are adapted to the latest manufacturing practices (Question 56, N=70)



Question 56 was asked to: economic operators, industry associations, and national competent authorities.

Considering the challenges posed by digital technologies, in particular the ability of products to change more frequently post market placement, certification stakeholders have suggested the possibility of introducing a new component within the suite of conformity assessment modules. More specifically,

it was suggested that a new module or aspect of the regime could require ongoing validation and verification to cover situations where products change over their lifecycle.

Furthermore, stakeholders from all groups noted that **coherence with other EU legislative initiatives should be of paramount importance and proactively managed by the Commission**. In this respect, ensuring alignment between the NLF, the proposal for an AI Act and the proposal for a GPSR were noted as particularly relevant considering these initiatives are led by three different Commission DGs, but intend to ensure alignment.

6.3.2 Impact of the circular economy

As the NLF did not explicitly include a circular economy dimension when it was drawn up in 2008, the case study considers how far the NLF is sufficiently flexible to accommodate the circular economy. The baseline situation is that:

- The NLF does not explicitly mention the circular economy or circular economy actors, such as refurbishers, remanufacturers and reprocessors in the common definitions of economic operators.
- Currently, the NLF does not provide a definition as to what constitutes a new product, although in underlying legislation and in the Blue Guide, the concept of a 'substantial modification' has been outlined. Such a modification means that a product undergoing substantive refurbishment, reprocessing and / or remanufacturing, constitutes a new product requiring placement on the European market and for all relevant conformity assessment procedures to be followed.

The extent to which the absence of explicit references to the circular economy in the NLF raises questions as to the NLF's fitness for purpose is considered in the case study.

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[111] (SPI) extending the requirements in the current Ecodesign Directive[112] to include not only energy efficiency, but also materials efficiency.

The circular economy *"has emerged as an alternative industrial paradigm to the traditional 'take, make, dispose' economic model, with the aim to promote more sustainable resource consumption patterns and production processes"*[113]. As such, it is a central component of the EU's industrial strategy[114] to implement the green and digital transitions.

Remanufacturing: Remanufacturing has been defined by the European Remanufacturing Network as "*returning a product to at least its original performance with a warranty equivalent or better than that of the newly manufactured product*".[115] There are currently different types of practices related to 'remanufacturing':[116]

[111] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12567-Sustainable-products-initiative_en
[112] Directive 2009/125/EC
[113] Circular business models in the European manufacturing industry: A multiple case study analysis - Andrea Urbinatia, Paolo Rosa et al.
https://www.sciencedirect.com/science/article/pii/S0959652620330092
[114] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en
[115] European Remanufacturing Network. (2015). Remanufacturing Market Study.
[116] All-Party Parliamentary Sustainable Resource Group and the All-Party Parliamentary Manufacturing Group. (2014). Triple Win – The Economic, Social and Environmental Case for Remanufacturing.

Table 6-4: Overview of key economic roles related to the circular economy

Practice	Description
Recondition	The potential adjustment to components bringing an item back to working order, though not necessarily to an 'as new' state.
Refurbish	The largely aesthetic improvement of a product which may involve making it look like new, with limited improvements to functionality.
Repair	Fixing a fault but with no guarantee on the product as a whole.
Recycle	Extracting a product's raw materials to use in new products. This is a good option for products which are easily constructed and have minimal numbers of components

Source: *Triple Win – The Economic, Social and Environmental Case for Remanufacturing*

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. 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 equipment, and rail, among others.

As manufacturing is responsible for about 11% of the waste generated in EU-27 countries,[117] 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.[118]

Refurbishing: The refurbishment of equipment to be reconditioned to 'as new' status is common in some industries, such as medical devices and equipment. Refurbishment has been defined by COCIR, the EU medical devices and equipment industry association as: *"a systematic process that ensures the safety and effectiveness of medical equipment without significantly changing the equipment's or system's performance, safety specifications and/or changing intended use"*[119].

The good practice guide points out that *"compared to new equipment, used equipment may bear additional risks (e.g. contamination, worn parts and misalignment) for the patient, user, third parties and the environment if not adequately maintained. The target of the refurbishment process is to restore such used equipment to its original condition (as good as when it was new)".* However, these risks must be mitigated by refurbishers as they increasingly have legal responsibility for ensuring their product is safe if it has been subject to a substantial modification made by a refurbisher.

Reprocessors: Reprocessors are manufacturers that take a product intended for single use and restore it to its original condition so that it can be reused for multiple uses. There are examples of reprocessors in the medical devices sector, such as surgical forceps, scalpels, biopsy instruments and urinary catheters.[120] If single-use devices (SUDs) are reprocessed and made safe for use, this saves waste, reduces landfill and can be more economical (e.g. for public healthcare services). Insofar as a used product is returned to the original manufacturer's performance specification, reprocessing is similar to remanufacturing.

Repairers: Repairers play a crucial role in the circular economy, repairing products, enabling their intended lifecycle to be maintained or extended. Unlike remanufacturers and refurbishers, repairers generally provide services to repair used products and do not commonly make substantial modifications to products.

[117] Eurostat. (2021). Waste generation by economic activities and households, 2018 (% share of total waste), 30-04-2021.
[118] European Commission. (2020). Innovation Union.
[119] https://www.cocir.org/fileadmin/6.1_Initiatives_Refurbishment/Good_Refurbishment_Practice_V2.pdf
[120] https://www.medicaldevice-developments.com/features/featuregood-as-new---reprocessing-single-use-devices-5663983/

According to an individual firm in the repair sector, there is a general lack of understanding of "refurbishing" activities, resulting in challenges in arriving at a commonly accepted definition. For instance, the SPI proposal has a definition for consideration that isn't at all a reflection of what refurbishment is. Refurbishment should be understood as the functional or aesthetical maintenance of a device, which sometimes (but not always) implies repair. Industry representatives stated that do not modify the device in any way, and certainly not its functionality as intended by the original manufacturer. By extension, refurbishers cannot be considered to be final manufacturers. However, it has been the case on occasion that public authorities consider reselling under a different brand name makes an operator become a "manufacturer".

Fitness for purpose of the NLF in light of circular economy developments

An assessment of the NLF's fitness for purpose to accommodate the circular economy was carried out.

Extent of regulatory certainty: Despite remanufacturing becoming a growing industry and linchpin of the circular economy, **the rules in guaranteeing the safety and compliance of remanufactured goods are perceived by stakeholders as being unclear**. However, stakeholders have different views as to whether the NLF is the appropriate place to address the growing role of the circular economy within the European economy.

The different components that may be re-utilised in the manufacturing process may cause issues for both producers and market surveillance authorities (MSAs) when determining whether a re-manufactured product is an existing product, or a new product that needs to go through conformity assessment procedures. Thus, the current legal framework may deter the development of remanufactured products by creating uncertainty or by adding additional administrative burdens on producers or MSAs. This legal ambiguity represents a barrier to this form of production, and to the flow of remanufactured products within the internal market.

Impact of recent EU legislation and regulatory proposals on NLF's ongoing fitness for purpose: Three recent legislative developments discussed the concept of a **substantial modification**, with three differing definitions, but based on broadly similar approaches. Specifically, the ways of defining the concept appear to have various impacts on the level of responsibility of the original manufacturer:

- **Machinery Regulation** proposal discusses a modification "not foreseen by the manufacturer" and that affects the safety, thereby ensuring a link with safety;
- **AI Act** proposal discusses a modification "which affects the compliance of the AI system with the requirements" for high-risk AI systems or "results in a modification to the intended purpose for which the AI system has been assessed", thereby linking any change with any impact on the machine output (meanwhile, in a way similar to machinery, documented and validated pre-determined changes are not considered substantial modification); and
- **GPSR** proposal discusses a modification that "changes the intended functions, type or performance of the product in a manner which was not foreseen in the initial risk assessment of the product", thereby linking particular types of changes with an impact on many aspects, not only safety.

While industry stakeholders generally acknowledge that it is difficult to define a substantial modification in a common way across all products and sectors, as there tends to be some product-specific variations, they noted with concern that the European Commission has proposed three different definitions in the recent legislative proposals described above. Moreover, none of these proposals refer to the (non-legally binding) definition of the 'Blue Guide' 2016[121], which qualifies the

[121] "Substantial modification" in the 'Blue Guide' 26.7.2016, C272/16 is characterised as "a product, which has been subject to important changes or overhaul aiming to modify its original performance, purpose or type after it has been put into

resulting state of a substantially modified product as a "new" product; to avoid jeopardising the development of the circular economy. This finding is supported by the targeted consultation, where 51.5% of respondents (103 of 200) stated that the obligations and administrative requirements for economic operators (re)placing products on the market that involved substantial modifications were only partially clear and appropriate, while a further 18.5% (37 respondents) stated the rules were not clear at all.

Although the definition of substantial modification in the draft GPSR is considered to be the least problematic, it could conflict with the text of Directive 2009/104 on work equipment used by employees in the workplace; as also highlighted by industry stakeholders. More specifically, Directive 2009/104 includes repairs and modifications in the definition of "use of work equipment"[122], without any reference to the manufacturer or his intended use for the product, contrary to the above-mentioned proposals of definitions for "substantial modification". As such, the responsibility for safety issues related to work equipment (i.e. machinery) under Directive 2009/104 sit with the owner of that machinery (i.e. the employer), rather than the manufacturer. The definitions recently proposed by the Commission are more far-reaching. According to certain industry stakeholders, this is an example where the broader regulatory framework should be considered before amending some of its key concepts in the NLF, such as a substantial modification, to ensure a common and consistent approach.

The **Product Liability Directive (PLD)** is presently subject to an impact assessment ahead of its likely updating and modernisation. One of the key drivers of a legislative recasting to update the Directive is the need to address the circular economy. This would involve updating the definition of a product to include products having undergone a substantial modification (which would be considered as a new product) and updating the definition of a producer such as to include refurbishers and remanufacturers as economic operators within the Directive's scope, recognising their growing importance in today's industrial value chains. These changes would however be designed to reflect changes already proposed to underlying legislation mentioned in the regulatory proposals outlined above.

Additionally, from a repairers' perspective, the **Digital Product Passport (DPP)** within the SPI proposal[123] is a potentially interesting initiative. Repairers could be liable for the parts that have been serviced (provided that industry can ensure traceability). An industry stakeholder (individual firm) from the repair and refurbishment industry stated that the DPP is interesting on the assumption that the information could be transparent and passed on to each EO within value chains. Making the marking digital (e.g. CE mark through the software for consumer electronics) would bring significant changes and improvements.

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 opinion regarding the best way forward in dealing with this. Some stakeholders were in favour of reforming the NLF to explicitly accommodate the circular economy. Many stakeholders responding to the targeted consultation and taking part in interviews called for the nature and responsibilities of remanufacturers, refurbishers and reprocessors to be clarified through the NLF; and

service, having a significant impact on its compliance with Union harmonisation legislation, must be considered as a new product."

[122] "Use of work equipment" is defined in Directive 2009/104 as "any activity involving work equipment such as starting or stopping the equipment, its use, transport, repair, modification, maintenance and servicing, including, in particular, cleaning".

[123] https://www.euractiv.com/section/circular-economy/news/eu-plans-digital-product-passport-to-boost-circular-economy/

highlighted the need to proactively manage coherence between the NLF, Union harmonisation legislation and the Circular Economy Action Plan and other EI policy and legislative initiatives.

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

- **The Blue Guide revision**, as this 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 HS mentioned were: TR 45550[124] – definitions relevant to the circular economy and EN 45559 on material efficiency[125].

All industry stakeholders consulted agreed on the need for the EU legislator to harmonise the proposed definitions of a '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 question of **conformity assessment procedures** relates to whether a remanufactured or refurbished product that has been substantially modified should be: i) assessed against the essential requirements and standards in place at the time of the placing of the original product on the market; or ii) assessed against the most up to date requirements and standards.

Industry stakeholders highlighted a contradiction in terms, with one respondent to the evaluation roadmap stating that: "*if the objective is to extend the lifetime of a given product, then it cannot be presented as a new product*"; highlighting that "*the consequence of the 'new product' legal status would be the obligation to comply with all the regulations in force at the date of the new making available on the market (product safety, energy efficiency, presence of regulated substances in materials, etc.)*". On the contrary, however, certifiers have noted that a remanufactured product should be regarded as new.

Industry stakeholders noted that comparisons with the B2B capital machine goods and medical equipment sectors could be useful. These sectors make a **distinction between 'as produced' and 'as new'.** According to some industry stakeholders interviewed, (e.g. medical equipment producers), this distinction can make a key difference as to the viability of circular business models.

For instance, if equipment is required to be placed on the market 'as new', this means that the full set of applicable EU regulatory requirements and conformity assessment procedures must be fulfilled again. However, changes to legal requirements since the product was originally manufactured, especially EU environmental legislation such as the REACH Regulation and RoHS Directive, would mean that it would be cheaper to redesign and reproduce the equipment from scratch rather than to remanufacture it. The reason for this is that the product would need to be remade using substitute chemicals which can mean it is easier to product a new product than to remanufacture an existing one. It was therefore by some industry associations (e.g. COCIR, FEM) suggested that it should be possible to put some equipment back to "as produced" status, i.e. to the technical specifications and legal requirements applicable at the point that the original equipment manufacturer (OEM) placed on the market.

Some stakeholders in the sector expressed the view that the obligation to ensure that the other market players in the supply chain have fulfilled their obligations does not work as intended in a refurbishment scenario. A firm in the repair industry noted that if there hasn't been a substantial modification to the device (i.e. in functionality or destination) the DoC should be passed on to the

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

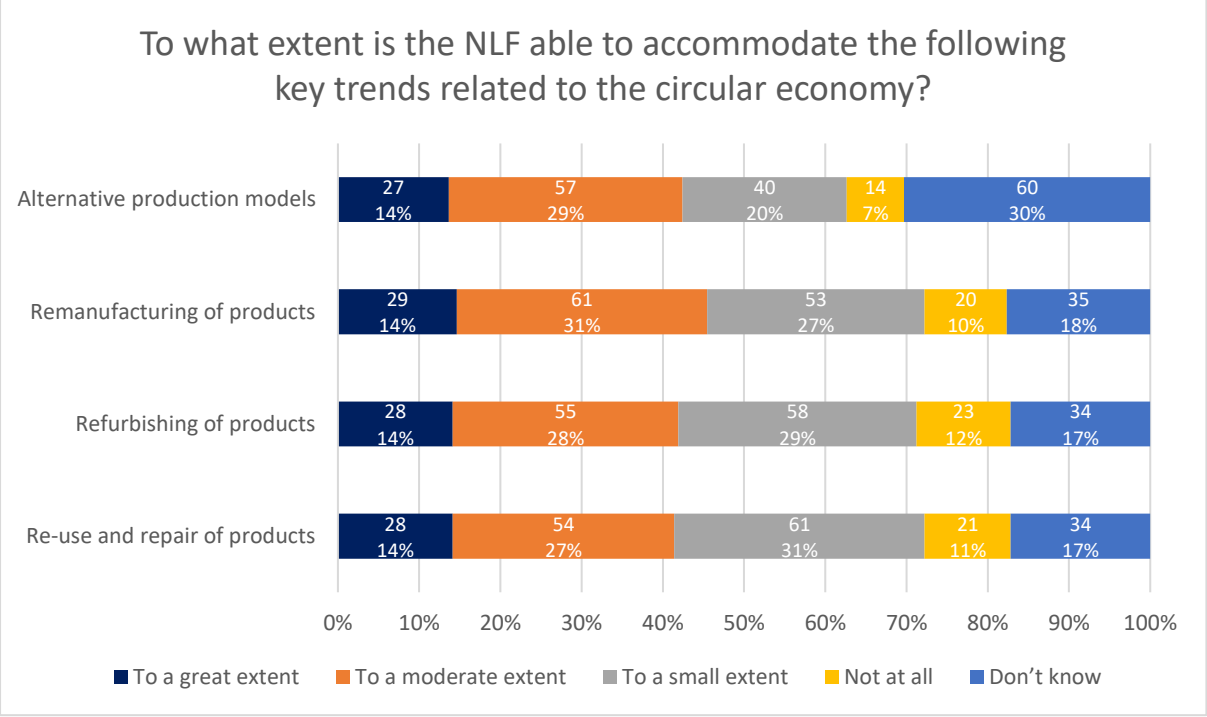
refurbisher or remanufacturer. However, in practice, OEMs are unlikely to agree to this as they are concerned about their ongoing responsibilities for product compliance and strict liability for the product for 10 years following its placement on the market. However, without the proper compliance documentation, including technical information and the DoC, refurbishers or service providers would not be able to carry out a risk assessment against the specifications of the original device.

Further stakeholder perceptions on fitness for purpose related to the circular economy are now provided drawing on feedback from the targeted consultation.

A stakeholder in the repair industry suggested that the NLF only takes into account direct supply chain scenarios, and not second-hand used product markets where the value chain includes end-users who are not economic operators. However, used, second-hand goods are out of the Directive's scope.

Many stakeholders across all categories noted that the **NLF's reference provisions and NLF-aligned product legislation are unclear in the context of the circular economy.** As illustrated below, stakeholders responding to the targeted consultation had mixed views on the ability of the NLF to accommodate key trends related to the circular economy. More specifically, respondents are quite evenly split between: i) thinking the NLF is able to a great or moderate extent to accommodate the four trends highlighted; and ii) thinking the NLF is not able or only able to accommodate these trends to a small extent.

Figure 6-5: Ability of the NLF to accommodate key circular economy trends (Question 54, N=198)



This lack of clarity creates uncertainty for economic operators fulfilling the role of remanufacturers and refurbishers, as well as potentially impacts the safety of products available on the European market. This, in turn, restricts the realisation of the EU's circular economy goals. As such, industry stakeholders have highlighted a contradiction in terms between the EU circular economy objectives and the NLF system and point to two key questions that need to be answered to ensure the NLF is fit to accommodate circular economy developments: i) to what extent does a product need to be modified for it to require a new conformity assessment and how can this be legally defined; and ii) if re-certification is required, to which level is the product required to achieve. According to representatives from all stakeholder groups, both questions remain legally unclear.

Conclusions and gap analysis

- Although the Medical Devices Regulation and proposed new and updated sectoral legislation (e.g. the AI Act, GSPR, Machinery Regulation proposals) have defined the role of refurbishers and remanufacturers within manufacturing value chains, and what a substantial modification is, the NLF framework does not currently address the circular economy.
- This does not represent divergence from the NLF, but rather the fact that the 2008 legal framework has become outdated in certain areas. The growth of the circular economy has arisen with rapid changes in the nature and composition of value chains, in which there is a broader range of economic operators present.
- As the NLF is meant to provide a horizontal legal framework for all underlying and aligned Union harmonisation legislation, this legal gap may undermine the NLF's ongoing relevance if left unaddressed, especially as the circular economy, product sustainability and lifetime extension and materials efficiency are trends likely to grow in future, driven by industry and consumer needs, with further impetus from EU policy makers and regulators (e.g. the SPI proposal to extend ecodesign principles).
- Industry associations representing circular economy stakeholders were generally in favour of clarifying the role of refurbishers and remanufacturers and making this clear under the NLF's common definition of economic operators as they are presently missing from the definitions of EOs within product legislation, which may hinder regulatory certainty, given their increased role within value chains.

6.4 Analysis of the need for a crisis instrument in the NLF

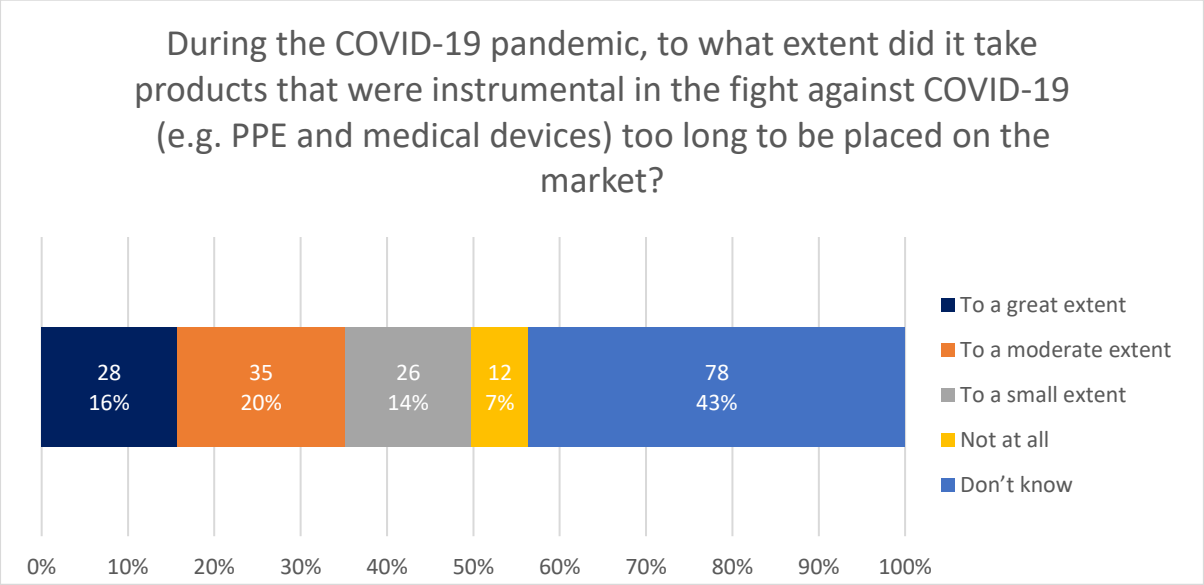
A range of economic challenges emerged following the implementation of national lockdowns and restrictions on movement during the first phase of the COVID-19 pandemic. One key challenge resulted from the urgent need for personal protective equipment (PPE) and certain medical devices. New market entrants who wanted to place such products on the market to support the fight against COVID-19, reportedly faced time to market challenges. This section explores the evaluation question **'To what extent does the lack of a crisis instrument render the NLF less effective or efficient?' (EQ5.3)** by examining the situation that emerged in the first phase of the COVID-19 pandemic.

This focus on the pandemic and the PPE / Medical Devices Regulations to support this analysis has been confirmed through the evaluation of responses to the evaluation roadmap, the interviews, and the online targeted consultation. Most stakeholders, with the exception of those involved in the areas of PPE and medical devices, have been unable to comment on this issue.

As there were shortages of PPE and certain medical devices during the pandemic, new market entrants wanted to access the market in these sectors from inside but especially outside the EU. Many producers were neither familiar with the relevant EU legislation and harmonised standards, nor the relevant conformity assessment procedures. Given the short time to market needed in the crisis resulting from the pandemic, stakeholders have reported that, in many cases, it took **too long for these new market entrants to familiarise themselves with the legislation and go through the necessary procedures** to place products important in the fight against COVID-19, such as PPE and medical devices, on the Union market.

This finding was validated to some extent by the targeted consultation. Although most stakeholders (43.6%, 78) responded that they don't know whether it took too long for such products to be placed on the market during the COVID-19 pandemic, only 6.7% (12 responses) perceived this situation not to have happened. Amongst stakeholders who felt able to judge, **62.4% (63 of 101) agreed with the statement to a great (27.7%, 28 responses) or moderate (34.7%, 35) extent**.

Figure 6-6: 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)



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

Prominent stakeholders from the PPE and medical device sectors, including industry associations and notified bodies, highlighted the following key reasons for this challenge:

- **COVID-19 required rapid development and certification of both new and repurposed products**, primarily in the two highlighted sectors.
- Although steps were taken to support quicker certification, manufacturers faced difficulties with time to market. For instance, while the MDR provides for emergency procedures, the implementation of such procedures was the responsibility of the national authorities. As such, there was no EU-wide procedure to address challenge and **huge divergences in the approach to facilitating quicker certification occurred** across the EU.
- **Achieving certification was very difficult in practice**, due to: i) the inability to conduct audits as a result of national lockdowns and restrictions on movement; and ii) the process of transferring from the old regulatory regime to the new Medical Devices Regulation, which, for the most part, was applicable from 26 May 2020. Furthermore, similar challenges in other sectors were alleviated through the use of remote conformity assessment techniques (as examined in further depth in Chapter 4.2.5.2). However, remote conformity assessment techniques were not permitted in the medical devices sector and were not initially permitted under the PPE Regulation. This position reportedly exacerbated the challenge of conducting conformity assessment activities during the pandemic.

Furthermore, it was acknowledged by stakeholders across all groups that, even in such a crisis situation, the requisite steps need to be taken to **ensure the safety and compliance of all products** placed on the EU market.

The combination of these factors resulted in the abovementioned difficulties ensuring timely placement on the market for products that were instrumental in the fight against COVID-19.

A key finding, emerging from both the responses to the evaluation roadmap and the interviews, is that these **challenges do not stem directly from the NLF**. Although there was an issue around inexperienced economic operators entering the PPE or medical devices markets in an unprecedented global health pandemic, the NLF provisions were not considered to be the main factor limiting or

hindering market access by those stakeholders who have commented. This is illustrated in the below box.

Table 6-5: Role of the NLF in the COVID-19 pandemic

Emergency crisis and control of notified bodies
It has been reported that some conformity assessment bodies acted beyond their field of accreditation to deliver certificates that were questionable.[126] For instance, in Sweden, there were only a small number of notified bodies in the area of personal protective equipment (PPE), due to the limited local production of such equipment. However, during spring 2020 and the surge of the COVID-19 pandemic, production and quality testing of PPE was acute; new manufacturers appeared but faced a shortage of conformity assessment bodies in Sweden and they did not have the capacity to go to another Member State to get their product certified. Consequently, until some conformity assessment bodies acquired the competence and got notified, authorities had to deliver some market approvals and chase false certificates delivered by non-existent bodies. However, the NLF was not considered to be a hinderance or a facilitator in this situation by relevant stakeholders. What was more concerning was the lack of cross-border cooperation between national accreditation bodies to tackle a situation which may not last, and where there is no long-term need for maintaining accreditation and conformity assessment services for PPE.

In fact, notified bodies have highlighted the flexibility in the implementation of the conformity assessment system, as a supporting factor during the pandemic. More specifically, one survey respondent noted that "*we have prioritised customers [and] tested for free for some products (breathing aid), which have played a role in the fight against COVID-19*", further adding that "*the first confinement resulted in a temporary stoppage of testing services, but not for medical products*". This illustrates the ability, within the NLF system, to prioritise conformity assessment efforts in crisis situations. Another example is the use of remote assessment techniques to facilitate the compliance process, as detailed in Chapter 4.2.5.2.

Although the challenges faced during the pandemic may not have resulted from the legal provisions of the NLF, a national authority noted that there was clearly an issue with market access and a need remains "*to establish procedures for any crisis, urgency or other special situations*" within the conformity assessment system. This statement was supported by stakeholders representing the PPE and medical device sectors, notified bodies and national accreditation bodies, who noted that an **overarching procedure for a more efficient EU-wide response would have been beneficial**.

These could build on the examples of prioritisation and use of digital tools highlighted above.

6.5 Conclusions

Considering the question of **whether the NLF remains relevant**, the findings point to the following main conclusions.

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.

[126] https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppe

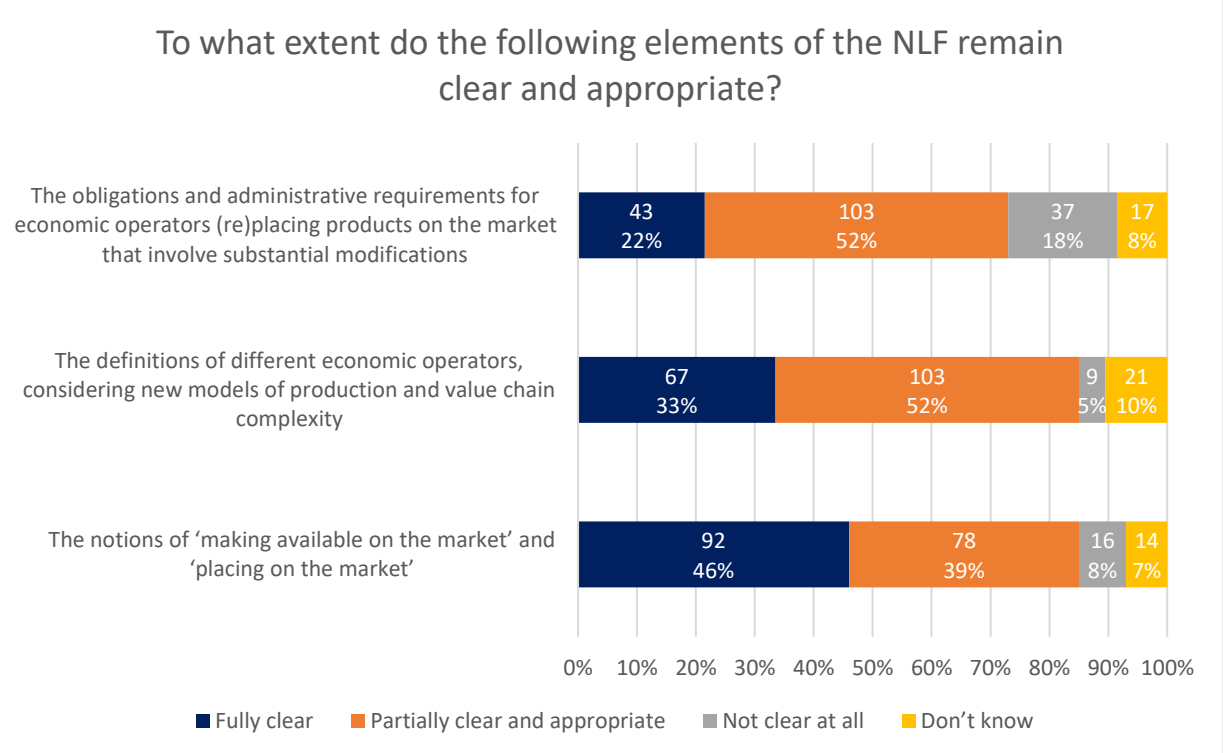
Moreover, although significant progress has been made towards addressing these needs, stakeholders clearly feel that **these needs, the related general and specific objectives and the overarching framework implemented by the NLF remain relevant** moving forward.

However, **key changes in product markets, driven by technological, scientific, environmental and societal developments, have emerged since 2008**. These changes 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. As such, the Commission has recently adopted and proposed Union harmonisation legislation and other horizontal legislation, outside the remit of the NLF, to tackle these issues. Examples include the proposal for an AI Act and the proposal for a GPSR.

These **market and regulatory developments raise issues regarding the ongoing relevance of the NLF**, as other individual pieces of legislation are increasingly being updated and modernised to reflect digitalisation and the circular economy. In this context, the following figure illustrates the extent to which stakeholders perceive certain elements of the NLF to remain clear and appropriate. Only a minority of stakeholders agreed that the following elements were fully clear: 21.5% (43 of 200 responses) perceive that the requirements for economic operators related to (re)placing products on the market that require substantial modifications 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. However, stakeholder views were more positive in relation to the clarity and appropriateness of the existing notions of 'making available on the market' and 'placing on the market', with 46% (92 respondents) stating that these rules are fully clear.

The obligations and administrative requirements for economic operators (re)placing products on the market that involve substantial modifications was the NLF element that stakeholders were most likely to find not clear at all: 18.5% of stakeholders (37 responses) took this view.

Figure 6-7: Extent to which elements of the NLF remain clear and appropriate (Question 52, N=200)



Consequently, these findings raise questions as to whether the NLF remains sufficiently fit for purpose.

To address these challenges, stakeholders believed there may be a need, for instance, to accommodate new types of economic operators (e.g. refurbishers, remanufacturers, software developers, online marketplaces, fulfilment service providers) into the NLF. Similarly, whilst the definitions in the NLF remain relevant, there are a series of additional definitions that are already beginning to be defined in other EU legislation and should be considered in the context of the NLF. Examples include the need to define what constitutes a new product in terms of a substantial modification and the question of whether new but often integral aspects of products should be explicitly defined, such as software, intangibles, and services.

Furthermore, in early 2020, the COVID-19 pandemic caused challenges related to market access for certain types of products, such as some essential PPE and medical devices. Although these challenges were significant, most stakeholders do not see them stemming directly from the NLF. In fact, certification stakeholders highlighted ways in which the NLF's flexibility allowed national authorities and notified bodies to appropriately prioritise their activities and make use of digital tools to ensure certification activities for vital product types could continue. However, these stakeholders also highlighted the efficiency benefits that would have been delivered by having an overarching EU-wide procedure in place, instead of the national level solutions that emerged.

7. Conclusions and lessons learned

Overall, the **NLF has made a significant positive difference in strengthening the overall efficacy and coherence of the body of Union harmonisation legislation**, which has helped to strengthen the free movement of goods. However, the fast-paced nature of changes to product markets due to digitalisation and the circular economy, and associated changes to the EU legal framework raises questions as to whether the NLF can remain fit for purpose without updating and modernisation. This chapter summarises the key conclusions.

7.1 To what extent was the NLF successful and why?

Considering the overarching question guiding Chapter 4 – **To what extent was the NLF successful and why?** – the research findings indicate the following conclusions.

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. For the first two general objectives, the positive impact of the NLF has primarily been achieved indirectly through NLF-aligned Union harmonisation legislation. Progress towards achievement of the third general objective has, however, been direct. More specifically, alignment with the NLF's reference legal provisions and use of the NLF's common implementation mechanisms has been ensured across 16 directives and 7 regulations to date, with further alignment expected through the proposal for a Machinery Regulation.

Positive progress has also been made across the specific objectives of that NLF that are relevant to this evaluation. However, certain implementation challenges were highlighted in many cases. More specifically:

- **Reinforcing the New Approach** and, in particular, the principle of technology-neutral essential requirements. The commitment to expressing essential requirements that avoid going into technical detail has been clearly implemented across NLF-aligned legislation. Challenges exist in relation to the current approach to standardisation, which has been highlighted as an important pillar of the framework of Union harmonisation legislation; however, this is not a prominent focus of this evaluation due to ongoing work focusing specifically on this topic.
- **Supporting the consistency and coherence of EU harmonisation legislation**. Tied strongly to the third general objective, the process of aligning 23 pieces of EU legislation to the NLF has heavily strengthened the consistency and coherence of these laws. As mostly minor challenges and examples of divergence exist across the body of NLF-aligned legislation, it remains important to consider the cumulative impact of these minor challenges and divergences. Underlining this objective, the evaluation also found that the **internal coherence of the two NLF legal texts examined was considered to be strong**; no particular inconsistencies or overlaps have been identified.
- **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 real 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. As such, the overall experience of the conformity assessment system, considering the performance of these aspects in combination, has been positive, with stakeholders highlighting benefits of greater simplification of compliance activities and increased fair competition between businesses. However, many stakeholders remain convinced 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 in relation to the procedures and criteria for the accreditation of conformity assessment bodies.

- **Enhancing the clarity and credibility of the CE marking**. Although the CE marking regime was well established prior to 2008, the NLF's rules on the issue were considered to be clear and thus contributed to increasing industry attention on CE marking requirements, strengthening the visibility of CE marking, and ironing out minor inconsistencies between different pieces of legislation.

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.

Furthermore, by tackling the NLF's weaknesses and taking the opportunities created by digitalisation, there are **opportunities for the further simplification and burden reduction** for economic operators and other stakeholders; namely, through the use of e-labelling and remote assessment techniques. Based on an extrapolation of an analysis on three segments of the European consumer electronics market, the estimated cumulative cost saving associated with the introduction of an e-labelling scheme can be conservatively placed at EUR 490 million per year. Although quantification of the economic benefits of remote assessment techniques are not possible, the positive impacts related to the implementation of such techniques include: reduced travel time and costs, reduced travel risk, reduced environmental footprint; and increased accessibility for people with disabilities.

However, the **ability for the evaluation study to quantify the scale or magnitude of the costs and benefits is limited**, as a result of conceptual complexities primarily related to: i) the difficulty attributing costs and benefits between the NLF and NLF-aligned UHL; and ii) the nature of the NLF, as a framework that improved coherence and consistency across existing legislative provisions but did not introduce many novel elements.

Although the effectiveness and efficiency of the NLF are viewed positively, the performance of the NLF should not be viewed in a vacuum. As such, assessing the **NLF's coherence with the wider EU regulatory framework** is important, particularly given the significant market and regulatory developments that have occurred since the adoption of the NLF.

In this respect, although many pieces of Union harmonisation legislation are not aligned to the NLF, 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 itself, NLF-aligned legislation and relevant non-NLF aligned legislation. Examples of such divergence, as highlighted in Chapter 4.3, include the definition of a 'manufacturer' in Directive 2009/125/EC on ecodesign of energy-related products, and the definitions of 'placing on the market' and 'making available on the market' in Directive (EU) 2019/904 on the Single Use of Plastics.

However, in response to prominent market developments related to the digital and circular economies, **notable coherence-related challenges have emerged in the last few years**. These relate to both (prospective) NLF-aligned and non-aligned laws. More specifically, these challenges can be categorised in three groups:

- **Inclusion of more extensive conformity assessment procedures** within product legislation. Industry stakeholders, in particular, highlighted the risk of movement towards generalised third-party conformity assessment, citing the example of the proposal for a Machinery Regulation, where the updated list of high-risk machinery products includes general coverage of software and AI systems ensuring safety functions.
- **Inclusion of detail technical specifications within product legislation**. In opposition to the principle of technological neutrality enshrined in the New Approach and the NLF, industry stakeholders highlighted examples of non-NLF-aligned product legislation that include significant technical detail in the legal text. In this regard, a key example noted by stakeholders was the proposal for a Regulation concerning batteries and waste batteries, where very specific requirements have been included within the proposed legal text.
- **Addition of new rules to tackle emerging challenges.** The ever-increasing digitalisation of the European market, as well as the drive for a more circular economy, have brought a wide range of challenges related to, amongst others, remanufacturing, cybersecurity, servitisation, and AI. These are issues that did not exist when the NLF was adopted. As such, over the last few years, EU legislators have been developing approaches to tackle these challenges, both within the context of existing legislative provisions (e.g. in the case of the RED Delegated Acts on cybersecurity, the proposal for a Machinery Regulation and the proposal for a GPSR) and in completely new areas (e.g. the proposal for an AI Act).

  Although in many cases these initiatives build on the NLF or its aligned legislation, they inevitably go beyond the rules established in the NLF, thus highlighting potential gaps in the NLF's coverage. Furthermore, in some cases, this results in inconsistencies and incoherencies between the legal texts. A key example is the approach to defining the concept of a 'substantial modification'; in three recent EU legislative proposals (for the Machinery Regulation, GPSR and AI Act), the definition of the concept has been worded differently.

Although stakeholders generally recognised the need to tackle the emerging challenges related to the digital and circular economies, **measures need to be proportionate and coherent**. Moreover, a lack of coherence on these issues could lead to reduced flexibility of the legal framework to deal with market changes, increased burden and costs of compliance for industry, erosion of the principle of technological neutrality, and reduced innovation and competitiveness.

7.2 How did the NLF make a difference?

Overall, the NLF was viewed – especially by industry – as having **contributed significant added value** to enhancing the free movement of goods through a more common, coherent, and consistent approach across the body of applicable EU sectoral legislation to products.

However, some stakeholders argued that the **NLF's added value was mainly concentrated in its first 10 years**, when the alignment process of updating 23 directives and regulations with common provisions meant growing consistency and coherence between different pieces of legislation. In this sense, the NLF has added value to what already existed through the New Approach and in individual pieces of sectoral legislation. However, definitions and requirements in certain laws that move beyond the core NLF principles have increasingly emerged. While certain divergences may be justified by the specific nature of the laws in question and the protected interests at stake, the added value of NLF in those circumstances remains to be further evaluated. Despite the identification of AI as being high-risk and needing specific technical requirements to be specified (e.g. in the AI Act and Machinery Regulation), the principle of technology-neutrality remains at the core of the NLF.

There was broad agreement that, in order to continue to add value in future, the **NLF may need to be updated in the near future so as to reflect developments in product markets** linked to digitalisation (e.g. cybersecurity, data protection and privacy) and the circular economy (e.g. growing role of

refurbishers and remanufacturers, questions as to how the putting on the market of goods that are being replaced on the market should be facilitated). Moreover, recent developments in EU legislation have seen the emergence of slightly differing definitions (e.g. of a substantial modification) leading to stakeholders calling for greater consistency in definitions across sectoral legislation with the NLF being the preferred mechanism through which a wider set of definitions could be developed so as to ensure consistency across the body of legislation.

Stakeholders were however unanimous that, overall, the NLF has added value and that **repealing it would be negative for different stakeholders** (although in the case of consumer associations, this was premised by the imperative of updating the NLF urgently for it to remain effective). For EU legislators, the absence or repeal of the NLF would be detrimental as there would be a lack of a common framework and regulatory toolbox upon which to develop revisions to existing, or to draw up new sectoral legislation for products. There would also be negative impacts for industry and industrial competitiveness, as there would potentially be many more divergent requirements in EU sectoral legislation.

Similarly, relying on a **national approach to product legislation** would imply losing the many benefits that economic operators, consumers and other stakeholders receive from the single market and free movement of goods generally, which the NLF has enhanced through the development and application of a more common approach.

In this context, stakeholders across all groups felt that the **needs and challenges addressed by the NLF continue to require harmonisation action at the EU level**. Even if the NLF needs to be updated, the notion of having common definitions, common requirements for economic operators, a common suite of conformity assessment modules, etc. was strongly welcomed by industry. They argued that the **NLF needs to be reinforced, modernised and strengthened rather than repealed** in light of developments in product markets and in underlying legislation due to digitalisation and the circular economy.

7.3 Is the NLF still relevant?

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.

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. As such, the Commission has recently adopted and proposed Union harmonisation legislation and other horizontal legislation, outside the proviso of the NLF, to tackle these issues. Examples include the proposal for an AI Act and the proposal for a GPSR.

These **market, and related regulatory, developments raise issues regarding the ongoing fitness for purpose of the NLF**, as other individual pieces of legislation are increasingly being updated and modernised to reflect digitalisation and the circular economy, thereby going beyond the provisions of the NLF.

To address these challenges, stakeholders believed there may be a need, for instance, to accommodate new types of economic operators (e.g. refurbishers, remanufacturers, software developers, online marketplaces, fulfilment service providers) into the NLF. Similarly, whilst the definitions in the NLF remain relevant, there are a series of additional definitions that are already beginning to be defined in other EU legislation and should be considered in the context of the NLF. Examples include the need to define what constitutes a new product in terms of a substantial modification and the question of whether new but often integral aspects of products should be explicitly defined, such as software, intangibles, and services.

Furthermore, in early 2020, the **COVID-19 pandemic caused significant challenges related to market access for certain types of products**, such as some essential personal protective equipment (PPE) and medical devices. This situation resulted from: i) the need to develop and certify products very quickly; ii) huge divergences in the approaches taken to facilitate quicker certification across the EU; iii) the inability to conduct audits due to national lockdowns and restrictions on movement; and iv) the process of transferring from the old regulatory regime for medical devices to the Medical Devices Regulation, which was applicable from May 2020.

From the perspective of the NLF, stakeholders highlighted that its flexibility allowed the prioritisation of conformity assessment activities in these key sectors during the early stages of the COVID-19 pandemic.

Although these market access challenges did not stem directly from the NLF, and the NLF was beneficial in some ways (e.g. in allowing prioritisation of conformity assessment services in vital sectors), stakeholders in these sectors clearly stated that an **overarching EU-wide procedure would have been brought benefits beyond what was possible under the current framework**.

7.4 Lessons learned

Building on the main findings and conclusions, the main **lessons learned** identified through the evaluation are now outlined.

First, 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**.

For instance, there are now many new economic operators in modern industrial and production value chains that are not reflected in the NLF, yet are increasingly being addressed in recent legislation (e.g. Market Surveillance Regulation) and legislative proposals (e.g. Machinery Regulation, AI Act, GPSR). For the NLF to remain relevant and effective, a key lesson is that it **needs to adapt to the times**.

A further lesson is that, whilst the NLF has provided a more harmonised regulatory framework across NLF-aligned legislation, **continued policy debate and engagement with stakeholders is needed regarding the advantages but also the limitations of harmonisation through a common regulatory framework**, and the extent to which, if the NLF provides the basic building blocks and common regulatory approach, some divergence should be permissible in certain circumstances to ensure that the framework remains flexible and fit for purpose. For example, some degree of divergence appears to have been necessary for EU regulators in the context of NLF-aligned legislation, but also in a number of recent regulatory proposals (see above). Allowing some divergence may be essential until such time as the NLF itself is updated, as product markets and wider global trends (technology-driven, circular economy-related) happen at an ever-accelerating pace.

Within this context, however, the legislator needs to consider: i) the **potential for cumulative costs and burden** arising from lots of minor divergences across Union harmonisation legislation; ii) **coherence with the NLF principles and provisions across all EU secondary laws that apply to products**, as much of the divergence identified is between NLF and non-NLF aligned laws. Linked to this, ensuring the proportionality and necessity of sector-specific divergence, the inclusion of more extensive conformity assessment procedures and the inclusion of more detailed technical specifications in legislation is uniformly and comprehensively assessed, as well as clearly communicated to stakeholders, remains crucially important.

In this respect, an **overarching structure to address these challenges could be to expand the NLF regulatory framework in the following two directions**, so as to continue to provide a high level of protection of the end-user and society at large, while supporting the single market in the best possible way:

- A wider spectrum of essential requirements that NLF-aligned product legislation could address, beyond health and safety and environment protection, such as sustainability, recycling, cybersecurity, privacy, and personal data protection.
- Greater harmonisation of the basic roles and obligations of economic operators throughout the life-cycle of a product, beyond the first making available of a new product on a market, throughout its use, maintenance, reconditioning, until its recycling and even disposal.

Considering the **conformity assessment system**, including the rules on accreditation and notification, it is clear that the landscape is complex. For instance, the relevant stakeholders include: national competent authorities responsible for transposition of directives and other implementation issues; national accreditation bodies; national notifying authorities, who have varying responsibilities for NLF-aligned and non-aligned legislation; accredited notified bodies, who can also be accredited across different conformity assessment activities and laws; non-accredited notified bodies; and other conformity assessment bodies.

This complexity, in addition to other challenges, has led to the emergence of **application difficulties and weaknesses that limit the effectiveness of the conformity assessment system**. In this respect, significant consideration needs to be placed on:

- Ensuring greater harmonisation of approaches, criteria, and procedures for accreditation of conformity assessment bodies and notification for notified bodies. Although the possibility of mandatory accreditation for notified bodies should be considered, as it will ensure a known level of competence in each country, additional measures will still be required to ensure any attestation of competence through accreditation means the same thing across the EU. More specifically, linked to the above:
  - Ensuring greater clarity on the rules for subcontracting and use of subsidiaries by notified bodies, and, on that basis, greater harmonisation of approaches to implementing those rules.
  - Ensuring greater clarity and coherence between the conformity assessment services described in the suite of conformity assessment modules, the specific pieces of Union harmonisation legislation and the harmonised standards related to the provision of conformity assessment activities. In the first instance, the uniform implementation of EA-2/17 would be beneficial. However, stakeholders also proposed the development of one overarching standard with requirements on key principles, such as impartiality and objectivity, that are identical across all sectors. These could then be accompanied by specific standards for the various types of accreditation categories.
- Ensuring appropriate mechanisms for formal cooperation between national notifying authorities within the context of specific pieces of UHL, as well as assessing and ensuring the competence of notifying authorities.

- Safeguarding the role of harmonised standards in the NLF.

Beyond the weaknesses identified by the evaluation, key lessons should be learned regarding the **future opportunities for administrative simplification and burden reduction**. In particular, many industry stakeholders have called on the Commission to follow up on previous commitments to adopt digital labelling practices, while conformity assessment stakeholders have recognised the benefits that can be delivered by the appropriate and considered use of remote conformity assessment, accreditation and peer evaluation techniques.

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- 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).
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Annex 2: Evaluation methodology

This Annex presents the methodology used to conduct the Supporting Study for the evaluation of certain aspects of the New Legislative Framework (NLF). First, it provides an overview of the key evaluation issues and the methodological approach, before detailing a range of conceptual evaluation challenges and presenting the full evaluation questions matrix.

Overview of the key evaluation issues

This study supporting the evaluation of certain aspects of the NLF requires an assessment of the five key evaluation criteria named above. More specifically, it will be important to examine the following issues under each criterion:

- **Effectiveness** considers the extent to which the NLF has achieved its general and specific objectives, based on a comparison between its anticipated effects and those that actually resulted. Within this context, the evaluation examines four key features of the NLF: the alignment of specific product legislation with the NLF and its common reference provisions; the rules and procedures for conformity assessment, the framework for the accreditation of conformity assessment bodies and the rules on CE marking.
- **Efficiency** considers the relationship between the economic benefits achieved and the inputs used by the NLF. How these benefits and costs accrue to different stakeholders over time is an important consideration.
- **Relevance and ongoing fitness for purpose** examines the extent to which the general and specific objectives and the provisions of the NLF are clear and meet the ongoing needs of EU policy makers that need to use the regulatory toolbox and of industry that have to follow the common obligations set out in NLF-aligned sectoral directives and regulations. This assessment focuses on both retrospective aspects of relevance, but also the ongoing fitness for purpose of the NLF, considering key market developments since 2008.
- **Coherence** considers the extent to which the provisions of Decision No 768/2008/EC and Regulation (EC) No 765/2008 are coherent (internal coherence), as well as the extent to which the NLF is coherent, complementary and does not duplicate other EU legislative and policy initiatives (external coherence).
- **EU added value** examines whether the effects achieved by the NLF could have been achieved by similar initiatives at the national / regional level, or through individual product legislation.

The following table presents the key evaluation questions related to each evaluation criteria. A full evaluation matrix, presenting detailed sub-questions, judgement criteria and indicators, is provided below.

Overview of key evaluation questions, per criteria

Evaluation criteria	Key evaluation questions
Effectiveness	• To what extent have the general and specific objectives of the NLF been achieved? ▪ What are the factors that have influenced positively and negatively the achievements observed? ▪ Has the NLF had unintended positive or negative consequences or collateral effects? ▪ To what extent does the NLF ensure the safety and compliance of products during its lifetime?

Evaluation criteria	Key evaluation questions
	These overarching questions are supported by more specific evaluation questions related to the key features of the NLF, covering the alignment of product legislation with the NLF, the rules and procedures for conformity assessment, the framework for the accreditation of conformity assessment bodies, and the rules on CE marking (see the full list below).
Efficiency	• What are the benefits and how beneficial are they for the various stakeholder groups? • What are the regulatory and administrative costs associated with the NLF and are they affordable for the various stakeholder groups? • To what extent are the costs incurred proportionate to the benefits attained? *These aspects are considered across all the key features of the NLF, as noted above. They will also consider how the costs and benefits relate to different stakeholders, with a particular focus on SMEs. More specific evaluation questions are detailed below.*
Relevance and fitness for purpose	• To what extent are the NLF's objectives and provisions still appropriate? *Considering, in particular, the development of the needs of the EU across different stakeholder groups and the clarity of the NLF's provisions.* • To what extent has the NLF allowed for technological, scientific, environmental and social developments? *Considering developments related to the digital and circular economies, such as product changing during their lifetime, new models of production, and increasing supply chain complexity.* • Are the provisions of the NLF clear enough in respect of the roles and responsibilities of the different economic operators? • How far does the lack of a specific crisis instrument make the NLF less effective or efficient?
Coherence	• Are there any inconsistencies, overlaps or gaps within the different provisions of Decision No 768/2008/EC and Regulation (EU) No 765/2008? • To what extent is the NLF still consistent with other existing and proposed EU policy legislation, or with older legislation like Directive 2001/95/EC?
EU added-value	• What is the added value of the NLF compared to what could have been achieved at merely national level? • Do the needs and challenges addressed by the NLF continue to require (harmonisation) action at EU level? • What would be the most likely consequences of repealing the NLF?

Methodological approach

Phase 1: Inception activities

In phase 1 of the project, which ran from March to June 2021, the following activities were conducted:

- **Kick-Off Meeting (KoM)** held on 9th March 2021 with the Commission services and the Inter-Service Steering Group (ISSG). Meeting minutes were provided shortly after and were revised based on comments from participants.
- **Preliminary literature review** was undertaken, covering existing evaluations and impact assessments of relevant legislation, responses to the evaluation roadmap consultation and other core literature. On this basis, three key outputs were developed in the inception phase and submitted as part of the inception report:

- *Preliminary assessment of the intervention logic for the NLF*. A preliminary version of the intervention logic was submitted as part of the inception report.
- Strategic reflections on how the NLF framework might need to evolve in future to reflect regulatory and technological developments and trends. These reflections have been incorporated into the assessment of relevance in Chapter 6.
- Preliminary review and analysis of the responses to the evaluation roadmap consultation.

- **Data collection and research framework** was further refined. In particular, the following were developed:
  - Key research questions and issues for exploration through the study in the form of an evaluation matrix, supported by appropriate judgement criteria and indicators.
  - Set of tailored interview questionnaires, targeted to the following stakeholder groups: economic operators, industry associations, consumer associations, national authorities, and market surveillance authorities (MSAs), and notified bodies / conformity assessment bodies.
  - Draft survey questionnaires for the targeted and public consultations.
  - Letter of introduction to facilitate the engagement of stakeholders.
  - Privacy statement to be provided alongside the stakeholder consultations.
  - Proposed framework for collecting data on the NLF's costs, benefits, and impacts.
- **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.
- **Inception report and inception meeting**. To conclude Phase 1, a draft inception report was developed and submitted to DG GROW on 19th April 2021. Building on the above, the inception report included: an introduction and background to the evaluation of the NLF; a detailed analysis of the NLF's intervention logic; a refined methodology and approach to the core evaluation tasks; and an overview of next steps related to finalising the research tools and initiating phase two of the project. Annexed to the inception report were: a bibliography; the provisional analysis of fitness for purpose-related issues; the detailed evaluation framework; the provisional assessment of the responses to the evaluation roadmap consultation; the preliminary mapping of costs and benefits generated by aspects of the NLF being evaluated; and the minutes of the kick-off meeting.

  In line with the project timelines, the research tools (including the interview guides, as well as the targeted and public consultation questionnaires) were submitted to the Commission shortly after the inception report. The first drafts of the interview guides were submitted on 23rd April 2021 and the targeted and public consultation questionnaires were submitted on 1st July 2021.

  Following submission of the draft report and interview guides, an inception meeting was held on 6th May 2021 with the Commission services and wider Steering Group. Meeting minutes were drafted following the meeting and quickly finalised with DG GROW. On the basis of feedback received through the inception meeting and in writing, the inception report and the interview guides were the focus of amendments through May and June 2021. The finalised inception report was submitted on 22nd June 2021 and subsequently approved by the Commission. Although the interview guides were approved at this point, further efforts to refine the targeted and public consultation questionnaires were conducted in Phase 2.

Phase 2: Data collection and preliminary analysis

In Phase 2 of the project, which ran from July to November 2021, the following activities were conducted.

Interview programme. 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.

Implementing and monitoring the stakeholder consultations. In addition to monitoring the coverage of issues across the interview programme, the progress of the stakeholder consultations was closely monitored via a contacts database. All team members have access to the database and were required to update the status of interviews for their assigned contacts on a regular basis. The overall numbers of stakeholders contacted, as well as scheduled and completed interviews, are automatically generated. In particular, progress towards the target number of interviews per stakeholder group detailed in the inception report was monitored.

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.

Interviews per stakeholder type

Stakeholder type	No response	Completed	Total contacted
Economic operators	1	21	22
Conformity assessment stakeholders	2	18	20
Consumer association		3	3
Industry association	10	30	40
EU and national authorities	9	14	23
Legal experts & academics	2	1	3
Standardisation bodies	1	5	6
Grand Total	**22**	**92**	**117**

Online survey questionnaires. As part of the inception phase, online survey questionnaires were developed for both the targeted and public consultations. Through the initial stages of Phase 2, the targeted and public consultations were amended based on feedback from the Commission through the autumn, before being uploaded online and tested in November 2021.

- 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 laws. 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.

Beyond the stakeholder mapping exercise, the following measures were taken to ensure the targeted consultation reached as many relevant stakeholders as possible: i) liaise with relevant industry, consumer, and other associations to encourage them to share the survey with their members and partner organisations; ii) publish the details of the targeted consultation on the CSES LinkedIn page; and iii) send regular reminders to all stakeholders invited to participate. The Commission also supported this process by circulating the targeted consultation to relevant industry stakeholders through the European Enterprise Network (EEN).

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

- 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.

Mapping of legislative provisions. Building on the framework developed in the inception phase, the legal texts of all 23 NLF-aligned legislation were reviewed, alongside related evaluations, impact assessments and other studies, to further develop the mapping of legislative provisions across NLF-aligned directives and regulations. This focused on analysing the level of divergence or difference between the NLF reference provisions (Annex I to Decision No 768/2008/EC) and the provisions implemented in the 23 pieces of NLF-aligned legislation. More specifically, it examined the extent to which the definitions (Chapter R1); the obligations for economic operators (Chapter R2); the provisions on conformity of the product (Chapter R3); and the provisions on the notification of conformity assessment bodies (Chapter R4). The mapping is presented in Annex 7 and analysed in Chapter 4.1.1.1.

Interim report and interim report meeting: Phase 2 culminated in the submission of the draft interim report on 6th December 2021. Building on the data collection activities described above, the interim report presented the refined intervention logic for the NLF, before detailing the preliminary evaluative analysis across all evaluation criteria and preliminary conclusions. Project progress and the preliminary findings were presented and discussed with the Steering Group at an interim meeting on 10th December 2021. Meeting minutes were drafted following the meeting and quickly finalised with DG GROW. An updated interim report was submitted on 13th January 2022 and subsequently approved. Most oral and written feedback provided by the Steering Group was addressed in the updated version; however, it was agreed with DG GROW that a small number of comments that required significant additional research would be addressed in the final project phase. These outstanding comments were clearly recorded in an Excel document shared with DG GROW.

Phase 3 Progress: Final analysis and reporting

Phase 3 of the project began in December 2021 and ran until the submission of the final report on 29th March 2022. The following activities were conducted:

- **Finalising the Phase 2 data collection activities**. To address remaining data gaps, additional desk research and interviews were conducted. These efforts focused on addressing Steering Group feedback to the interim report and engaging certain stakeholder groups, primarily national authorities, who lacked representation in the core interview programme.
- **Targeted and public consultation summary analyses.** For both the targeted and public consultations, standalone summary reports have been developed. For each of these analyses, accompanying this report, an assessment of the profile of respondents is first provided, before a descriptive analysis of the results of the consultation by evaluation criteria is detailed. In addition, the results of both consultations have been incorporated throughout this final report.

- **Updating the evaluative assessments** and aligning the reporting structure with the updated Staff Working Document (SWD) structure. In addition to incorporating additional research based on feedback from the Steering Group, the results of the targeted and public consultation analyses have been incorporated into the assessments of all evaluation criteria and the analysis has been enhanced throughout by examples and four case studies. The evaluative assessments were further enhanced by comprehensive analyses of the NANDO database and Safety Gate data from 2005-2021.
- **Stakeholder validation workshop**. Delivered on 9th March 2022, the stakeholder validation workshop tested and validated the preliminary findings and conclusions of the evaluation. As agreed with DG GROW, the workshop was conducted online. A total of 46 external stakeholders participated in the workshop covering all key stakeholder groups.
- **Reporting.** A draft final report was submitted on 2nd February 2022 and was followed shortly by a Steering Group meeting on 10th February and the stakeholder validation workshop. Building on the feedback from the draft final report meeting and the validation workshop, as well as incorporating additional evidence, such as the results from the analysis of the public consultation, the final report was developed and submitted on 29th March 2022.

Conceptual evaluation challenges

In addition to the practical challenges highlighted above, there are a range of conceptual challenges related to the evaluability of the NLF that are important to consider and that are specific to this project. These challenges primarily exist because of the NLF's horizontal nature and include:

Limited new elements in the NLF. The NLF builds on the existing long-established regulatory regime built up over three decades, since the advent of the New Approach in 1985. As a result, the NLF is primarily concerned with ensuring greater harmonisation across EU product legislation and preventing the emergence of divergence in order to ensure greater overall coherence and consistency across the applicable body of EU legislation. Except for the new accreditation framework for notified bodies, the alignment of administrative requirements between legislation and the introduction of common definitions and requirements for economic operators, the majority of the NLF built on, and reinforced what already existed (e.g. by reinforcing awareness of CE marking requirements, reinforcing implementation of the technology-neutrality principle).

Therefore, as detailed in Chapter 4.1 and Annex 7, the mapping of legal changes to the NLF in individual pieces of legislation reveals that only minor changes have been implemented, and that the added value of the NLF is more subtle, being derived from having a more common, coherent, and consistent approach rather than anything new *per se.* For instance:

- Considering the **menu of conformity assessment modules**, the NLF brought pre-existing provisions together in a more coherent way. The menu of modules provides a more structured approach in the form of a regulatory toolbox, but when individual directives and regulations were recast and aligned to the NLF, this did not necessarily mean that the conformity assessment modules used in individual pieces of legislation changed. Indeed, they remained the same.
- Considering the **reference provisions,** the process of recasting product legislation through NLF-alignment often only involved the inclusion of new horizontal text applicable across all Union harmonisation legislation, but did not require substantive changes to the legislation itself.

Therefore, **assessing and attributing the key achievements and impacts of the NLF, as well as establishing clear causal chains between these achievements and the provisions of the NLF requires some subtlety and poses a challenge** from an evaluation perspective. More specifically, the complex interplay between the contribution made by the NLF to achieving some of its objectives, and the role

played by individual pieces of harmonisation legislation raises the question of attribution (i.e. whether certain effects, including costs and benefits, can be directly attributed to the NLF, as opposed to the impacts associated with the implementation of individual pieces of sectoral Union harmonisation legislation applicable to products).

Although the distinction between the two will not always be clear-cut, there are some general and specific objectives in the NLF, especially in Decision No 768/2008/EC, such as putting in place a common horizontal toolbox for EU regulators, that were new, and which were addressed to EU regulators responsible for recasting existing and drafting new Union harmonisation legislation. Such examples will be easier to assess as they were new and introduced directly through the NLF.

However, if there were not that many perceived changes to individual pieces of legislation, it may be more difficult for stakeholders to identify the value added and impacts resulting from the NLF-alignment of specific pieces of legislation. Rather, it is the common horizontal approach itself and the making of minor incremental changes, such as aligning administrative differences between legislation that could have had a positive impact, led to reduced costs for industry and individual economic operators, or resulted in other notable impacts. In other words, some of the NLF's inherent value added stems less from what was new, and more from how the common regulatory approach required EU regulators to maintain a common and consistent approach, and how divergence in sectoral legislation was actually resisted (as whilst the general principles of the NLF are robust), there may be occasions when the regulator identifies the necessity to diverge from the NLF.

A related issue is how far the NLF has been able to cope with the increased pace of regulatory changes due to digitalisation and the circular economy, which have resulted in a number of recent regulatory proposals, which may diverge either somewhat or even significantly from the NLF as conceived in 2008 in order to recognise new market realities. Examples are the Machinery Regulation Proposal (April 2021), the GPSR Proposal (June 2021) and the proposed horizontal Regulation on AI of 2020. This in turn raises questions regarding the NLF's ongoing fitness for purpose and whether it needs to be revised and reframed in future in order to remain relevant.

To address this challenge, as discussed with the DG GROW, we have conducted a legal mapping exercise to ensure the changes resulting from the NLF, and any related divergence from the NLF, are clear. This mapping exercise is presented through Chapter 4.1.1 and Annex 7 and ensures the analytical tasks are based on a clear understanding of the differences made by the NLF.

Evaluation matrix

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 market for economic operators? (Regulation (EC) 765/2008)	• 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 easier to implement;	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	• 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
• 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)?	• 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	different pieces of legislation (using NLF as the common framework) • Context indicator – evolution in market size and structure across product legislation aligned with the 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 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?	• 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 European internal market; and • Increased quality of the conformity assessment services	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
• 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**?				
• 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	• 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
		• Perceptions on their impact on the achievement of the objectives of the NLF		
• 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 • 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 product legislation	• 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	• 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
		• 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		
• 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.[127]	• 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,	• Survey (targeted) and interviews with economic operators and industry associations • RAPEX • EU - European Injury Data Base (IDB) • Desk research	• Qualitative assessment of 'efficiency' criterion • Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

127 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
	• Greater reliability in the quality of the conformity assessment services provided by notified bodies • Rules on requirements for the 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.	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 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.)	• Eurostat data on cross-border trade in 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**?	• Cost of NLF implementation in terms of human and financial resources	• Preparing the documentation and	• Desk research • Survey (targeted) and interviews with economic	• Triangulation with the number of reported accidents or injuries for

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
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 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?	• 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 • 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…)	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	operators and industry associations • Budget spent on market surveillance vs. size of the population • Survey of European/ national standardisation bodies	certain NLF regulated products. • Sectoral CBA and Societal CBA
• How far do current conformity assessment procedures and the role of NBs guarantee product compliance, without creating any disproportionate costs?	• Proportionate cost of conformity assessments • Extent of product compliance • Availability of relevant and updated information on applicable legislation, procedures and standards	• Average time and cost for producers to ensure conformity of equipment • Number of products being rejected by notified bodies due to failing conformity assessments • Number of non-compliant products withdrawn from	• Survey and interviews with economic operators and industry associations • Desk research RAPEX reports • ICSMS database • Survey of Notified Bodies (e.g., incl. product	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
		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	blacklists on their own web sites	
• 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	• 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
		NBs, including for those that mostly 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 regulatory compliance aspects) along industry value chains?	• 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
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 • 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	• 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
• To what extent has the NLF allowed for technological, scientific, environmental and social developments? *Sub-questions:* 1. 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 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	• The features of the NLF are considered appropriate to apply to e.g.: ○ evolutive products during their lifetime ○ products resulting from distributed design software	Perception of stakeholders as to 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.	• Desk research • 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
close interactions between manufacturers, service providers and software and apps developers both in product development and post-market placement)?		• Number and type of manufacturing practices that may impact the NLF features.		
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 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)?	• 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
How far does the lack of a specific crisis instrument make the NLF less effective or efficient? Sub-questions:	• 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	• Survey (targeted) and interviews with economic operators and industry associations, especially in the medical device and	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
• 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 on cybersecurity)?		• 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	personal protective equipment sectors • Survey of European/ national standardisation bodies	
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	• 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	• 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
business models where products are placed on the market 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?		• Perceived regulatory certainty by economic operators		
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 compared to what could have been achieved at merely national level?	• Stakeholder perceptions on counterfactual considerations relating to added value.	• Estimated costs saved by complying with a harmonised regime over several national regimes.	• Survey (targeted) of economic operators and industry associations	• Qualitative assessment of EU value added

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
• 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?	• 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.	• 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		• 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 essential requirements and identified needs	• Survey (targeted) and interviews with economic operators and industry associations	• Descriptive statistics analysis • Case studies • Contextual multi-stakeholder analysis of perceptions
• 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	• Survey (targeted) and interviews with economic	• Contextual multi-stakeholder analysis of perceptions

Questions	Judgement criteria	Indicators	Data and information sources / evidence base	Assessment methods
		costs of the enforcement activities) • Difference in the enforcement costs by MS • Trends of internal market trade and exports	operators and industry associations	

Annex 3: 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 cost of creating one	**0**	The approximate cost of creating one standard was estimated at approximately 1 million Euro. This cost is financed by	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
					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.		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 (continuous	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 the Italian body

Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		[Other]	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
monitoring costs, maintenance fee)									(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
Indirect benefits									
Increased safety, health, and reduced	Recurrent	**Not quantifiable**	Benefits deriving from the reduction of differences in the activities carried out	N/A	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
environmental damages			by the notified bodies (thanks to the NLF).						
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 a 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								
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	**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

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
						savings should be passed on to CABs. Potential additional costs related to developing / familiarisation with new guidance / standards on remote techniques.		developing guidance and standards related to remote assessment techniques.

Annex 4: 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 Union harmonisation legislation (UHL) 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 law through examples of industrial products falling under both Union harmonisation legislation (UHL) 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 UHL 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	UHL-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 Contact Materials

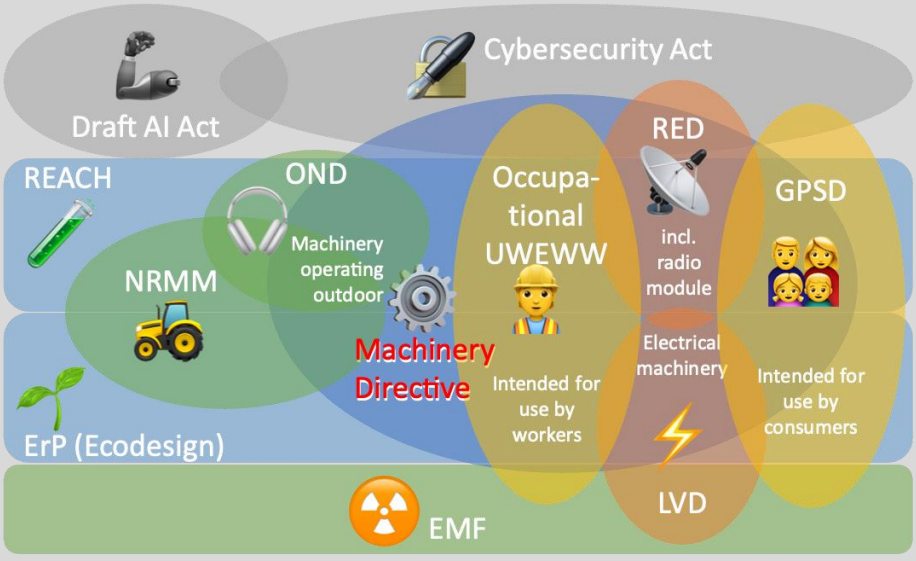
Type of products	UHL-NLF	Other Union legislation
Appliances for cooking, heating, hot water production, refrigeration, lighting and washing	Regulation (EU) 2016/426 on appliances burning gaseous fuels	
All wireless appliances	Radio Equipment directive RED (2014/53/EU)	
Refrigerating appliances		F-gas 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**: APPLiA and authors*

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 draft Regulation to replace the Directive has been put forward (cf. below figure).



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)[128], 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[129].

Machinery Directive vs. workers' protection: In the Guide to the application of the Machinery Directive (MD)[130], 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)[131], "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 framework and "*cause unnecessary costs and burdens*" to manufacturers.

[128] https://www.cema-agri.org/index.php?option=com_content&view=article&id=710&catid=21&Itemid=212

[129] European Commission, (2019), Cost-benefit analysis study for impact assessment on road circulation of non-road mobile machinery.

[130] Guide to application of the Machinery Directive 2006/42/EC, Edition 2.2 – 2019 (Update of 2nd Edition)

[131] European Commission, (2020), Impact Assessment report on the revision of Directive 2006/42/EC on machinery (08/2020)

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 UHL 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 to ensure 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 and the relevant harmonised standards cited in the *Official Journal of the EU* (OJEU). These other elements all have an impact on the performance of the accreditation framework:

- **Conformity assessment modules**: Annex II to Decision No 768/2008/EC details the conformity assessment modules. These modules are incorporated into and implemented through NLF-aligned legislation. The modules are relevant to this case study as they detail the product compliance checks to be conducted by NBs.
- **Rules on notification of CABs**: Annex I to Decision No 768/2008/EC provides reference provisions on notification of CABs (Chapter R4). As for the conformity assessment modules, these rules are then incorporated into and implemented through NLF-aligned legislation. In particular, Article R17

details requirements relating to notified bodies (NBs). NABs evaluate the fulfilment of these requirements through the accreditation process.

- **Harmonised standards**: 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"[132]. 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.[133]

  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 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

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

Accredia's online databanks.

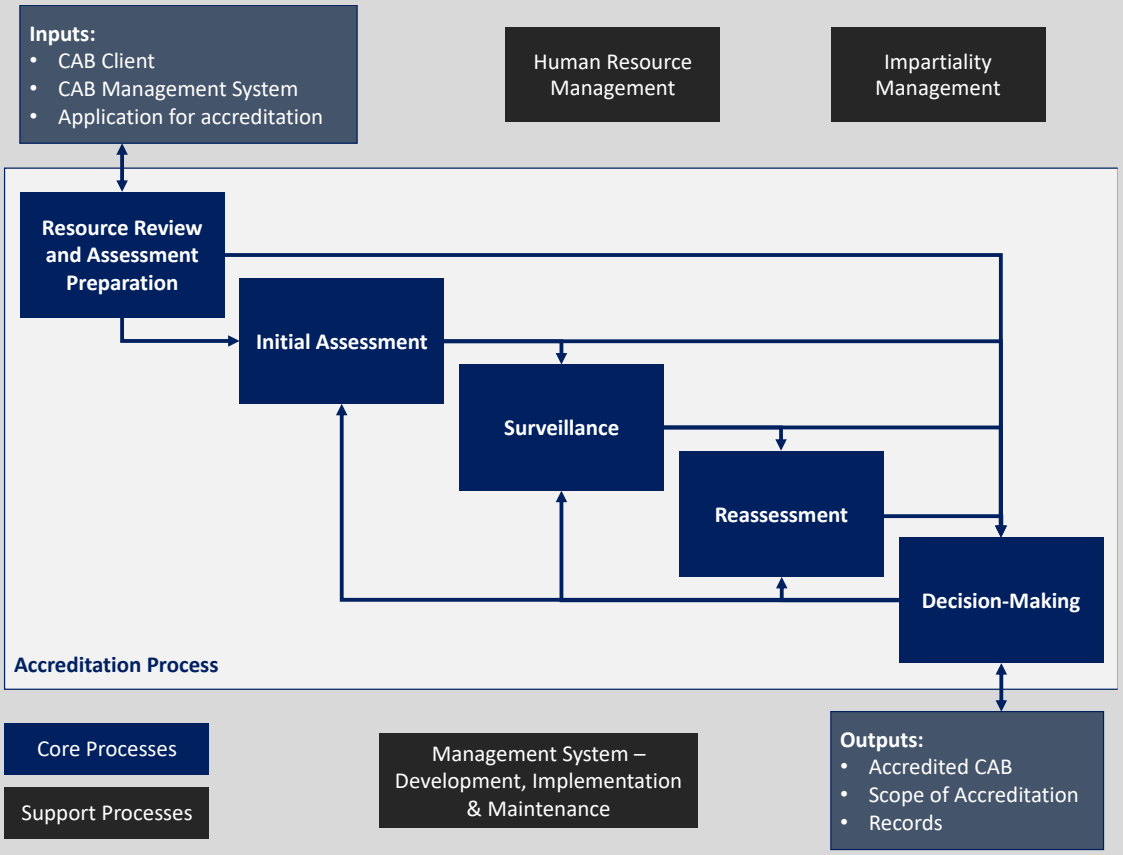
The key output of the initial assessment is an accredited CAB with a clear scope, and comprehensive records of the CAB and the accreditation assessment.

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.[134]

- **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.

Illustration of a typical accreditation process



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

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

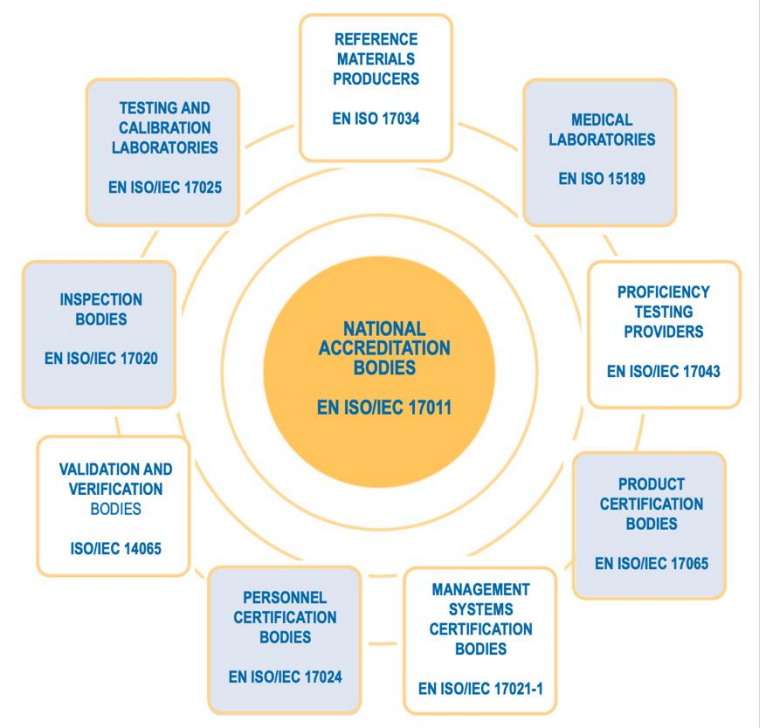
Analysis and stakeholder feedback: Although the approach to the process of accreditation is well understood and established through Regulation (EC) No 768/2008 and EN ISO/IEC 17011, stakeholders have highlighted related challenges that can impact the effectiveness and efficiency of the accreditation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

ii) Descriptions of conformity assessment activities and procedures in the suite of conformity assessment modules and aligned UHL, 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.

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.



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 UHL 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"[135].

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

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

pieces of UHL. 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 UHL 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.

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. This practice of 'forum shopping' can thus result in variable competence across CABs and unfair competition.

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.

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).[136] 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

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

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 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.

Type of cost	Name of cost	Relationship with NLF
		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**.
	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: *Authors.*

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	Can be **partially attributed to the NLF**.

Type of benefit	Name of benefit	Relationship with NLF
	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	
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: *Authors.*

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)[137] 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.

[137] European Commission, SWD(2020) 287 final.

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 and supply chain information, translation of product documentation).	As defined in the evaluation, the cost related to technical documentation can be **partially attributed to the NLF**.
	Other costs borne by manufacturers: a) Purchasing standards. b) Testing of raw materials and testing of 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: *Authors.*

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: *Authors.*

Annex 5: International accreditation standards

Many stakeholders referred to the importance of international standards for harmonising the accreditation procedures of testing laboratories, conformity assessment bodies and inspection bodies. The main international standards on accreditation, as developed and updated by ISO and IEC, are detailed in the following table.

Standard and title		Description
ISO 15189 (Accreditation) Second edition 2012-11	Medical laboratories — Requirements for quality and competence (ISO 15189:2012)	This International Standard specifies requirements for quality and competence in medical laboratories. This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies. The related European standard EN ISO 15189:2012 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17020 (Accreditation) Second edition 2012-03-01	Conformity assessment — Requirements for the operation of various types of bodies performing inspection	This International Standard contains requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities. It applies to inspection bodies of type A, B or C, as defined in this International Standard, and it applies to any stage of inspection. *NOTE The stages of inspection include design stage, type examination, initial inspection, in-service inspection or surveillance.* The related European standard EN ISO/IEC 17020:2012 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17021-1- (Conformity assessment) Second edition 2015	Conformity assessment — Requirements for Bodies Providing Audit and Certification of Management Systems	This part 1 of ISO/IEC 17021 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems. Certification bodies operating to this part 1 of ISO/IEC 17021 do not need to offer all types of management system certification. Certification of management systems is a third-party conformity assessment activity (see ISO/IEC 17000:2004, 5.5) and bodies performing this activity are therefore third-party conformity assessment bodies. *NOTE 1 Examples of management systems include environmental management systems, quality management systems and information security management systems.* *NOTE 2 In this part 1 of ISO/IEC 17021, certification of management systems is referred to as "certification" and third-party conformity assessment bodies are referred to as "certification bodies".* *NOTE 3 A certification body can be non-governmental or governmental, with or without regulatory authority.* *NOTE 4 This part 1 of ISO/IEC 17021 can be used as a criteria document for accreditation, peer assessment or other audit processes.* The related European standard EN ISO/IEC 17021-1 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17024 (Conformity assessment) 2012 Edition	Conformity assessment — General requirements for bodies operating certification of persons	This International Standard contains principles and requirements for a body certifying persons against specific requirements, and includes the development and maintenance of a certification scheme for persons. The related European standard EN ISO/IEC 17024:2012 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17025 (Accreditation)	General requirements for the competence of	This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

Standard and title		Description
Third edition 2017-11	testing and calibration laboratories	This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel. Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories. The related European standard EN ISO/IEC 17025:2017 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17043 (Conformity assessment) First edition 2010-02	Conformity assessment - General requirements for proficiency testing	This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application. The related European standard EN ISO/IEC 17043:2010 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.
ISO/IEC 17065 (Conformity assessment) First edition 2012-09-15	Conformity assessment— Requirements for bodies certifying products, processes and services	This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000:2004, definition 5.5). The related European standard EN ISO/IEC 17065:2012 is harmonised and cited in the OJEU under Regulation (EC) No 765/2008.

Annex 6: Analysis of Safety Gate data

The Safety Gate system, formerly known as the Rapid Exchange of Information System (RAPEX), is the EU's rapid alert system for sharing information between national authorities on measures taken against dangerous non-food products. The system operates as follows:

- When a national authority in an EU Member State or EEA/EFTA country adopts measures against dangerous products placed 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**: This field contains information on the identified defect, the risk associated to it and the applicable legal provisions. 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 often also contain a description of the risk identified and the relevant harmonised standards. 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 law 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[138]. These factors strongly influence both the number of non-compliant products identified and reported via Safety Gate, and their proportion by product category from one Member State to another.

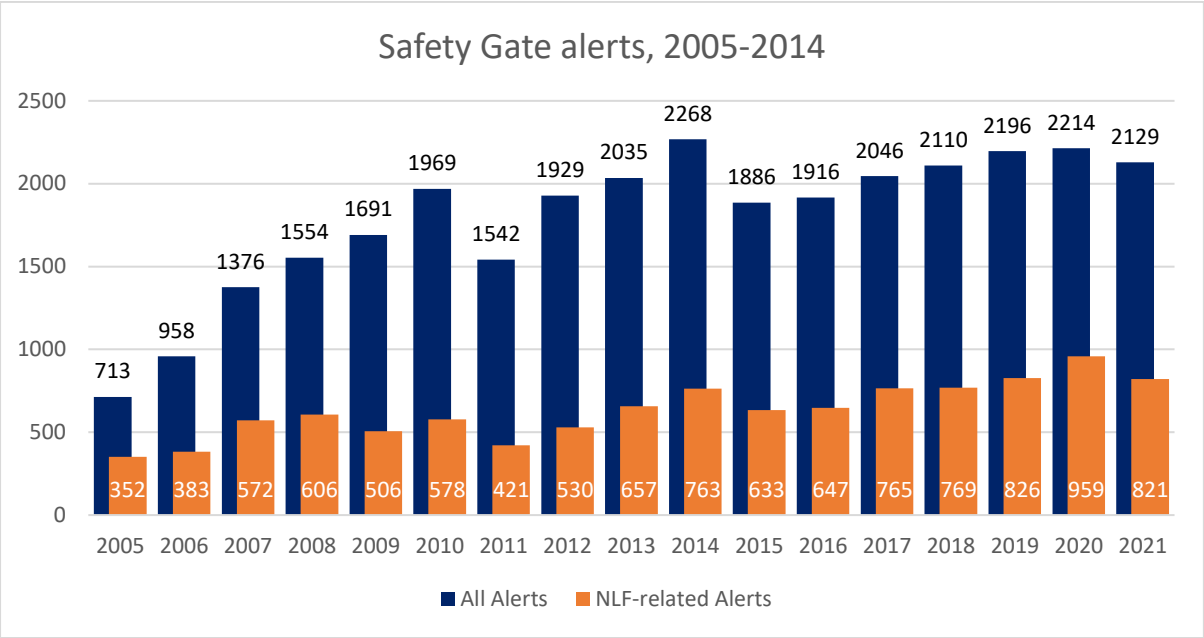
These external factors, as well as others, **significantly restrict the ability of the analysis to attribute or link any product safety trends identified to the NLF**. As a result, this analysis will focus on providing contextual descriptive statistics, highlighting this caveat where relevant.

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 non-compliant 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.

[138] SWD(2013) 33 final of 13.2.2013, Commission staff document on an impact assessment accompanying the document "Product Safety and Market Surveillance Package"

Total number of Safety Gate alerts and NLF-related alerts, 2005-2021

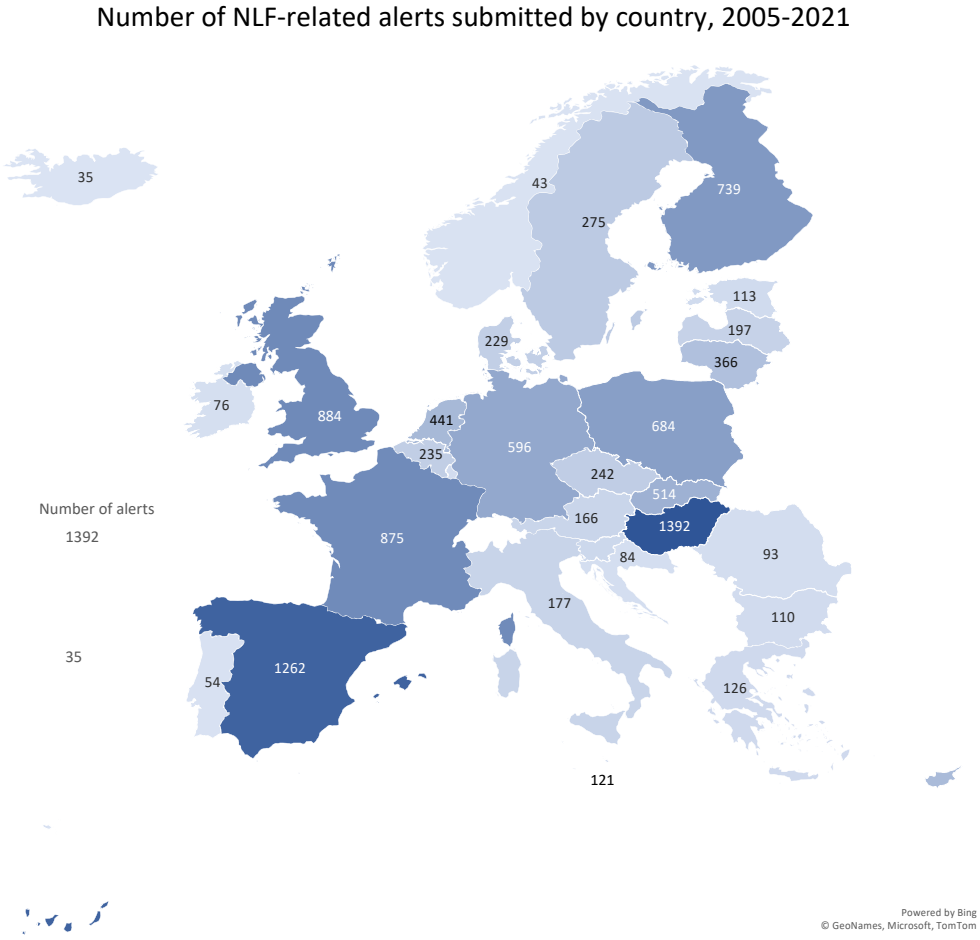


For each NLF-related alert, the **reporting national authority** and the product's **country of origin** are also recorded. As illustrated in the below map, the countries that most commonly report products with clear reference to NLF-aligned legislation or its predecessor laws in the period 2005-2021 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. 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.

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.

Top 10 countries of origin – NLF-related alerts, 2005-2021

	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

	2005-2013	2014-2021	Total
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**

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).

Number of NLF-related alerts, by risk type

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**

Disaggregated analysis by NLF-aligned law

Of the 23 NLF-aligned laws, 16 are directly referenced in Safety Gate alerts. These include both current NLF-aligned laws and their non-aligned predecessor laws (for instance, the Radio Equipment Directive and the Radio Equipment & Telecommunications Terminal Equipment Directive are both referenced).

The below table lists these laws, 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 references laws 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 laws on PPE (629 over this period). Other regularly referenced laws 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 non-compliance 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 laws.

Number of alerts per NLF-aligned legislation, pre- and post-NLF-alignment

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**

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 laws 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 laws (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 7: 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 laws. 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 Directive	Article 20-22 - significant variation in required modules based on product type and other aspects	No difference in definitions of traditional economic operators Novel definition of “private importer”	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 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).

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)
	Article 23 – Additional novel module for post-construction assessment (Module PCA)		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) / 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)	Minor differences: e.g. "intended use"; Manufacturer is a person who either markets the designed product or uses it for own purposes.	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 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.

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)
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 Regulation	Article 52 – as for the *In Vitro* Diagnostic Medical Devices Regulation. CA procedures set out in Annexes 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.

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)
			- 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" - 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)	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

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)
	Cat 3 - Module B (Annex V) + C2 (Annex VII) / D (Annex VIII)		- 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 and Electronic Equipment Directive	Minor differences (e.g. location of Art 16(1) text is different from other laws); no difference on DoC	No	Minor differences: e.g. Art.9 RoHS compared to Article R4; and Art.9(e) refers to keeping a register of non-compliant 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 laws, 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'

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)
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 laws)	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 laws); 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 laws)	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'
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 laws)	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 laws)	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'

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)
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 laws) 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 laws)	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 laws; 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 intended)	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*
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 laws)	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 laws); 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.'

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)
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 possibility of products being subject to multiple laws)	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'
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 laws; 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 laws; possibility for delegated acts)	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

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)
	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.)		
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 laws) 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 laws, 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 laws)	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'

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