



## **NOTAT**

01 March 2022  
2022 - 2345  
otfruh

### **The Danish Government's response to the public consultation on the evaluation of the New Legislative Framework**

#### **General remarks**

The Danish Government looks forward to the evaluation of the New Legislative Framework (NLF). The NLF is still a vital tool that needs to be updated in a technologically neutral way to continuously support the safety and compliance of industrial products throughout their life-cycle. Therefore, the Danish Government supports the ambition of the evaluation to encompass the broader context of the performance of the NLF, in particular the digital and green transitions as well as recent market trends.

The Danish Government notes that the digital and green transitions create certain challenges for the general principles of the NLF. First, the emergence of new digital and circular business models results in increased complexity and makes it increasingly demanding for innovative businesses to comply with the principle that products made available on the EU market shall comply with all applicable legislation. This has many reasons, including the gradual integration of goods and services and more frequent changes to products post market placement that comes with the twin transitions. Second, the emergence of new economic operators in ecommerce and refurbishment value chains has sparked legal uncertainty. The roles and responsibilities of online marketplaces and remanufacturers should be addressed, and a "catch-all"-clause could be considered to ensure that there is always a responsible economic operator in the EU, even if new actors emerge that are not listed in the NLF. The overall view of the Danish Government is that these developments can only be accommodated in the existing NLF to a small, unsatisfactory extent, despite the technology-neutral approach.

Continuity of the basic principles of the NLF is a fundamental precondition to EU's competitiveness. Therefore, it is vital that the evaluation analyses both the needs and impacts of potential changes in as much depth as possible. On one hand, the basic principles must not be changed unnecessarily, as they function well and because unnecessary changes would risk negative impacts to effective compliance in all ecosystems concerned. Businesses are already familiar with and recognise the basic principles. On the other hand, it should be updated where necessary to achieve the twin transitions

and sustain the well-functioning single market for goods as a driver and a global springboard for European companies. This includes changes needed in light of new business models and developments in global supply and distribution chains.

Further, the Danish Government believes that finding long-term solutions to current challenges within the European system for harmonised standards will be another cornerstone to future-proofing the NLF. Overall, the Danish Government believes that the current standardisation regulation is fit for purpose and should not undergo a general revision. The Danish Government welcomes a horizontal approach to ensure that common technical specifications will only be adopted as a last resort alternative to harmonised standards in emergency situations.

### **Specific remarks**

In the following, we have listed our main points to the public consultation on the NLF.

- The NLF should be applied per default and deviations should be explained

The NLF is a valuable tool for sustaining the internal market for goods to the benefit of the whole EU economy. It has potential to ensure consistency and predictability via reuse of well-known methods for new EU product rules, minimising barriers for businesses. Therefore, the NLF should be applied continuously, and its mandate should be strengthened to ensure that the Commission uses the NLF per default whenever making a legislative proposal for harmonisation of product rules.

Further, to improve transparency, the Commission should explain it thoroughly in the proposal whenever they find reason to deviate from the NLF for specific purposes. A similar practice could be endorsed by the Parliament and the Council. The principle of comply or explain should be clearly stated in article 2 of Decision 768/2008.

- Terminology and conformity assessment procedures should be updated in light of new business models to accommodate ‘adjustments’ and ‘additions’ to products

The NLF should be able to accommodate products that undergo changes during their lifetime, as this is a rising trend in new business models. In the digital sphere, software upgrades and updates are increasingly important, including for artificial intelligence and cybersecurity purposes. In the circular sphere, remanufacturing, refurbishment, upcycling and repairs are also on the rise. Terminology should be defined in the NLF to avoid fragmentation. Essentially, the NLF should make it easy and attractive for innovative businesses, especially SMEs, to engage in these practices and make safe, secure and sustainable products available on the single market without unnecessary burdens. But the focus on the ‘making available’ of a product offsets more agile practices that come with innovation.

Therefore, updated terminology may be necessary to accommodate ‘changes’ to a product after it is made available on the market, some of which take form of ‘adjustments’ or ‘additions’ within a well-defined, limited scope. The evaluation should also consider to what extent changes could be accommodated without requiring the conformity assessment process to start over in every circumstance, for example by adding new modules for conformity assessment. As another partly solution to this question, this could be achieved by limiting the responsibility of a repairer to the part of the product they have repaired, rather than making the repairer responsible for the full product after performing their service. Like other ‘adjustments’ or ‘additions’, repairs are usually well-defined and limited in scope. Thus, the evaluation should consider experiences with this model and to what extent it could be harmonised and/or applied in a broader sense.

- Economic operator roles and divisions of responsibilities should be suited for digital and circular supply and distribution chains

The NLF aims to ensure that all involved economic operators take appropriate measures in accordance with a distribution of obligations corresponding to their roles in the supply and distribution process. However, new economic operators play increasingly important roles and should become responsible for certain new activities. This is especially the case for fulfilment service providers and online marketplaces in ecommerce, but also remanufacturers and other operators performing various ‘changes’ to a product after it is first made available on the market (as illustrated above). The current NLF does not address the roles and responsibilities of these operators directly, and while some operators mentioned may fit certain categories, the legal uncertainty is a hindrance for effective enforcement and an opportunity for ‘free riding’ in the single market for goods.

Therefore, it should be considered in the evaluation whether there is a need to integrate and elaborate existing roles and responsibilities connected with new activities articulated in related legislation, such as Fulfilment Service Providers covered in Regulation 2019/1020 and online marketplaces covered in the General Product Safety Regulation currently under negotiation. Addition and elaboration of new roles and responsibilities related to various ‘changes’ of products should also be considered.

- Align online marketplace roles and responsibilities with importers’ in global ecommerce

Special dynamics are at play in global supply and distribution chains, especially in ecommerce. Effectively, online marketplaces act as a gateway for third country sellers to place their products on the EU-markets from a distance, like importers have traditionally done. However, there is a compliance deficit connected with the lack of a responsible importer in the EU and it is not clear how online marketplaces can be held responsible for their contribution to this development.

Therefore, the roles and the responsibilities of online marketplaces in global ecommerce should be modernised to improve legal certainty and compliance. We suggest aligning online marketplace roles and responsibilities with those of importers. Further, the Commission could consider adding a “catch-all”-clause to ensure that there is always a responsible economic operator in the EU, even if new actors emerge that are not listed in the NLF.

- Digital information ‘by default’ should be considered as an enabler for new digital services and market surveillance tools

A clear framework for provision of information in a digital format could be a driver for new data-driven business models and greatly reduce administrative burdens for businesses, for example making it easy to update to relevant information and provide it in various languages. Further, the availability of digital product information would support more efficient, risk-based market surveillance, including new tools to cover a larger volume of products and perform data-driven prioritisation of activities. Positive consumer impact would result from these improvements in form of derived consequences such as cost-reductions and improved safety of products.

Therefore, we recommend that the Commission evaluate whether product information for the purpose of market surveillance (CE-marking, other traceability information and product information) could be provided digitally by default. We welcome the analysis on to what extent information affixed on the product remains necessary and invite the Commission to thoroughly explore the potential of providing digital information instead or in parallel. In this context, on-going initiatives such as the upcoming product passport should be taken into account.

- Further harmonisation of the accreditation process may be needed to ensure an effective and consistent competence assessment of notified bodies

Notified bodies help shape the trust in products made available on the single market in accordance with applicable harmonised legislation, but different procedures are used across Europe to establish their competences and ensure the continuous quality of their assessments. The lack of a harmonised approach creates an un-level playing field for Notified Bodies and, in extension, risks lowering the trust, validity and consistency of certificates issued and conformity assessment procedures.

Therefore, the Commission should consider options for further harmonisation of the accreditation process and assess the feasibility of deciding on a harmonised approach. For example, the intensity of controls could be streamlined through more collaboration between accreditation units, and further instruments could be added such as peer-reviews (with which we have positive experience in Denmark) and sanctions in case of recurrent incompetence.

- Supplementary market surveillance activities should be encouraged as light options for risk-based market surveillance

Efficient monitoring is a key component to effective market surveillance. Supplementary activities that focus on businesses' knowledge and ability to ensure safety as well as their internal quality assurance processes has proven a valuable tool in this respect. For example, authorities and businesses may cooperate on a voluntary basis to review internal processes and enter into dialogue about guidelines that may strengthen the ability of individual businesses to comply with applicable legislation.

Businesses may welcome such supplementary activities as a supplement to traditional procedures for market surveillance that focus on compliance of each product. This may be especially impactful for surveillance of new green and digital business models, where products more often change throughout their life-cycle. Authorities also stand to benefit from the opportunity to use insights to perform data-driven prioritization based on overall risk assessments per company. Therefore, we invite the Commission to explore and encourage such practices in the evaluation and raise caution that adaptations to the NLF should not preclude them.

- Maintain the European system for harmonized standards

A well-functioning standardisation system is vital for delivering harmonised standards in time to support new EU legislation, helping businesses and authorities to ensure compliance. On a larger scale, a future proof standardisation system can support the green and digital transitions as well as Europe's global competitiveness and enhance the European footprint on international standardisation in strategic areas, such as critical new technologies - in alignment with the objectives in the Commission's new EU standardisation strategy.

The evaluation must consider the recommendations of 17 Member States at the COMPET Council on 25 May 2021 to 1) find the right balance in standardisation requests between qualitative requirements set by EU legislation and flexibility for the European Standardisation Organisations required for state-of-the-art standards; 2) publish clear criteria for technical evaluation of harmonised standards to align expectations between involved parties; and 3) ensure a short processing time for citation of new harmonised standards in the Official Journal of the European Union, for example by introducing key performance indicators. Furthermore, the Commission's empowerment to adopt technical/common specifications should be based on horizontal requirements that ensure that this remains a last resort for emergency situations, and not a way to circumvent the NLF system. We refer to our incoming response to the Standardisation Strategy for more detailed comments.

- The NLF has performed well during the COVID-19 Pandemic

We appreciate the intention of the Commission to ensure that the NLF remains adequate to perform in crisis situations. It should be noted that the NLF performed well during the first wave of coronavirus in Europe in spring 2020, where parties within the European system for harmonised standards cooperated to deliver relevant harmonised standards for personal protective equipment and medical devices within a very short timeframe. We hope that this experience can serve as inspiration for joint efforts in times of a new crisis and for finding long-lasting solutions to the current challenges mentioned regarding standardisation.

However, it is not possible for us to assess to what extent the lack of a crisis instrument rendered the NLF less effective in supporting fight against the COVID-19 pandemic, as we still need to see more details about the contents of such an instrument. We look forward to further dialogue about the upcoming proposal for a Single Market Emergency Instrument, which we generally find is the right place to improve the free movement of goods on the single market in times of crisis.

- Avoid legal uncertainty by aligning reference provisions with Regulation 2019/1020 on Market Surveillance

We would like to highlight that recent proposals for harmonised legislation based on the NLF (including the Battery Regulation and the Machinery Product Regulation) have contained provisions overlapping with Regulation 2019/1020 on Market Surveillance. Such overlaps should be avoided in order not to create legal uncertainty, unless it is intended to regulate in a more specific manner (in accordance with the *lex specialis* rule in article 2(1) of Regulation 2019/1020).

It seems that the overlaps stem from the fact that the reference provisions in the NLF Framework Decision (Decision 768/2008/EC) have not been updated to fit recent changes in Regulation 2019/1020. Therefore, an update is needed to avoid legal uncertainty going forward.

**We look forward to contributing further to the evaluation, and we anticipate that any changes to the NLF could be performed through a revision of Decision 768/2008 and implementation of the changes across NLF legislation in an omnibus.**