BUSINESSEUROPE

COMMENTS

18 February 2022

NLF Evaluation: Public Consultation

KEY MESSAGES

- The NLF is the best and most efficient framework to enhance compliance and support the integration of the Single Market, and it is still broadly effective in achieving its objectives.
- The challenges identified are mainly due to implementation issues rather than to the NLF concept itself, i.e., deficiency in enforcement, inconsistent use of NLF principles across legislations and the back log of harmonised standards.
- Targeted adjustments should aim at fostering the development of an even stronger platform for the integration of the internal market for products, including, promoting the use of digital labelling, clarifying allocation of responsibilities in modern supply chains through a well-defined concept of substantial modification, and improving transparency and competences of notified bodies.
- The integration of an additional crisis instrument for emergency situations could be considered, however, we need to clarify a) if the NLF is the right place for such an emergency mechanism, and b) if strict and clear criteria defining such situations and applicable conditions therein are possible to define.
- It is crucial to maintain and preserve fundamental principles of NLF, as their implementation and enforcement:
  - NLF legislation should remain technology neutral.
  - The separation of essential health safety requirements (in legislation) from voluntary and state-of-the art harmonised standards.
  - Economic operators are responsible for the compliance of their products and for providing accurate, complete, and compliant information regarding their products.
  - Conformity assessment procedures should follow the specified modules and be chosen in accordance with appropriateness, and type and degree of risk, as laid down in Decision 768/2008/EC.
  - The conformity assessment procedure is carried out before the product is placed on the market and considers intended use and reasonably foreseeable misuse.
  - In the context of a modification the party carrying out the modification should assess whether the modification is substantial.

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COMMENTS

PERFORMANCE OF THE EU LEGAL FRAMEWORK FOR PRODUCT-EFFECTIVENESS

1. To what extent has the NLF been effective in its contributions to achieving the following objectives of EU product legislation, through providing a common regulatory toolbox to be applied across all different product laws, establishing a framework for the accreditation of notified bodies, and reinforcing the rules on CE marking?

	Very effective	Somewhat effective	Neither effective nor ineffective	Somewhatineffective	Very ineffective	Don' t know
* Reinforcing a highlevel of protection of public interests (e.g., health and safety, consumer and environmentalprotection)	X					
* Reinforcing the free movement of products within the single market	X					

2. To what extent has the NLF performed well or faced challenges in relation to the following issues:

	Strong performance	Performing well, but some challenges	Strong challenges	Don' t know
* Improving the regulatory alignment of EU product legislation	X			
* Introducing clear and transparent rules for the accreditation of conformity assessment bodies		X		
* Strengthening the clarity and credibility of the CE marking system		X		

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* Reinforcing the technology-neutral approach to setting essential requirements	X	○	○	○

3. To what extent has the NLF had a positive or negative impact on the following?

	Very positive	Positive	Neutral	Negative	Very negative	Don't know
Regulatory certainty and ease of compliance with EU product legislation	X	○	○	○	○	○
Compliance levels and product safety	X	○	○	○	○	○
Quality and consistency of conformity assessment services provided by notifiedbodies		X	○	○	○	○
Product innovation	X	○	○	○	○	○
EU's industrial competitiveness	X	○	○	○	○	○
Global importance and relevance of EU productlegislation	X	○	○	○	○	○

Please identify and explain any challenges, negative impacts, or unintended consequences stemming from the NLF:

The main issues that we have identified are mainly related to deficiencies in enforcement of the NLF. For example, Businesses are often confronted to different competences and qualifications of notified bodies across the EU, leading to different interpretation and use of standards across the EU, non-acceptance of test reports issued by inhouse test laboratories, and different quality levels. Although part of the challenges relates to a lack of enforcement, there is a need to ensure further alignment of notified bodies and to strengthen their competences. We recommend strengthening enforcement at national level by Market Surveillance authorities and investigating the untapped potential of other tools that are being used to improve competences of notified bodies, e.g., guidelines

from the European Accreditation or documents developed under the auspices of the Groups of Notified Bodies (GNB) for specific EU-harmonization regulations. European accreditation system could also be strengthened through more harmonization and definition of uniform minimum standards. However, this should be done in a proportionate manner and not become a cost driver or invoke even higher requirements for the manufacturers.

CE MARKING AND INFORMATION OBLIGATIONS

4. To what extent do you agree with the following statements?

	To a great extent	To a moderate extent	To a small extent	Not at all	Don't know
* The meaning of the CE marking is clear	○	X	○	○	○
* The CE marking is a trustworthy indicator thata product will function safely and as intended	X	○	○	○	○

5. To what extent do the following general information obligations remain necessary and appropriate?

	To a great extent	To a moderate extent	To a small extent	Not at all	Don't know
* Affixing the CE marking visibly and indelibly on theproduct	○	○	X	○	○
* Affixing other traceability information visibly and indelibly on the product (e.g. postal address of the manufacturer / importer)	○	○	X	○	○
* Providing paper copies of product information (e.g., safety documentation, instruction manuals)	○	○	○	X	○

6. To what extent would providing the following information in a digital form positively or negatively impact consumers?

	Very positive	Positive	Neutral	Negative	Very negative	Don't know
* CE marking	X	○	○	○	○	○
* Other traceability information (e.g. postal address of the manufacturer / importer)		X	○	○	○	○
* Other traceability information (e.g. postal address of the manufacturer / importer)	X	○	○	○	○	○

EFFICIENCY OF NLF

7. Please indicate the scale of the most important costs stemming from the conformity assessment procedure established by the NLF? (Note – this should exclude the costs of compliance with individual sectoral / product legislation, and ONLY relate to the NLF).

	Very high	High	Moderate	Low	Very low	Don't know
* Costs of purchasing standards	○	○	○	X	○	○
* Overall costs of conformity assessmentprocedure	○	X	○	○	○	○
* Costs of performing laboratory test(s)	○	X	○	○	○	○
* Costs of keeping and updating technical documentation and EU declaration of conformity	○	○	X		○	○
* Costs of involvement of notified bodies	X	○	○	○	○	○

Please identify and provide further detail on any other costs not listed above

The non-acceptance of test reports issued by manufacturers inhouse test laboratories by either Notified Bodies or Market Surveillance Authorities does create problems and results in additional costs and delays time to market.

8. **Please indicate the scale of the costs and burdens experienced by your organisation resulting from the introduction of the accreditation framework for conformity assessment bodies:**

NO response.

To what extent have the following benefits been achieved as a result of the NLF?

	Strong benefits	Some benefits	Neutral	Some dis-benefits	Strong disbenefits	Don't know
* Cost savings due to facilitated familiarisationwith different EU legislation (e.g. due to common definitions, reduced market fragmentation etc.)	X	○	○	○	○	○
* Cost savings in the process of demonstrationof conformity across different EU product legislation	X	○	○	○	○	○

Please identify and provide further detail on any other benefits/disbenefits not listed above:

BusinessEurope considers that the NLF is broadly fit for purpose and able to address new aspects of a digital environment and green policy objectives. As a technological-neutral regulatory framework based upon essential-requirements it is well suited to cope with the higher speed of technical innovation and degree of customization coming with digitization, avoiding the stiffness and in flexibility of technical provisions fixed in laws. Options such as module A are well equipped to accommodate digitally enabled modifications through a relatively lean and fast process. This not only lowers costs, but also reduces time to market for innovations.

The NLF is also an ideal lever for Europe to enhance its global competitiveness: EU institutions set safety and health requirements for products and services. The technical content of these requirements is left to industry experts and stakeholders. The result is harmonised standards throughout Europe. As a result, the NLF gives companies producing in the European Union a global competitive advantage. In accordance with the principle of "one standard, one test, accepted everywhere", products can be freely marketed throughout the single market.

To summarise, the NLF has been very effective in terms of putting in place common definitions and obligations for economic operators. It has enabled:

- High level of protection of public interests (e.g., health and safety, consumer and environmental protection)
- Strengthened CE marking use and functioning
- Costs savings in familiarisation with legislation due to common definitions.
- Cost savings in conformity assessment activities due to greater coherence between legislations
- Administrative simplification
- Legal certainty
- Better functioning of the internal market in terms of movement of goods due to the reduction of market barriers brought by the NLF.

RELEVANCE

9. To what extent do the following objectives of the EU legal framework for products remain relevant?

	To a great extent	To a moderate extent	To a small extent	Not at all	Don't know
* Improving the regulatory alignment of productlegislation	X	○	○	○	○
* Ensuring clear and transparent rules for the accreditation of conformity assessment bodies	X	○	○	○	○
* Improving the quality and consistency across the EU of conformity assessment services provided by notified bodies	X	○	○	○	○

* Creating a level playing field among operators	X	○	○	○	○
* Strengthening the clarity and credibility of the CE marking system	X	○	○	○	○

10. To what extent has the lack of a crisis instrument rendered the NLF less effective in supporting the fight against the COVID-19 pandemic? (For example, due to delays in placing products on the market, which are essential for personal protection).

To a moderate extent

IMPACT OF DIGITAL AND CIRCULAR ECONOMY TRENDS

11. To what extent is the NLF able to accommodate the following trends due to its technology-neutral approach?

	To a great extent	To a moderate extent	To a small extent	Not at all	Don't know
* Increasing servitisation of products	X	○	○	○	○
* Increasing complexity and interconnectedness of products (e.g., Internet of Things)	X	○	○	○	○
* Increasing cyber risks	X	○	○	○	○
* More frequent changes to products post market placement (e.g. due to software updates and up-grades, the integration of AI technologies andma-chine learning)	○	X	○	○	○
* Increasing product refurbishment andremanufac-turing	○	X	○	○	○
* Emergence of new types of economic operators due to new models of production and increasing value chain complexity	○	X	○	○	○

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COHERENCE

12. To what extent are the provisions of the NLF coherent with one another? In particular, whether Decision 768/2008/EC containing a model to be used in preparing and revisiong Union harmonisation legislation is coherent with Regulation 765/2008/EC applicable to accreditation and CE marking.

Coherent

13. Please identify and explain any incoherencies or inconsistencies between the NLF and other EU legislation that may apply simultaneously or in complementarity with NLF-aligned legislation.

Inconsistent implementation of the NLF concepts in existing and new legislation and between the harmonised and non-harmonised sectors remain an important issue. Indeed, increasingly the definitions of important NLF concepts (e.g., placing on the market) and definitions (e.g., economic operators) are not used consistently in the most recent product legislation, including the GPSR, DSA, AI Act, Single-Use Plastics Directive, Construction Product Regulation, Batteries Regulation, among others. While the NLF allows deviations, the increasing lack of coherence has a negative impact on compliance and adds unnecessary costs and burden on businesses due to overlaps and conflicting requirements. New legislative proposals should be aligned with NLF principles and not create conflicting or competing frameworks to the NLF.

Thus, when proposals for new Union harmonization legislation are presented to the Scrutiny Board, an evaluation of the alignment with the NLF principles should be required. Co-legislators should always duly justify divergence from NLF principles, or at least clarify how new definitions may interfere with other NLF legislation, for example by the means of explanatory recitals or guidance. Some specific examples:

- The GPSR proposal includes disproportionate and inconsistent requirements for economic operators concerning internal safety control processes, quality management, placing on the market, traceability, etc. It also includes additional requirements for market surveillance as compared to what included in Regulation 2019/1020.
- Based on 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 Single Use Plastics 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 3 July 2021. This narrow interpretation is inconsistent with the NLF and will further fragment the single market and the cross-border provision of goods/services.

- The AI Act and the Machinery Regulation introduce the concept of “high risk” products, which is not in line with NLF. This concept of “high-risk” will notably determine whether a product needs to undergo a third-party conformity assessment process. This is not aligned with the well-established NLF modules for conformity assessment.
- Different definitions of cybersecurity features are currently included in different pieces of legislation or proposed legislation (ENISA cybersecurity act, proposal NIS 2 Directive, AI Act and GPSR). We believe cybersecurity products should be regulated through the introduction of a horizontal legislation on cybersecurity for networkable products which would follow the NLF principles. This would ensure a coherent regulatory framework.
- The creation of parallel approaches to harmonised standards, i.e., Implementing acts, codes of conduct or legislative and other related technical specifications, by the European Commission should be avoided wherever they are intended to replace standards, as they undermine the NLF basic principles. Such an alternative approach would be only acceptable, when used exceptionally and under strict and clear criteria, in reference to topics for which standardisation is not appropriate.

EU ADDED VALUE

14. In your view, to what extent has the NLF delivered added value compared to what could have been achieved through the development of product legislation without the NLF?

High-added value.