Position Paper

Ensure adequate transition periods for a functioning EU Single Market

Executive Summary:

- The **implementation of short transition periods for legislative proposals in connection with mandatory third-party certification is** causing major problems for German and European manufacturers. This strongly affects their ability to continue selling their products after the deadline for the implementation of those legislative proposals without delays.
- **Capacities of third-party conformity assessment bodies** are **designed for regular demand** and **not** for the assessment of a large number of products on the market for a **target date.**
- **Delays in the citation of harmonised standards** in the EU Official Journal additionally burden third-party conformity assessment bodies. This is because more and more legislative proposals stipulate the mandatory **involvement of a Notified Body (certifier) in cases where** harmonised standards **are not cited or not applied** (e.g. **Radio Equipment Directive, Machinery Regulation, Cyber Resilience Act, AI Act**).
- **There is need for an extension of the transitional period for the Radio Equipment Directive.** Without such an extension and without the timely citation of harmonised standards for cyber security in the EU Official Journal, there is a threat of market disruptions as of 1 August 2024.

Core Issues

- **Ensure sufficient duration of transition periods:** Delays in the process of implementing a legal proposal (e.g. late publication of a standardisation mandate, delays in the standardization process, duration of the examination of the standards by the EU Commission for listing in the EU Official Journal, build-up of expertise and personnel at the third-party conformity assessment bodies) must not be borne by the manufacturers and impact the competitiveness of the industry. Transition periods must be adequate in view of the number of standards to be revised or developed for the first time. This is especially important for new legislative proposals in the digital sector, where all actors (including standardization organisations, manufacturers, market surveillance, third-party conformity assessment bodies) are faced with new requirements, In such cases longer periods for implementation should be set. Alternatively, a staggered approach could be used, as currently proposed by ZVEI for the Cyber Resilience Act. Deadlines could thus be adjusted according to the criticality of the product (incl. its dissemination), the existence of relevant (industry) standards that can be used for harmonised standards, and the existing impact of other legal acts. It must also be taken into account whether the third-party conformity assessment bodies have to be newly accredited and notified for the legal act, as for example in the case of the Medical Devices Regulation (MDR). This may result in further delays.
- **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).
- **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 processes. At the same time, shorter deadlines in the standardisation process itself must not be counteracted by long review procedures of the standard by the EU Commission and delays in the citation of standards. 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 mandate by the EU Commission or an early involvement of the HAS consultants with a sufficient allocation of time.

- **Introduce plausibility checks:** In the legislative process, it should be checked in future whether the envisaged transitional period allocated for the industry to implement the changes can be realistically met. Also, if certain product groups are subject to a (de facto) third-party certification, it should be checked whether the existing third-party conformity assessment bodies have sufficient capacities to realistically assess this volume of products within the deadlines of the legal act or whether the necessary capacities can realistically be built up in time.
- **Radio Equipment Directive requires need for immediate action**: Without timely listing of harmonised standards, which currently seems inevitable, there is a threat of market disruption for radio equipment as of 1 August 2024. A sufficient extension of the transition period is necessary to avert a sales stop of internet-connected radio equipment. This would pose massive problems for German and European industry and damage competitiveness in the international environment.

Problem at stake

For companies in the electrical and digital industries, future-oriented, coherent market access conditions in the European Single Market are key for 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 this development since their introduction in 1985. However, German and European industry have been facing increasing problems with the implementation of these harmonisation acts in recent years. As new, more far-reaching requirements for products are foreseen to be implemented, increasingly short transitional periods are implemented before the entry into application. This is in many cases done without consideration of whether these requirements can actually be implemented within the foreseen time frame.

Delays in the implementation of these legal acts ultimately lead, as is currently the case with the Medical Devices Regulation, to the industry not being able to place products on the market in a timely manner. Often, when deadlines are tight, a small bottleneck at just one juncture is enough to delay the implementation schedule. There are many reasons for this: delayed standardisation requests, delays in standardisation (often also caused by unclear terminology in legal texts), late citation of standards in the EU Official Journal by the European Commission, delays in the notification of Notified Bodies (certifiers) by the competent bodies in the member states or, in the case of mandatory third-party conformity assessment, insufficient capacities at Notified Bodies.

In the end, such delays shorten the time provided for the manufacturer to adapt products to new or changed requirements and to carry out the relevant conformity assessment procedures before it can be placed on the market. To avoid manufacturers from running the risk of not being able to place their products on the market, it is necessary to work more intensively during the legislative process to prevent such problems from arising.

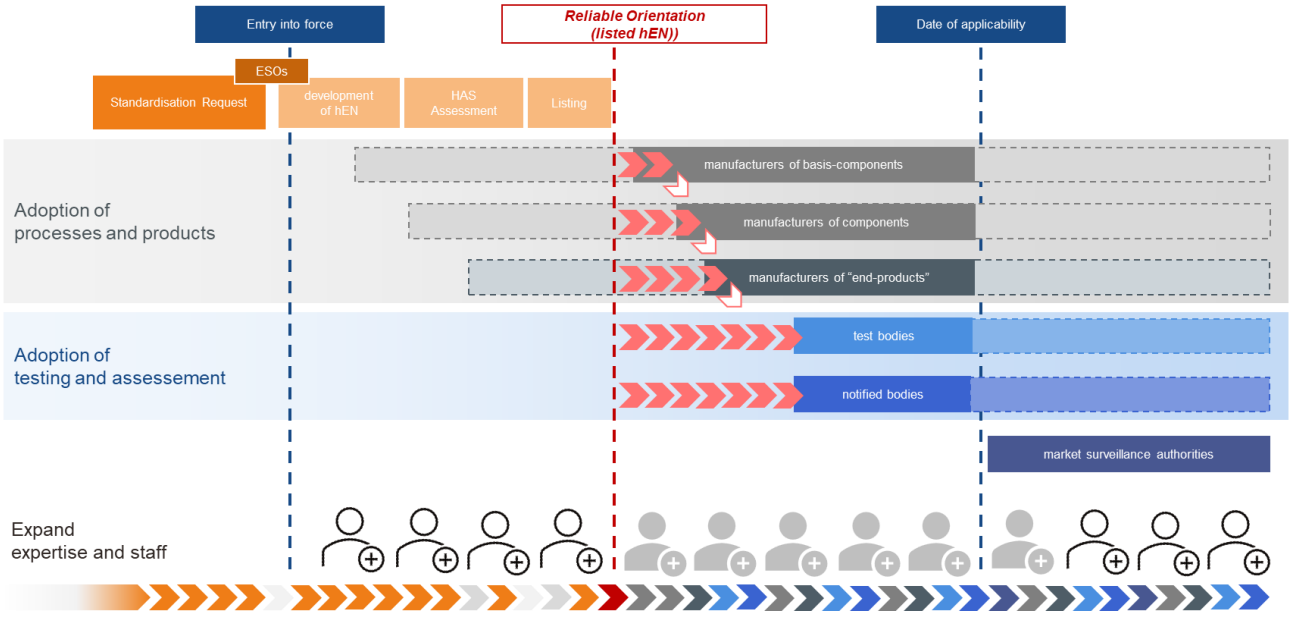

Figure 1: Timeline for the implementation of new European legislation for standards organisations, manufacturers and market surveillance, source: ZVEI own depiction

Main challenges to be addressed:

I. **Sufficiently long transition periods** are important so **that economic operators** as well as all other **actors involved** in the implementation of a legal act (market surveillance authorities, notified bodies, national authorities) **have sufficient time to implement new or amended requirements in due time**. This is particularly important when new legal acts or legislative amendments lead to changes in the technical requirements for a product or if new product groups are covered by a legal act and as a result, these products have to be adapted to the requirements and reassessed for conformity. Delays in implementation must not be to the detriment of downstream actors (e.g. a delay in the development or listing of harmonised standards leads to less time for manufacturers to make adjustments to the product and carry out conformity assessments).

II. **In recent years,** the problems and delays in the **citation of harmonised standards in the EU Official Journal have caused major problems, especially for those legal acts where the choice of conformity assessment module depends on the availability of harmonised standards**. That are cases where the internal production control by the manufacturer (manufacturer's self-declaration) can only be used if a standard relevant for the product is listed in the OJEU and applied. **If such a standard is not available (or not available in time), a Notified Body (certifier) must be involved in the conformity assessment of the product. This problem affects, among others, the Machinery Regulation, the Radio Equipment Directive or the drafts of the AI Act and the Cyber Resilience Act.** As a result, especially during the transitional period (from an existing) to a new legal act, the number of assessment enquiries to Notified Bodies increases at short notice and is difficult to predict. For such products, **timely conformity assessment** becomes **increasingly dependent on the availability of Notified Bodies,** especially in the initial phase of the implementation of a legal act. At the same time, the lack of standards also has an impact on the work of Notified Bodies, which often use the requirements in the standards in order to ensure uniformity in the assessment.

III. **The capacities of notified bodies are finite**. **If a new legal act or the revision of a legal act makes a** new conformity assessment involving a third-party mandatory for placing on the market, **Notified Bodies** face a **peak in demand.** They not only have to assess newly placed products on the market, but also all existing products that, for example, require a new type examination certificate by a deadline. The lack of harmonised standards cited in the EU Official Journal further increases this effect for some legal acts (see II). Notified bodies thus find themselves to deal with significantly higher demand during the transitional period for temporary periods. This requires a large number of employees for a certain period that won't be needed once the transitional period is over. At the same time, in this exceptional situation, (new) personnel must be trained or recruited for new requirements, who must be able to carry out corresponding assessments even for completely new aspects (e.g. AI or cybersecurity) even in the absence of harmonised standards. This challenge is likely to be exacerbated by the fact that several legislative proposals are currently being developed at the same time, which entail new regulatory aspects.

IV. **Take into account bottlenecks in human resources in industry**. Here, too, we see that experts are often not available in sufficient numbers to develop new or further products and to be involved in standardisation at the same time. Especially since there is often a strong overlap in the profile of experts who are active in product development and standardisation or are employed in Notified Bodies. For example, there is a shortage of 100,000 specialists in the field of cyber security in Germany alone.

For manufacturers, this resembles a lottery in several respects: On the one hand, the question of whether to decide early on for the higher costs of a conformity assessment procedure involving a third-party conformity assessment body or to rely on the harmonised standards relevant for the products being developed and cited in the EU Official Journal in good time before the deadline. On the other hand, if a third-party conformity assessment body is involved, the question arises as to whether the conformity assessment body is notified in good time and whether the manufacturers own products are still assessed in good time before the deadline in case of long waiting lists. If this is not the case, the products concerned cannot be placed on the market for an indefinite period. Especially for manufacturers with small quantities, many affected product groups or products that have to undergo individual conformity assessment, this can threaten their existence. For this reason, 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.

Radio Equipment Directive

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

The problem of short transitional periods is particularly evident with the Radio Equipment Directive (2014/53/EU). Already at 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 cited in the EU Official Journal. At that time, harmonised standards were not cited in time in the EU Official Journal by the EU Commission within the one-year transition period from the old to the new directive. This meant that for a large number of radio equipment, companies could only place their products on the market with the involvement of a third-party conformity assessment body. These Notified Bodies, which normally primarily examine applications for new products coming onto the market, were overwhelmed by the enormous number of enquiries, especially for the many 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. Manufacturers sometimes had to put up with long waiting periods in order to be able to continue selling their radio equipment in the EU beyond the deadline from which on only the new directive could be applied.

This situation now threatens to repeat itself with Delegated Regulation (EU) 2022/30, which was published in January 2022 and will enter into application as of 1 August 2024. This Delegated Regulation is intended to address the requirements in Article 3(3)(d), (e) and (f), i.e. requirements to protect the network, improve consumer privacy and reduce the risk of fraud in electronic payments. The 30-months transitional period chosen by the legislators to quickly anchor these cybersecurity requirements for internet connected radio equipment in the product legislation was chosen very short from the beginning, a circumstance that was repeatedly criticized, especially by the industry. This short time frame has been further reduced by the standardisation request, which was delayed by more than six months. The standardization activities are currently further delayed, due to different opinions between the EU Commission and the European standardisation organisations on fundamental questions of the standard and the procedure. For example, some of the relevant terminology is unclear and there are different expectations regarding the level of resilience that can realistically be achieved. A timely citation in the EU Official Journal before 1 August 2024 thus seems almost impossible.

If no standards are available, manufacturers will have to involve a Notified Body for these aspects concerned in order to be able to continue placing their internet-connected radio equipment on the market beyond the deadline. This would affect a large part of all radio equipment available on the market. In addition to consumer products connected to the Internet, a large number of wireless IoT devices in the industrial environment as well as in the transport and energy sectors would also be affected.

This large number of affected products is not compatible with the current number of only 72 Notified Bodies listed in the European NANDO database, which are allowed to assess the conformity of radio equipment worldwide. At present, it is not even certain that this number will not be reduced even further, as each of these current Notified Bodies will in future also have to demonstrate competence in cyber security in addition to the current requirements relating to the use of the radio frequency spectrum, safety and electromagnetic compatibility in order to continue to be allowed to carry out their work. As of the beginning of March 2023, only four Notified Bodies worldwide had the necessary notification.

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