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Orgalim Position Paper on the New Legislative Framework

Executive summary

Orgalim, representing Europe's technology industries, is a strong supporter of the New Legislative Framework (NLF) and remains convinced that it is the best tool to support the proper functioning of the European Single Market for Goods. Our industries are directly and deeply impacted by harmonised legislation and we are convinced that the NLF is a success story for the Single Market and that it is still fit for the future. For this reason, we believe that changes should be made only in response to clear needs and that they should also be assessed in relation to the inevitable disruption that changes to the legal framework will bring.

In particular, Orgalim calls on legislators to maintain the fundamental principles outlined in the NLF, as they are essential parts of the framework and the reason why it has been so successful (see Annex I for a list of these principles).

We thank the European Commission for the opportunity to contribute to the evaluation of this cornerstone of Single Market legislation and we look forward to continuing to share our expertise on this important matter.

1. The NLF: a successful framework that is fit for the future

The New Approach and the New Legislative Framework (NLF) are success stories for the European Union and the EU Single Market. The New Approach has significantly contributed to limit fragmentation of national rules, increase harmonisation and promote European standardisation. Thanks to the introduction of the NLF and its key principles¹, the New Approach has been improved to support the proper functioning of the European Single Market for Goods, streamlining and simplifying processes for the entry into the market of products across all the Member States, and benefitting competition. The NLF has also been beneficial for SMEs in that it has opened the EU market to them, thanks to the use of harmonised standards and the option for manufacturer self-declaration of conformity (module A). Having a stronger Single Market has further benefitted the global competitiveness of European industries abroad and it has

¹ See Annex I for a list of what Orgalim considers as key NLF principles.

improved the speed of adoption of state-of-the-art technologies, as compared to the Old Approach. The introduction of the NLF has also benefitted European consumers by improved market surveillance mechanisms.

After more than ten years of application, Orgalim believes the NLF is still fit for the future, including to address the new challenges brought about by the green and digital transitions. One of the reasons why the NLF has aged so well is the fact that it is technology-neutral and provides a common toolbox of measures for use in future legislation. Nevertheless, we welcome the evaluation initiated by the Commission in 2020 as we recognise that there are some limited areas for improvement which are worth considering. However, we believe that changes should be made only in response to clear needs and only if the expected benefits outweigh the costs involved in changing a robust and well-developed system, whose ultimate goal remains that of strengthening the Single Market by applying the same clear rules across the European Union. In particular, we remain convinced that the NLF principles are a cornerstone of the Single Market and that they should be embedded in 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.

1.1. Conformity assessment procedures

One of the key principles of the NLF is the establishment of conformity assessment procedures according to specific modules, to be used in accordance with criteria linked to appropriateness, nature of the risk (type and degree of risk) and level of burden compared to risk.

Orgalim is a strong supporter of the modules approach, and of the criteria to select them, and does not believe that additional modules are needed to respond to the existing needs. However, we do believe that the use of module A (internal production control) should remain a cornerstone in new legislation and revised regulations. We are concerned to see that several of the current legislative proposals tend to require third party conformity assessment for products over self-assessment, disregarding the risk-based approach for selecting conformity assessment procedures mentioned above.

It is important to underline that, ultimately, the manufacturer remains responsible for product compliance and safety, regardless of the conformity assessment procedure used. Under module A conscientious manufacturers strive to achieve high levels of compliance by carrying out multiple tests and risk assessments during the process of development and production that are set out in the Essential Requirements and standards. Some manufacturers may choose to recourse to notified bodies to reconfirm these procedures, or are required to do so where harmonised standards have not yet been developed. Self-assessment is linked to faster time-to-market, which is an important element for the competitiveness of European manufacturers and something that the Commission is keen to support through other initiatives, including the new Standardisation Strategy. It also supports the standardisation system because it creates an incentive for industry experts to participate in standardisation activities, knowing that they will then be applying those standards for self-assessment.

1.2. Economic operators: definitions and obligations

We recognise that the appearance of new economic operators may require an update of the definition of economic operators in the NLF. Notably, the recently revised Market Surveillance Regulation has added "fulfilment service providers" to the list and we believe this should be reflected in the NLF to ensure alignment between the two pieces of legislation.

When it comes to the obligations of economic operators, and particularly of manufacturers, we believe that the obligations foreseen by the NLF are still fit for purpose and that there is no need for an extension of these obligations, except in order to align the NLF with the new Market Surveillance Regulation. For example, in relation to Article 4 of this regulation on tasks of economic operators regarding products subject to certain EU harmonisation legislation.

1.3. Digitalisation can facilitate information obligations

Orgalim welcomes and supports technological advances that can facilitate information obligations when these satisfy the needs of the stakeholders. We believe digitalisation can facilitate and speed up compliance by simplifying the way in which manufacturers meet information obligations, both towards authorities and consumers or users of professional products. Considering the existing digital solutions for providing information, the ever more digitalised ways in which we consume information and the positive impact that the reduced need for paper would have on the environment, we support a reassessment of how relevant information for products under the NLF can be made available in a digital format as an alternative to the traditional paper form.

Particularly when it comes to the consumer or user's right to access information, which remains a fundamental requirement, we believe the digitalisation of information, such as the postal address of the manufacturer or the type of product, does not infringe this right.

However, providing information in a digital format should be an 'either/or' option, not an additional requirement, and manufacturers should not be asked to store such information in a centralised platform. The development of common standards and specifications for the content and the format of the required product information could be helpful to further align and ensure adequate information for the consumer.

The Sustainable Products Initiative (SPI) is an important opportunity for a win-win situation for the environment and the economy, and applying digital solutions for product information, such as Digital Product Passports (DPP), could have benefits for some end-users such as consumers as well as for our industries – provided that they are properly designed. For more information, please see Orgalim's [Position Paper](#).

1.4. Impact of new technologies and the circular economy

Orgalim believes that the NLF remains fit for the future and should be the cornerstone of all product legislation, even if the regulations address product-related environmental requirements and new technologies (AI and cybersecurity).

Considering the growing complexity of new products and the many implications that must be taken into consideration, we strongly encourage close coordination and exchanges between DG GROW, DG ENV and DG CONNECT regarding developments in the circular economy and digitalisation with an impact on product legislation. One of the successful features of the NLF, which has maintained this framework as effective, efficient, relevant, coherent, and providing EU added value for all these years, is the fact that it is technology-neutral and provides a common toolbox of measures for use in future legislation.

For this reason, Orgalim considers it to be crucial that the same conditions to decide when a conformity assessment is needed and who is responsible for it are applied across different pieces of legislation. Fragmentation and uneven conditions would bring legal uncertainty and an increased level of complexity which would be counterproductive for the competitiveness of European products and detrimental to the development of the circular economy. In the end the product must always be safe for the end-user and in conformity with existing legal requirements.

1.5. Coherence between the NLF and other legislation

In recent years we have detected a growing lack of coherence between the NLF and other legislation. This is applicable to NLF-aligned legislation, to other horizontal legislation and to other relevant legislation. We are concerned by the interaction between some of the legislation that is currently being revised, reviewed or newly proposed and the NLF. In principle, when proposals for EU legislation on products are presented, an evaluation of the alignment with the NLF principles should be required. Any divergences should be justified as they cause unnecessary costs and burdens, and they may even generate legal uncertainty. Moreover, experience from the alignment processes with the NLF shows that divergence from NLF principles often leads to problems due to inconsistencies.

As a rule, the NLF should act as the leading framework for horizontal definitions across legislation. Instead, we find some concerning discrepancies not only in other horizontal legislation, but also in NLF-aligned legislation and in other relevant legislation. For example, the proposals on AI, machinery and cybersecurity should ensure consistency with the NLF,

which should act as the leading piece of legislation for horizontal definitions. Also non-harmonised legislation, such as for general product safety, should be aligned with the NLF, at least for that which concerns definitions and requirements. Instead, we find some concerning discrepancies which should be addressed. Some examples:

- the GPSR proposal includes disproportionate and inconsistent requirements for economic operators concerning quality management, placing on the market, traceability, etc. It also includes additional requirements for market surveillance as compared to what is included in Regulation 2019/1020.
- The AI Act and the Machinery Regulation introduce the concept of “high risk” products, which is not in line with the NLF (in the NLF there is reference to “level of risk”).
- Different definitions of cybersecurity features are currently included in different pieces of legislation or proposed legislation (see the ENISA Cybersecurity Act, the Radio Equipment Directive Delegated Act on Article 3.3 (d,e,f), the AI Act, the Machinery Product Regulation and the GPSR). We believe the cybersecurity of products should be regulated through the introduction of a horizontal legislation on cybersecurity for networkable products which should follow the NLF principles.
- Terminology is not implemented consistently between regulations, but there are also problems arising when terminology that differs from internationally accepted terminology is used in regulations.

1.6. Accreditation

The European Regulation for Accreditation (768/2008) should be implemented consistently in the EU Member States. The standards series EN ISO/IEC 17000 should form the normative base for requirements of conformity assessment bodies and for accreditation to achieve consistency with international requirements and avoid technical barriers to trade. Member States should not implement individual requirements for Conformity Assessment Bodies that go beyond the requirements for accreditation. Orgalim supports accreditation as a means to ensure consistency in competence levels across notified bodies.

1.7. Harmonised standards

While we understand that the ongoing NLF evaluation does not take into consideration Regulation 1025/2012 on European standardisation, we believe it is impossible to decouple the NLF from the role that harmonised standards have when it comes to the functioning of the system. In fact, one of the key principles of the NLF is the separation of essential requirements (included in legislation) from technical specifications (formulated in harmonised standards). Harmonised standards remain the best tool to provide presumption of conformity and accommodate state-of-the-art.

Orgalim is concerned that the new Standardisation Strategy does not reflect the close link between the NLF and standardisation. For this reason, we are also concerned that the Strategy does not provide much concrete information as to how the Commission intends to solve the long-standing issues affecting the availability of harmonised standards and that it does not provide for adequate involvement of the industry in the discussions around this point.

It is important to highlight that these issues affect the NLF’s ability to perform at its best. For example, when harmonised standards are not available, achieving conformity with the essential requirements becomes more costly, more time consuming and less certain. Also, market surveillance becomes harder, to the detriment of the level playing field. In addition, repercussions are also felt in terms of global competitiveness: more and more often the newest international standards representing state-of-the-art cannot be harmonised in the EU without making changes to the text which have no market relevance but are required from a legalistic point of view. Such changes are difficult to agree upon at international level. This either forces companies (especially those who operate globally) to document compliance with different generations of standards, with increased costs for them, or it forces companies to avoid using the newest standards, thereby losing competitiveness.

The recent provisions allowing the Commission to develop technical or common specifications through implementing acts further contribute to the risk of the decoupling of the ESS from the international system. Orgalim calls for strict and clear horizontal rules to be developed as regards the use of this tool, to ensure that it remains a last resort option. Such rules should be developed in close cooperation with all relevant stakeholders to ensure a balanced, proportionate, and shared approach. Furthermore, technical or common specifications should be withdrawn as soon as there is an appropriate harmonised standard available.

1.8. Market surveillance

Similarly, as to the point made regarding harmonised standards, we understand that market surveillance is not subject to this evaluation. However, we believe it is an important part of achieving an effective and efficient system for product safety. The NLF has set the basis for a strong market surveillance system, notably by providing for an EU framework for market surveillance comprising both competencies and obligations for national authorities, and by organising effective administrative cooperation between these authorities on one side and with the Commission on the other.

We strongly believe that the combination of modules (particularly the use of module A, self-assessment), acceptable time-to-market and an effective market surveillance system, provides 'good and fair opportunities for manufacturers and constitutes the most effective regime to preserve safety and the level playing field.

However, pending improvements brought up by the new Market Surveillance Regulation, in the past we have seen shortcomings in market surveillance activities. This distorts competition and creates uncertainty as to how the NLF legislation should be interpreted. Limited market surveillance levels indirectly benefit non-compliant products (usually cheaper) to the detriment of virtuous manufacturers. Orgalim believes that it will be important for the Commission to follow up on the implementation of the new Regulation and ensure that Member States will deliver on their obligation to share data on their market surveillance activities in a comparable way.

2. Annex I: Overview of key NLF principles

Orgalim considers that the following key principles (in no specific order) laid down in Regulation (EC) 765/2008 and Decision 768/2008 and supported by the Blue Guide (v 2016) are essential parts of the NLF and the reason why it has been so successful. We strongly believe any changes to the NLF should not affect these core principles:

- Economic operators are responsible for the compliance of their products – the manufacturer being the one responsible for the conformity assessment procedure and establishing the technical documentation – and for providing accurate, complete and compliant information with regard to their products.
- The economic operator making the product available must ensure that the product remains compliant with the appropriate regulations. The product must always be safe for the end-user and in conformity with existing legal requirements.
- The separation of essential requirements (in legislation) from technical specifications (formulated in harmonised standards).
- Harmonised standards are not binding and retain their character of voluntary standards (this is a primary reason why we do not consider that the CPR is an NLF legislation). However, Member States are obliged to presume that the products manufactured in accordance with harmonised standards comply with the essential requirements stipulated in the directive(s).
- 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 takes into account intended use and reasonably foreseeable misuse.
- Where Community harmonisation legislation requires a statement by the manufacturer that fulfilment of the requirements relating to a product has been demonstrated (EC declaration of conformity), the legislation shall provide that a single declaration shall be drawn up in respect of all Community acts applicable to the product containing all information required for the identification of Community harmonisation legislation to which the declaration relates, and giving the publication references of the acts concerned.
- Union harmonisation legislation is technology-neutral (from 2016 Blue Guide).

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 €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.