Brussels, 26 June 2023

Enhancing EU manufacturing competitiveness with a future-proof approach to placing products on the Single Market

Executive summary

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering and electronics, ICT and metal technology branches. As our industries work to absorb an unprecedented number of new legal requirements for products intended to accelerate the Green and Digital transition, greater political attention on preserving the competitiveness of the EU's industrial base is needed. This includes ensuring that the implementation of all the new rules that are being put in place is manageable, particularly for smaller companies.

Central to the implementation of much of the EU's harmonisation legislation for products are harmonised standards. Yet when new legal requirements are introduced there often are no relevant harmonised standards available. In those cases, manufacturers are confronted with two, equally problematic, options: 1) to delay the conformity assessment of their products until harmonised standards are available, with the risk of not having enough time to adapt their processes and their product design to the new requirements before their entry into application; 2) to request a third party conformity assessment for their products, which often entails higher costs, possibly long waiting time and other burdens. Either way, the absence of relevant harmonised standards jeodardises manufacturers' competitiveness and can lead to differences in the interpretation, application and implementation of the requirements. It is critical, therefore, that policy makers take into consideration the time needed to develop such standards when deciding transition periods and fully understand the role of the various actors in the implementation chain (standards organisations, manufacturers and market surveillance authorities) in achieving proper implementation.

In this paper we propose a number of solutions to ensure that the transition to new legislative requirements for products is implemented in a way that is manageable, particularly for a sector such as ours with many smaller companies and with products that are becoming increasingly complex and are often dependent on long value chains. These focus on the following:

- **Maintain focus on internal production control,** to reduce unnecessary burdens and to avoid bottlenecks in the need for **third party conformity assessment bodies** to be notified for a **target date.**
- Ensure the **sufficient duration of transition periods** in legislative proposals, in particular those **requiring mandatory third party certification, to allow Notified Bodies to acquire the necessary notification, capacity and expertise.**
- **Introduce plausibility checks** to assess whether the proposed transitional periods can be achieved on the basis of existing conditions.
- **Improve the timely citation of harmonised standards** in the EU Official Journal.

General Considerations

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering and electronics, ICT and metal technology branches. As such, we represent world leaders in connected machinery products and production systems for whom future-oriented and coherent market access conditions to the European single market are key to being competitive. The harmonised legal acts for placing products on the market in the European single market based on the New Approach have clearly supported the development of more coherent conditions since their introduction in 1985. However, European industry has been facing increasing problems with the implementation of these harmonisation acts in recent years. In fact, many new requirements for products are being implemented simultaneously with the aim to accelerate the Green and Digital transitions, while increasingly short transition periods before the entry into application of the new rules are stipulated. In many cases this is done without due consideration as to whether these requirements can concretely be implemented within the foreseen time frame. The standardisation process is a key step of the implementation, however, when deadlines are tight, a small bottleneck at one juncture is enough to delay the whole implementation schedule.

In the absence of relevant harmonised standards, manufacturers are faced with the following options to place their products on the market:

Option 1 – Manufacturers could decide to wait for the development of the harmonised standards that are relevant for their products, hoping that these standards will be available and published in the OJEU in good time before the deadline. This option includes the significant risk of being left with very little time to adapt the products using the new standards ahead of the entry into application of the legislation – with the consequence of not being able to place the products on the market using the presumption of conformity conferred by harmonised standards.

Option 2 – Manufacturers could decide at an early stage to apply for a third party conformity assessment for their products, although the Conformity Assessment Bodies (CAB's) often also rely on standards on which to base their assessments. This option involves a higher cost as opposed to self-assessment, with no positive impact on product safety[1]. In addition, this option also does not guarantee timely market access since in some cases there may be delays in the notification of Notified Bodies (this is particularly the case with products involving new technologies such as AI and cybersecurity components) and manufacturers may face long waiting times if the Notified Bodies are overwhelmed by requests.

Both options are far from ideal for manufacturers, who may as a result not be able to sell their products for an indefinite period. This is especially burdensome for, and can even threaten the existence of, manufacturers who produce small quantities and/or have many of their products affected. Global manufacturers may decide to withdraw from the EU market because they consider it to be over-regulated or too complex, especially for high-tech products. The Medical Devices Regulation has already had to be amended twice so that existing products do not have to be withdrawn from the market at short notice. Furthermore, this situation may lead manufacturers to continue to assess against "old" harmonised standards when marketing their products instead of applying the latest state of the art standards.

Unless policy makers take a more wholistic approach to implementation during the legislative process the current direction is set to become a major obstacle to the competitiveness of high-tech manufacturing in Europe.

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[1] Machinery Proposal: Mandatory third party certification is a step backwards, 11 October 2021
https://orgalim.eu/sites/default/files/attachment/Third%20party%20certification_FAQ_111021_.pdf

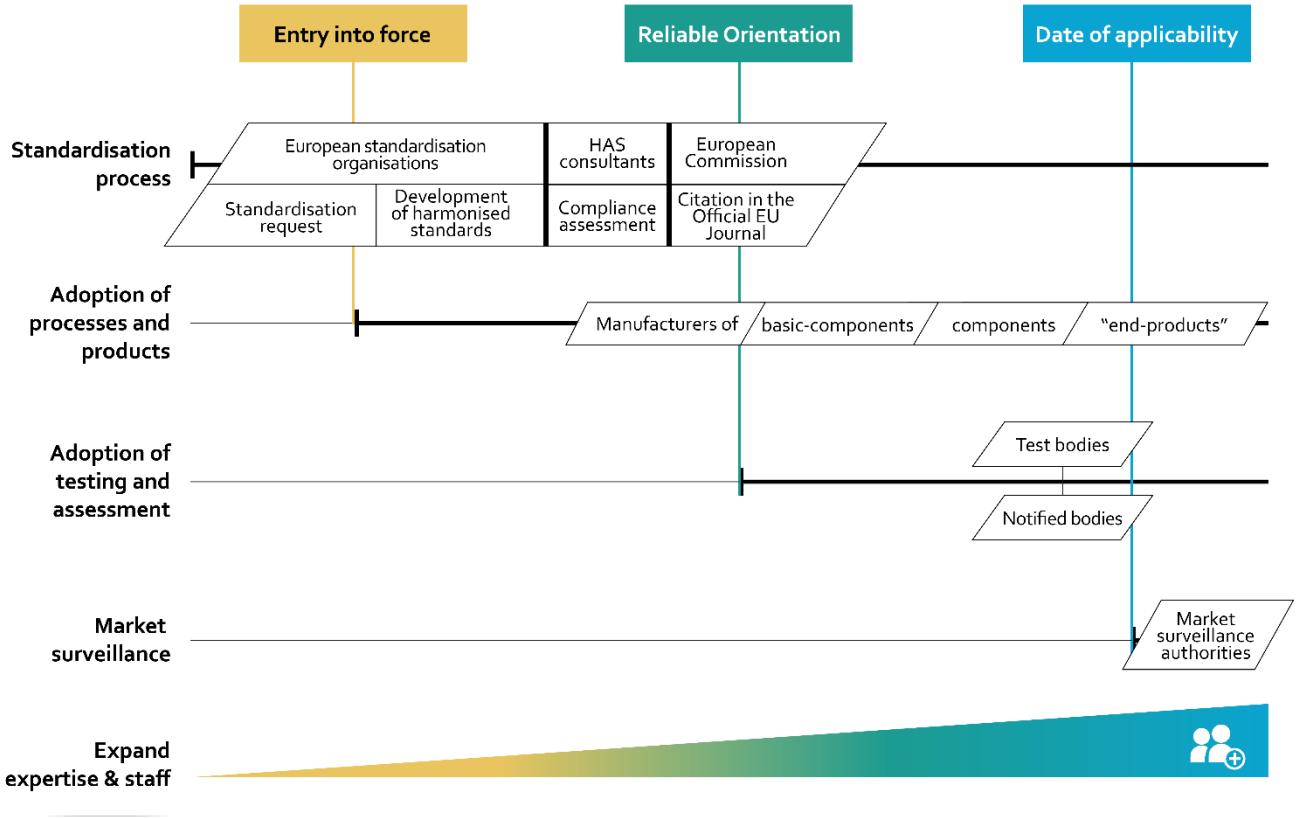

Figure 1: Overview of steps and players involved in the implementation of new European legislation for standards organisations, manufacturers and market surveillance

Steps and players involved in the implementation of new European legislation

The above overview shows the work that needs to be done to ensure a smooth and effective implementation of new European legislation. It is important that the various stakeholders (standards organisations, manufacturers and market surveillance authorities and the co-legislators) work together to achieve this implementation. The process begins as soon as the EU co-legislators negotiate a stable legislative text, and all the stakeholders should already be focused on expanding their staff's expertise on the new requirements proposed in the legal proposal before the entry into force of a new legislation.

At this point the **Commission** will need to develop the draft standardisation request. The **European Standards Organisations** should anticipate the work on standards needed to support the new requirements. For example, by creating a mapping of existing technical specification documents or by starting to develop the standards even before the standardisation request is drafted. It is important to note that the development process of a standardisation deliverable takes between two to three years. Harmonised standards that are to be cited in the Official Journal of the EU by the **European Commission** require the further checks of **HAS consultants** which can bring the process up to five years.

Manufacturers will start to anticipate and adapt their processes once the new legal text enters into force. However, many manufacturers, especially small companies, need support to adapt their processes, for example, guidance documents, answers to FAQs by national and European trade associations or the national authorities. In many cases, manufacturers do not start to adapt their processes until a standardised approach is ready in the form of a regional or international standard or not until the harmonised standards are reliably cited in the Official Journal of the EU. As many of these products are dependent on long value chains, the manufacturers of basic components need to be ready to provide relevant data to other economic operators earlier than those of more complex components and end-manufacturers who assemble the end-product.

Test bodies and notification bodies will need to be fully prepared and available to certify and assess products according to the new requirements at least six months ahead of the application date.

Finally, **market surveillance authorities** will start to check products according to the new requirements on the date of application.

Main challenges to be addressed

I. Increase in mandatory third party certification requirements

The recent tendency to require mandatory, independent third party certification for an ever-broader range of products is often explained as a measure to increase confidence in the compliance of products and processes. However, this is not in line with the NLF principle where the third-party intervention is linked to the risk of the product and not to perceived confidence and compliance of products and processes. Meanwhile, the verification of the compliance is a function of market surveillance, which remains essential to build and strengthen trust in the compliance of products entering the single market. The introduction of mandatory third party certification in recent revisions and regulation proposals is in our view a confusion between the services provided by Notified Bodies and the prerogatives of market surveillance authorities. Notified Bodies provide a service against payment which amounts to an opinion on the compliance of a product, which can be requested by the economic operator or the market surveillance authorities. Third party certification does not protect the users against non-compliant products offered via online platforms, for example, and does not protect European manufacturers from the unfair competition that comes along with these products. The Notified Bodies bear no responsibility in case of error or incomplete conformity assessments. Only the manufacturer can ensure that their products are safe, secure and otherwise compliant with all regulatory requirements and they alone bear responsibility for their products. Market surveillance authorities on the other hand bear responsibility for their risk management decisions.

Therefore, increasing mandatory third party certification of products to compensate for the weaknesses of market surveillance activities would not only put a strain on the system it would also increase costs for lawful manufacturers (as opposed to rogue traders) and erode their competitiveness.

II. Short transition periods

It is important to note that the implementation of the requirements of New Approach legislations by the manufacturer takes place in two steps:

1. The standardisation of the requirements included in the legal act by all stakeholders involved in the development of a standard and,
2. The adaptation / redesign / assessment of products / processes to these requirements by the manufacturer.

Therefore, sufficiently long transition periods between the legislation's publication and application are important so that all the actors involved in the implementation of a legal act (standards organisations, market surveillance authorities, notified bodies, accreditation organisations, national authorities and economic operators) **have sufficient time to implement new or amended requirements**.

III. Delays in the listing of harmonised standards

In recent years, the delays in the citation of harmonised standards in the OJEU have caused major problems, especially for those legislative texts where the selection of the conformity assessment module depends on the availability of harmonised standards. **If such standards are not available (or not available in time), a Notified Body (usually a certifier) must be involved in the conformity assessment of the product.** This problem affects, among others, the Machinery Regulation, the Radio Equipment Directive Delegated Act and will also concern the AI Act, the Cyber Resilience Act and the Outdoor Noise Delegated Act according to the current proposals.

In addition, uncertainty may arise as to which standard should be used by the manufacturer: the one listed in the OJEU and giving presumption of conformity or the state of the art version published by CEN-CENELEC but which does not (yet) give presumption of conformity. Finally, without a standard, it is difficult to maintain a level playing field across all EU Member States since different Notified Bodies may have different comfort levels in assessing safety and security.

IV. Limited capacities of Notified Bodies

As a result, of delays in the listing of harmonised standards or if a new legal act or a revision of an existing act makes the use of third party conformity assessment mandatory for placing the product on the market, **Notified Bodies will experience a peak in demand,** as they not only have to assess newly placed products on the market, but also all existing products that, for example, require a new type of examination certificate by a deadline. Notified bodies thus find themselves temporarily faced with significantly higher demands which require the employment of more staff who will not be needed once the transitional period is over.

V. Limited competency of Notified Bodies

Even assuming that Notified Bodies take the financially binding decision to hire the relevant new personnel, these people will need to be trained to carry out assessments, sometimes for completely new aspects (e.g. AI or cybersecurity). On average it takes at least 24 months for a Notified Body to demonstrate the new competencies that have been obtained and acquire a notification for new technologies in their portfolio. Moreover, the criteria that a Notified Body needs to apply to demonstrate its competencies are not always clear. In this context, we see the need for consistency in the quality of the work of Notified Bodies across Member States. This challenge is currently very evident in the area of notification for the RED DA where the criteria differ from country to country. It is therefore imperative to ensure alignment on criteria between Member States to create a level playing field for Notified Bodies and assurance for the manufacturers who are their clients.

Many manufacturers represented by Orgalim are world leaders in connected machinery products and production systems. Their products are the result of long value chains and the components that they integrate may require multiple conformity assessments by separate Notified Bodies. For example, smart metering and smart energy products consist of several components covered under the Measuring Instruments Directive (MID), the Radio Equipment Directive (RED) and cybersecurity requirements. The Notified Bodies with metrological expertise do not necessarily have radio expertise or cybersecurity expertise, but still need to assess security characteristics as specified in both directives, which might lead to differences in the evaluation result when it concerns the cybersecurity features of the product. This situation leads to additional costs, delays in certification, and unnecessary complication in the assessment process.

VI. Limited availability of expertise

Europe is currently facing a severe skills crisis, which also affects the availability of experts who can develop new products or further improve existing products while involved in standardisation. In addition to this, the fact that there is often a strong overlap in the profile of experts who are active in product development and standardisation, and of those who are employed in Notified Bodies, should not be ignored. If we continue to use the field of cybersecurity as

an example, **it is estimated that there is a shortage of over 1 million specialists in across Europe**[2]. Therefore, it is unreasonable to expect that the Notified Bodies have the capacity necessary to support the workload that the loss of harmonised standards, for example in regard to the RED DA, would mean for the majority of radio equipment manufacturers in the Union. For the same reason, it cannot be expected that the Notified Bodies have either the necessary resources or the skill levels necessary to provide a better assessment of the product, or that they will be able to procure them in time.

Solutions

Delays in implementation (e.g. late publication of a standardisation mandate, delays in the development of harmonised standards, the duration of the examination of the standards by the Commission which may delay the citation in the OJEU, or the slow build-up of competence and personnel at the third party bodies, untimely accreditation and notification of conformity assessment bodies) must not be to the detriment of manufacturers who will be left with too little time to make adjustments to the products and carry out conformity assessments. To keep the conformity assessment procedures manageable for the industry and to ensure that products can continue to be legally placed on the European market, Orgalim proposes the following solutions that can be introduced holistically or adapted to the specific regulatory needs:

- **Maintain** focus **on internal production control**: conformity assessment module A of internal production control by the manufacturer has proven its worth in many EU legal acts. The need to use a third party conformity assessment body in the absence of harmonised standards should be assessed on the basis of objective criteria (e.g. accident reports) that clearly demonstrate such a need and justify the additional burden that comes with it.
- Ensure **sufficient length of transition periods** in legislative proposals. A separate, thorough and fair assessment of the proposed duration could help to establish a realistic transition period, taking into account the two steps of implementation:
    1. Development of standards providing presumption of conformity to the legal requirements and,
    2. The adaptation / redesign / assessment of products / processes to these requirements by the manufacturer.

  Alternatively, a **staggered transition approach** can be used, as currently proposed by several stakeholders for the Cyber Resilience Act and as expressed in the Commission proposal for the Data Act concerning **the design and manufacturing obligations**. Deadlines could be adjusted according to criteria such as the criticality of the product (including its dissemination), the existence of relevant (industry) standards that can be used as a basis for harmonised standards, the existing impact of other legal acts, etc. Another approach could be, as proposed by some co-legislators in the current legislative process of the CRA, to link the start of transition times with the availability of harmonised standards.
- **Introduce plausibility checks:** When defining transitional periods, legislators should ascertain whether the envisaged period allocated for the industry to implement the changes can also be realistically met. If certain product groups are subject to a third party certification, the capacities of the existing third party conformity

[2] "LinkedIn data suggests that the demand for cybersecurity skills has grown by an average of 22% over the last year alone in the 12 European markets analysed": The urgency of tackling Europe's cybersecurity skills shortage - EU Policy Blog (microsoft.com).
According to an (ISC)2 study Germany alone has a gap of 100,000 specialists in the field of cybersecurity while France has a gap of 60,859 workers: ISC2-Cybersecurity-Workforce-Study.ashx

assessment bodies should be checked to see if they are sufficient to assess this volume of products within the deadlines of the legal act or whether Notified bodies have to be newly accredited and notified for the new legal act, as for example in the case of the Medical Devices Regulation (MDR), and/or whether the necessary capacities can realistically be built up in time.

- **Improve standardisation processes in order to cite standards in the EU Official Journal in a timely manner:** It is necessary to improve both the processes in standardisation and the efficient involvement of HAS consultants to accelerate the citation. Such improvements in the standardisation process itself must be matched with short and agile review procedures of the standards by the Commission and timely citation. Elements to accelerate the process are, for example, an early discussion of the draft standardisation request with the relevant standardisation bodies, the early provision of the standardisation request by the Commission, an early involvement of the HAS consultants with a sufficient allocation of time or a final review by the Commission services that would intervene before the submission of the candidate harmonised standard to Formal Vote.
- For products and components already certified by a sector-specific conformity assessment certificate showing conformity with essential requirements, the test results could be used to prove conformity through one certification with the essential security requirements in other product-focused legislation for market access such as the CRA, MID, RED, AI and MR. With such an approach, manufacturers would avoid unnecessary costs, duplication and delay of formal assessment procedures for market access which would help to achieve a level playing field for the EU single market. If required, EU Member States can still apply additional assessments based on Directives that cover the use of products such as the NIS-2.
- Finally, we recommend reviewing the peer evaluation of national accreditation bodies across Member States to ensure that a level playing field is maintained. The evaluation should include a check on the means and criteria required to obtain a notification.

Case Study: Delegated Regulation (EU) 2022/30 for cybersecurity, data protection and privacy requirements

The issue of inadequate transition periods to properly implement legislation was particularly evident with the Radio Equipment Directive (2014/53/EU). Even before the beginning of the application of the then-new directive during the one-year transition period between June 2016 and June 2017, the industry faced major problems due to the lack of harmonised standards for the use of the radio frequency spectrum listed in the OJEU. This meant that for a large number of radio systems the companies' only option to place their products on the market in conformity with the legislation was through the use of third party conformity assessment bodies. These Notified Bodies, which normally primarily examine applications for new products coming onto the market, were overwhelmed by the enormous number of enquiries, including many for existing products. In some cases, due to the lack of standards, they also lacked testing requirements and limit values to establish uniform requirements for the products. Many manufacturers had to contend with long waiting periods in order to be able to continue selling their radio equipment in the EU beyond the deadline after which only the new directive could be applied.

This situation threatened to repeat itself with Delegated Regulation (EU) 2022/30 (referred to as RED DA), which was published in January 2022 and which will enter into application on 1 August 2024. The Delegated Regulation is intended to address requirements to protect the network, improve consumer privacy and reduce the risk of fraud in electronic payments (Article 3(3)(d), (e) and (f)). The short thirty-month transitional period chosen by the legislators

to quickly secure these cybersecurity requirements for internet connected radio equipment was further reduced by setbacks in the drafting of the standardisation mandate, which was delayed by more than six months. Although the Commission has agreed to extend the implementation deadline, much will depend on the standardisation activities which are currently being delayed due to diverging opinions between the Commission and the European standardisation organisations on fundamental questions. For example, some of the relevant terminology is unclear and there are different expectations regarding the level of resilience that can realistically be achieved.

If no standards are available in time to allow manufacturers to adapt their products for the entry into application of the RED DA, manufacturers will have no choice but to involve a Notified Body for these aspects in order to be able to continue placing their internet-connected radio equipment on the market beyond the deadline. This would affect a significant part of all radio equipment already available on the market. In addition to consumer products connected to the internet, a large number of wireless IoT devices in the production environment and in the transport and energy sectors would also be affected.

The expected spike of requests to the Notified Bodies for this large number of affected products would generate a significant backlog, considering that there are only 72 Notified Bodies currently listed in the European NANDO database which are allowed to assess the conformity of radio equipment worldwide. A number which could be reduced even further, as each of these Notified Bodies will in future also have to demonstrate competence in cybersecurity in addition to the current requirements relating to the use of the radio frequency spectrum, safety and electromagnetic compatibility in order to continue to carry out their work. At the beginning of March 2023, only four Notified Bodies worldwide had the appropriate notification.

Taking all of these factors into account, we fully welcome the Commission's decision to extend the transition period taken at the RED Expert Group of 8 and 9 June.

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