

## Orgalim comments on the NLF evaluation roadmap

Orgalim thanks the European Commission for the opportunity to comment on the Commission's roadmap for the evaluation of the new legislative framework. As already indicated in our response to the Blue Guide revision, we remain convinced that the New Approach and the New Legislative Framework are the best tools to support the proper functioning of the European Single Market for Goods. Thus, we believe that changes should be made only in response to clear needs and we therefore welcome this initiative to evaluate the NLF after 10 years of application, insofar as it will identify the areas in which more clarity is needed.

Bearing in mind the ultimate objective of the NLF, which is to strengthen the Single Market by applying the same rules for conformity assessment, market surveillance, CE marking, etc., we are convinced that such rules should not become too cumbersome when applied concretely. Otherwise, they will risk hindering the very goal of achieving a stronger Single Market. In addition, we would like the Commission to promote the NLF principles when developing new legislation (e.g. use of essential requirements in annex, application of harmonised standards, applications of the modules for conformity assessment etc.) as a means to facilitate companies' compliance.

While we look forward to contributing to the upcoming official consultations, we believe it is relevant for us to provide our views on certain elements that should remain key throughout the evaluation.

### NLF basic concepts must be preserved

The NLF has worked well for 10 years and we would like to see the basic concepts preserved.

Any change to the current basic concepts will require businesses to adapt their compliance systems and invest in the adjustment of processes. This in turn will cause temporary disruption and hinder the efficiency of often costly, complex, and multifaceted compliance procedures. For this reason we believe that if limited gaps are identified during the evaluation, these should be assessed and balanced with the inevitable disruption that changes to the legal framework will bring.

### Fragmentation and contradictory requirements must be avoided

For our industry, the key to a well-functioning Single Market is to avoid regulatory fragmentation with overlapping and contradictory requirements for manufacturers. This is, for example, particularly important in the upcoming Revision of the Machinery Directive and its relation to new technologies such as AI and machine learning.

Orgalim is convinced that a coherent regulatory framework is of the utmost importance, especially in the context of the Single Market. Therefore, it is important that the legislation under the NLF remains consistent. For example, we propose the introduction of certain pieces of horizontal legislation, such as that on cybersecurity for networkable products within the NLF. Such horizontal legislation will also help to ensure a level playing field between manufacturers established within the EU and those established outside, while providing more legal certainty for the responsible economic operator acting on behalf of a non-EU-based manufacturer.

Orgalim believes that the NLF evaluation should identify such areas of potential fragmentation and contradictory requirements, and analyse potential implications for stakeholders.

## Harmonised standards are an integral part of conformity assessment within the NLF

A functioning NLF requires harmonised standards, which are needed to achieve presumption of conformity and free movement of products within the EU. We are concerned that the current system, as understood and operated by the Commission today, does not support the market needs of industry and is undermining the standardisation system as we know it, with serious consequences for the functioning of the Single Market, European competitiveness, and innovation. We therefore ask the Commission to include in the NLF evaluation an assessment of the current system for development and application of harmonised standards for developers and users.

## Compliance tools fit for the digital age

Orgalim welcomes and supports technological advances that can facilitate information obligations when these satisfy the needs of the stakeholders. We believe it is important to investigate how compliance can be made easier and also how this process can be made faster in order to make it easier for manufacturers to meet information obligations; this could apply to CE marking, conformity assessment, etc.

We look forward to working together with the Commission and other relevant stakeholders in the coming months, and to contributing to a balanced and coherent evaluation of the NLF.

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of over €2,100 billion, manufacturing one-third of all European exports and providing 11.5 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

Orgalim aisbl  
BluePoint Brussels  
Boulevard A Reyers 80  
B1030 | Brussels | Belgium

+32 2 206 68 83  
secretariat@orgalim.eu  
www.orgalim.eu  
VAT BE 0414 341 438