



## *The New Legislative Framework (NLF) evaluation: provisional comments*

### KEY MESSAGES

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- BusinessEurope considers the NLF as great success and a key instrument of a functioning Single Market, broadly fit for purpose and able to address new aspects of a digital environment and green policy objectives, therefore it is crucial to preserve the existing concepts and strengths of the NLF.
- While in the light of modern supply chains the present assessment of the NLF is timely, and if targeted adjustments are absolutely necessary, BusinessEurope considers that any action should strictly follow the principles of better regulation.
- The basic NLF principles of separation of the essential requirements laid down in product legislation, on one hand, and description of their technical realization according to the state of the art in product-specific voluntary standards, on the other, should be preserved; for the framework to bring benefits to businesses and society at large, the NLF assessment should seize this opportunity to urgently revise the Commission's practice of treating harmonized standards as part of the EU law.

### CONTEXT AND GENERAL REMARKS

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On 4 November 2020 the European Commission published its Roadmap for evaluation of certain aspects of the New Legislative Framework (NLF - Decision No 768/2008/EC and Regulation (EC) No 765/2008). The NLF has served to improve the Single Market for goods, boost the quality of conformity assessment of products and frame the market surveillance system across the EU.

Given the evolving technological landscape as well as new policy initiatives such as digital and green transitions, the NLF evaluation seeks to assess whether it remains fit for purpose in a digital and circular economy, focusing on:

- soft- and hardware updates & upgrades
- refurbishment & repairs
- conformity assessment & accreditation

The main purpose is to bring forward an informed analysis of the current performance of the NLF on the mentioned aspects and based on the Commission's questions outlined in the section of our comments, with the exception of the provisions of the Regulation (EC) No 765/2008 relating to market surveillance, which were already subject to an evaluation and resulted in the new [Market Surveillance Regulation EU/2019/1020](#).



In general, BusinessEurope considers the NLF as great success and a key instrument of a functioning Single Market, broadly fit for purpose and able to address new aspects of a digital environment and green policy objectives. The framework does not only enable companies to produce and sell easily throughout the EU and the European Economic Area (EEA) but also gives those producing in the EU a competitive advantage globally.

Therefore, it is crucial to preserve the existing concepts and strengths of the NLF to the greatest extent possible. If targeted adjustments are absolutely necessary, it is imperative to act strictly following the principles of better regulation. Any possible NLF adjustment should not disrupt the Single Market or distract from the key priority of improving uniform implementation and enforcement of harmonised rules through a strengthened market surveillance system. BusinessEurope highlights the need to strengthen market surveillance not only within the EU but also at our external borders; the guidance on implementation of Regulation (EU)2019/1020 is necessary in this regard.

BusinessEurope calls on the Commission to pursue a holistic approach to ensure consistency and alignment across the NLF evaluation, the upcoming strategy of European standardisation, and potential review of sectorial legislation. Furthermore, BusinessEurope considers there is a need to ensure that any other future product legislation is aligned with the NLF principles.

## COMMENTS *whether:*

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1. *the NLF is fit to address the way products may be changing during their lifetime to both support the take-up of smart connected or remanufactured products and to ensure safety;*
  - First and foremost, BusinessEurope considers this question as a very wide one and requiring more detailed elaboration to ensure that all relevant parameters are captured. In this regard, our provisional comments will be supplemented in the upcoming months.
  - BusinessEurope acknowledges 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. Technology also drives mass customization, which is not a digital phenomenon only but increasingly applies to physical products. This potentially changes the way risk assessment is done.
  - Technology changes and introduction of new product and services categories alongside new business models have an impact on relationships among different economic actors. Subsequently, it calls for clarification of the division of responsibilities in the modern value chain to ensure trust and fair competition on the market while the NLF principles themselves should be preserved.
  - Therefore, in the light of modern supply chains the present assessment of the NLF seems timely. Since the NLF has a function of a role model for several sectorial directives which are also currently under evaluation, it should be considered to suspend those sectorial evaluations until the future shape of the NLF is decided upon.



- Addressing the mentioned new elements should start with a clear objective of maintaining the stability of the basic NLF principles of separation of the essential requirements laid down in product legislation, on one hand, and description of their technical realization according to the state of the art in product-specific voluntary standards on the other. The voluntary application of those standards allows innovators to create alternative solutions while the presumption of conformity helps others – and in particular SMEs – with respect to development costs and time to market.
  - The NLF assessment should seize this opportunity to strengthen the European standardization system to support the application of NLF-based legislation. The Commission’s practice of treating harmonized standards as part of the EU law should be urgently revised, as suggested in the respective [Joint Industry Statement](#) and on many occasions of the events on this issue.
  - The EU should ensure stability, coherence and clarity in the European rules on market access for products. Use of the same definitions throughout the framework is a must to ensure consistency between the horizontal NLF acts and complementary legislation, as well as elimination of grey zones, overlaps and loopholes is.
  - Definitions of essential elements, e.g. the product, the placing on the market or of new concepts like remanufacturing and refurbishment, could be clarified or reviewed to ensure they are fit for the digital age. Common definitions in harmonized and non-harmonized sectors would be beneficial, in particular for SMEs.
  - However, the NLF should *not* aim to eliminate *all possible* risks in all level of detail, let alone an attempt to capture all future risks that *may possibly* occur due to to-be-expected product upgrades, changes or personalized varieties.
  - To keep up the pace with technology and ensure the NLF is a fit-for-future framework, the legislator should maintain the necessary flexibility and shift the emphasis from pre-market to post-market validation. It should be based on rigorous processes to spot risks that manifest themselves on the market immediately, then find and eliminate the cause. This approach should rest upon product- or technology specific standards as well as those defining the risk assessment methods, supported by the right checks and balances in procedures (risk and incident analysis, product development and validation).
  - It also means that there should be no proliferation of additional overly prescriptive requirements, be it through numerous changes by the co-legislators or through delegation of powers to the Commission.
2. *the conformity assessment procedures remain fit for purpose and ensure the safety and compliance with the applicable requirements of the products placed on the Union market;*
- BusinessEurope considers that the developed modules for assessing compliance are well-functioning. We find it is important the Commission does everything it can to ensure they are actually used when legislation is developed to reduce complexity and increase compliance of economic operators.



- It may be appropriate to investigate if the developed models sufficiently take into account the challenges related to circular economy, and clarity is needed on how information of compliance can be integrated in the conformity assessment declarations (DoC's) and other similar declarations.
  - BusinessEurope considers that if the manufacturer introduces *substantial* modifications affecting the safety of the product during its lifespan, this could be considered as placing of a new product on the market which could entail respective conformity (re)assessment procedures, new CE-marking and documentation by the manufacturer. However, there is a need for more clarity of what constitutes a *substantial* modification, and its legally certain definition is needed. Moreover, the current work under the expert group of the Machinery Directive is relevant in this regard, and the discussions could be extended to make them relevant beyond this piece of legislation.
  - The EU should further improve the conformity assessment system so that it is fit for purpose. The business-led conformity assessment based on standards should be explored, leaving only the products presenting a high risk for the approval procedure by authorities or notified bodies.
  - For the conformity assessment procedures to work, the system of European harmonized standards needs to function smoothly as referred to above under question 1. The Commission must allow for the standardisation mandates to be made more flexible and subsequently step back on its administrative requirements regarding the content and structure of the standards. Internationally developed state-of-the-art standards must be published quickly without amendments which bring no value added.
3. *the rules for notified bodies are robust enough to ensure the competence of those bodies;*
- The notified bodies' trustworthiness is of paramount importance, and it is a precondition for ensuring trust in the certificates they issue and avoiding requirements of re-testing or re-certification during market surveillance. However, today the EU accreditation system is not used in all cases under the harmonized framework. The evaluation should also answer if and how accreditation influences the competences of notified bodies and, subsequently, explore a possibility of making the accreditation of notified bodies mandatory.
  - It is necessary to investigate 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.
4. *the accreditation system functions well and ensures that the competence of the notified bodies intervening in the conformity assessment procedures is sufficiently guaranteed;*
- BusinessEurope considers that the European accreditation system could 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.

*5. affixing the CE marking and other product information to the product itself continues to be appropriate;*

- The CE marking rules are still appropriate. The CE marking is a key driver for the competitiveness of companies in the Single Market.
- However, there continues to be some confusion on what it means, including among professional users. Instead of looking for alternative solutions, BusinessEurope considers it necessary to increase the understanding in the market. The evaluation should look for information and competence needs in the market.
- The most important element is the possibility to access information whether a product is CE-marked or not, rather than the mark's physical location. BusinessEurope would like to see efforts towards increased use of URL codes as the digital infrastructure in Europe develops, and this evaluation could address the ways to achieve it. This applies to both the CE-marking and other product information (like instructions of use and safety information).
- We also recognize that other labels have been introduced in the past, addressing specific requirements from specific legislation, such as the Ecolabel and other environmental labels for example. BusinessEurope does not believe that the NLF is an appropriate piece of legislation for introduction of any new labelling that would likely address only a specific number of products.

*6. the lack of a crisis instrument for urgency situations renders the NLF less effective or efficient.*

- COVID19 crisis has shown that within the present scope of the NLF it is possible to quickly develop necessary standards for the personal protective equipment, if trust is demonstrated between the participating stakeholders. Additionally, we find that it is an experience one can build on in order to resolve the challenges in the harmonized standardization system mentioned above.
- The integration of an additional crisis instrument for urgency situations as such could be considered, however a few open questions remain: a) whether the NLF is the right place for such an emergency mechanism, and b) whether strict and clear criteria defining such situations and applicable conditions therein are possible to define.