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Position Paper

The New Legislative Framework: an instrument designed for the European Single Market

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Executive Summary

The New Legislative Framework (NLF) is key for the European Commission and its Member States to be successful in achieving their high ambition for a digital transformation and sustainable future. CEN and CENELEC welcome the European Commission's public consultation on the NLF, which is both timely and needed, to see how the NLF could be improved to become a more efficient and consistent tool.

While the questionnaire primarily focuses on the development of the CE mark (eg. soft- and hardware updates and upgrades, refurbishment and repairs, and conformity assessment and accreditation), CEN and CENELEC stress the importance of the NLF for the development of standards and standardization infrastructure within the European Single Market. The following position paper intends to emphasize not only the strengths of the NLF, but also highlight the opportunities available ahead. The cooperation between CEN, CENELEC and the European Commission, supported by a public-private partnership, enables standards to respond to regulatory needs and meet emerging needs, such those of the twin transition, green and digital. With regards to the European Union's pursuit of the Twin Transition, the NLF can make a significant contribution to achieving those objectives.

CEN and CENELEC recommend

Under the NLF, CEN and CENELEC have worked extensively in cooperation with the European Commission and all European stakeholders to produce standards in support of European policy objectives. The continued use and expansion of the NLF to establish clear and essential requirements in legislation, supported by voluntary technical standards, the delivery of technical detail needed by manufacturers and suppliers, will help European businesses meet legal requirements and support the needs of all stakeholders.

Introduction

The European Standardization System is based on a voluntary and inclusive approach, which can support the New Legislative Framework as an important element of supporting the EU's policy priorities. The CEN and CENELEC community is committed to ensuring Europe's sustained recovery and long-term resilience on the basis of a strengthened strategic public-private partnership with the European institutions. To maximise the benefits to policy makers of working with the private sector and other stakeholders via standards, the continued use of the NLF as a model for regulation will be of vital importance to ensure efficient and effective compliance, the greater harmonization of the Single Market, and greater opportunities for trade.

With digitization comes increasing speed and the need to ensure a broad input of requirements, which the NLF approach provides. Therefore, it should be the preferred option for new legislative initiatives regarding EU policy related to digital matters and paving the way towards a circular economy. Together, the European Commission, CEN and CENELEC can find ways to support European experts in contributing to international standardization (ISO/IEC JTC1) and facilitate a smooth adoption of international standards at EU level within the NLF, in order to underpin the global competitiveness of European companies.

The success of the New Legislative Framework (NLF)

The NLF, since its inception, has enabled the development of standards in support of legislation in a swift, efficient and open manner in a variety of policy areas. Through the NLF, standardization has become a critical resource in building the Single Market. Voluntary and consensus-based standards support the conformity of products to regulatory requirements, including those of EU regulation, across Europe, but provide the flexibility to manufacturers and importers to use other means to demonstrate that conformity.

At the core of the NLF is the practice of the 'presumption of conformity', meaning that by using a harmonised standard, a manufacturer is deemed to comply with the requirements of regulation. This has been a key asset for industry, in particular SMEs, and has enabled easier routes to market including self-declaration of conformity. Facilitating market access in this way, built on the trust provided by European standards developed by all stakeholders in an inclusive process, is a tremendous time and cost-saver for industry, helping to avoid needless third-party testing and certification.

Businesses must check the compliance to a harmonized and cited standard, which is a lot easier than looking at the technical file of the manufacturer. The technical and complex file that should prove the compliance with the essential requirements of a directive, allows the CE mark to be placed on the European market. The flexible, pro-innovation approach to regulation, which lies at the heart of the NLF has also led to the increased use and adoption of European standards as national standards in countries around the world.

This adoption of European standards, consistent with international best practice, brings significant advantage to European businesses as it reduces market access barriers to those countries, while helping to promote European values.

A portion of all European Standards (ENs) are developed based on standardization requests from the European Commission to support EU legislation, it is vital that any modification to the NLF's operational aspects should aim to improve its smooth functioning and should build on and learn from the successes of the past 40 years.

The European Standardization Strategy must build on this success

The European Standardization Strategy, newly released by the European Commission, aims to respond to the need to strengthen the strategic role standards play in the EU's Single Market and in global markets. Standards set the pathway to support Europe's competitiveness and strategic autonomy, to disseminate European innovation, and to ensure that European and international standards reflect the EU's interests and values and the interests and values of its trading partners as part of the global rules-based system.

CEN and CENELEC share the ambitions of the European Standardization Strategy, to recognise standards as a key tool to contribute to a resilient green and digital transformation of the EU's industrial ecosystem. A robust European Standardization System, which underpins the NLF, provides the basis for a strong and competitive European industry ready to lead in international trade.

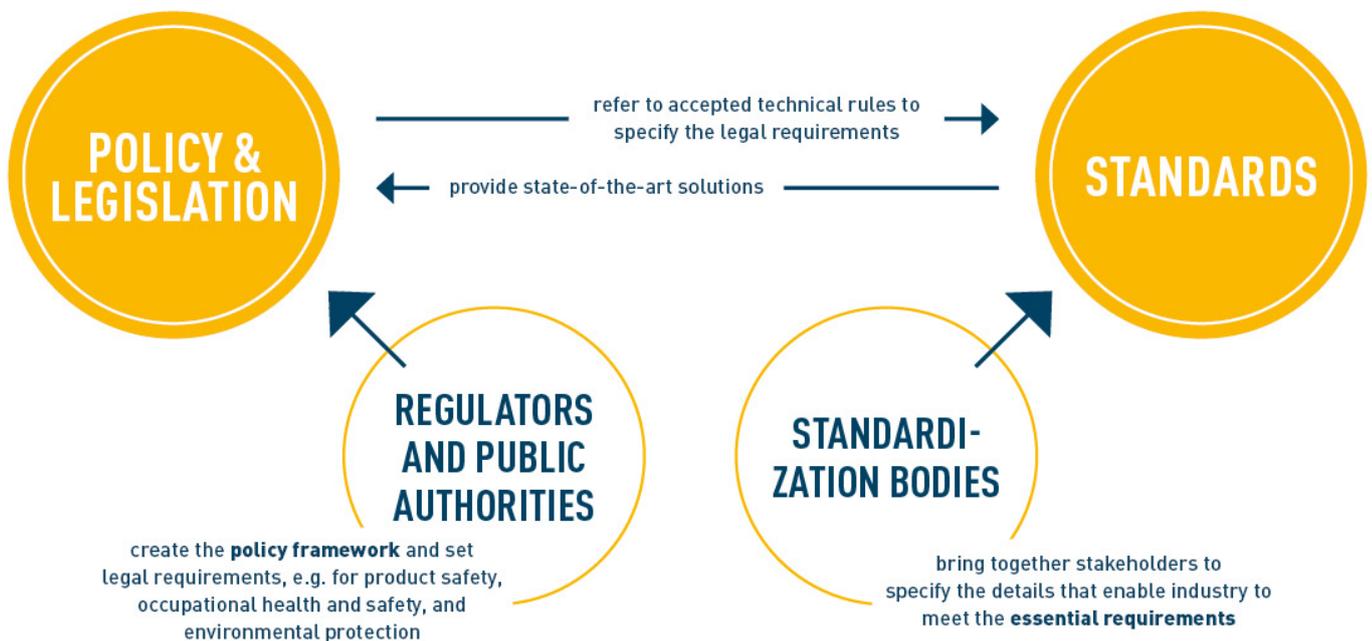
Therefore, the implementation of the European Standardization Strategy must build on the New Legislative Framework and strong investment in Harmonized Standards.

Standards help achieve policy goals

Harmonised Standards, listed in the *Official Journal of the European Union* (OJEU) offer a presumption of conformity to specific EU directives and regulations. Thus, the NLF enables an agile legal framework that ensures that products in the Single Market meet essential requirements in vital areas (e.g. Low Voltage Directive, the Radio Equipment Directive and the Toys Directive) and enables a custom-fit and agile legal framework that ensures that products in the Single Market meet essential requirements for safety, health and environmental protection).

When the state-of-the-art advances, the content of standards is revised. **Therefore, the legal text does not have to be continually adapted.** This shared responsibility ensures that stakeholders are involved in the development of technical rules through the open, transparent, and consensus-based standardization process. This approach provides a regulatory framework that enables new EU policy, directives or regulations to support innovation.

Referring to Harmonised Standards and, if necessary, involving a notified body, the manufacturer of a product can declare conformity with the respective legal act, affix the CE mark to the product, as appropriate, and place it on the market. The use of standards that have been recognized for the purpose of conformity through their listing in OJEU can save time and cost for industry, especially SMEs, through providing a tried-and-tested approach. This gives certainty to industry, to customers, and to regulators.



The benefits of the NLF are not limited to Europe. CEN and CENELEC cooperate with ISO and IEC to reach agreements on common standards that can be applied worldwide, on the topics closest to Europe's fundamental values and interest. **The alignment between European and international standardization is therefore crucial for the success of the NLF** - to facilitate international trade and the digitalization of industrial ecosystems, while ensuring consumers' safety and the protection of the environment. The cooperation between European and international standardization through the Vienna and Frankfurt agreements is crucial in support of the NLF: these frameworks prevent the duplication of work and provide a means for development of identical global and European Standards, including simultaneous commenting and acceptance procedures.

As the success of the European Single Market continues to grow, built around the free and safe trade of products, **the NLF has the potential to be expanded to other sectors and new technologies to tackle the twin transition.**

Considering the evolving technological landscape

Due to their increasingly complex nature and specifications, more products are now seeing their hardware and software modified after they have been placed on the market and throughout their lifecycle. Software and firmware upgrades improve the functionality, reliability, and security of everyday products on a regular basis. AI technologies will also have a greater impact on a product's functionalities. Moreover, products may integrate different, evolving services in complex designs.

New technologies can develop quickly, but an increased pace does not lessen the need to ensure a broad input of stakeholder views to help frame requirements. The NLF provides for this and should be the preferred option for new legislative initiatives emerging from EU digital policy and the path towards a more circular economy. However, addressing product conformity for products that are updated after being put on the market may represent a challenge for the future of the NLF.

The NLF should address whole-life updates to and evolution of products, to support their free trade and ensure their continued safety and security. Re-evaluation of the concepts of “making available on the market” or “placing on the market” will also be necessary for refurbished or repaired products, where quality, safety, security, or compliance with eco-design requirements may change after their first use. Building on this strength, **a renewed NLF should define clear roles and responsibilities for addressing product conformity after a product has been on the market.**

Furthermore, the definition of technology-neutral essential requirements, accompanied with a comprehensive toolbox of conformity assessment modules has ensured the efficient and coherent application of different European legislations in evolving environments. **This is why the NLF and the use of Harmonized Standards are particularly suited to address the Twin Transition, green and digital requirements** – enabling the necessary convergence between public and private actors, but also between digital and green technologies. CEN-CLC/JTC 21 ‘Artificial Intelligence’ is, for instance, already active in these topics. The activities of CEN-CLC/JTC 1 ‘criteria for conformity assessment bodies may have an important role to play in the context of the Twin Transition.

The ENs made available by CEN and CENELEC help achieve policy goals for technology neutral basis, and furthermore based on our agreements at the international level with ISO and IEC can also ensure global access. CEN and CENELEC standards should express requirements in terms of performance (e.g. energetic, safety, interoperability, ...) as well as design or descriptive characteristics. European Standards permit maximum freedom for technical development and reduce the risk of undesirable market impacts (e.g. limiting development of innovative solutions).

European Standards are ideally placed for this as they can be tools to create interoperability and smooth exchange of data, can provide methods for measuring and testing, and can open markets to the safe use of new technologies during their lifecycle, where values such as privacy and accessibility are ensured.

Conclusions

It is important to remember that Harmonized Standards offer state-of-the-art solutions, have legitimacy based on European consensus including consumer interest and broad industry acceptability, and are a tool for agile regulation.

In the scope of an evaluation for an NLF fit for the digital age, the question of Standardization Requests will undeniably emerge. Early and close interaction with CEN and CENELEC during the drafting of Standardisation Requests is crucial to ensuring maximum alignment and a frictionless process which in turn guarantees the timeliness of standards development. CEN and CENELEC are committed to working with the European Commission to further strengthen the NLF system and process, thus allowing the speedy citation of harmonized standards in the OJEU to the benefit of the European single market.

Looking forward, it will be worth highlight that the newly created Task Force between the European Commission, CEN and CENELEC, about "Timely citation of standards," should contribute to the resolution of the issues encountered in dealing with standardization requests and the citation of harmonized standards.

Annex

Annex 1

A standard is a formal, voluntary document that sets the specifications for a product, a system, a process or a service. Standards can help to make different parts of an infrastructure work together or to systemize processes, e.g. Machinery Directive, the Twin Transitions, and the Single Market.

Standards can lift barriers to the uptake of technologies and materials, by specifying tests, or provide robust definitions that avoid misleading claims.

European standards are identical in all Members of CEN and CENELEC and thus create an easy access to the European market. They can also have an impact at global level if they become international standards at ISO or IEC level or are adopted in countries outside Europe. They are flexible tools that can improve safety, performance, privacy and protect consumers.

The *New Legislative Framework* (NLF) was adopted in 2008 to serve as a regulatory instrument that would ensure the high level of protection for the technical safety of products, production facilities and services. It is based on the *New Approach*, a principle that states, how products are legally manufactured and marketed in an EU Member State, and then freely distributed throughout the Single Market.

Annex 2

Harmonised Standards

It is crucial to guarantee the market-driven nature of ENs and their role in supporting competitiveness, as well as the need for legal certainty for the economic operators through timely citation of harmonized standards in the OJEU. The non-citation of harmonized standards provides a negative impact on the competitiveness of the European industry, in all sectors, and on the economy as a whole. It is estimated that costs to demonstrate compliance with the European legislation are 4 times higher when harmonized standards are not cited in the OJEU.

About CEN and CENELEC

CEN (European Committee for Standardization) and **CENELEC (European Committee for Electrotechnical Standardization)** are recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 34 European countries including all of the EU member states plus Iceland, Norway, Switzerland, United Kingdom, Turkey and the former Yugoslav Republic of Macedonia.

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organizations and other societal stakeholders. Once adopted, these standards are implemented and published in all of the 34 countries covered by CEN and CENELEC.

CEN and CENELEC also work to promote the international harmonization of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

For more information, please see: www.cencenelec.eu