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## **WORKING DOCUMENT**

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
N° Cion doc.:	IM 5023 2025 INIT
Subject:	Omnibus IV (digitalisation and common specifications) - Compilation of written comments

Please find attached the compiled MS comments on Omnibus IV - Digitalisation & Common specifications as received from : BE, BG, CZ, DE, ES, FR, LT, NL, AT, SI and FI.

WK 8008/2025 INIT

**LIMITE**

**EN**

## MS comments on

### Simplification Omnibus IV – Digitalisation and common specifications

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# BELGIUM

Dear Presidency,

Belgium is still reviewing the text and wishes to maintain a scrutiny reservation. We would welcome further clarification by the Commission regarding the following questions:

## ***Common specifications***

- 1- Why did the Commission not align the wording on common specifications with provisions in recent legislative acts, such as regulation 2023/1230 on machinery or regulation 2024/1689 on artificial intelligence or of Art. 14 of the soon to be adopted Toy Safety Regulation?
- 2- Among the conditions enabling the Commission to adopt common specifications, condition (c) refers to a “need to act in response to urgent concerns regarding non-compliant products.” Could the Commission elaborate on how this condition relates to condition (b)? Are these conditions cumulative or alternative? How is urgency to be assessed?
- 3- Which legal regime is applicable when, after the adoption of common specifications, references to harmonised standards that cover the same essential requirements are published in the Official Journal of the European Union?

## ***Digitalisation***

- 4- Why does the text not provide for definitions of “*consumer*” and “*safety information*”?
- 5- The terms “*instructions*” and “*safety information*” seem to be used interchangeably and in various combinations (*and/or*) in i.a. the Pressure Equipment Directive and the Simple Pressure Vessels Directive. This could lead to confusion.
- 6- “*Digital contact*” has been introduced as a definition. Why did the Commission not introduce a corresponding obligation for manufacturers and importers to provide such a digital point of contact in the machinery regulation?
- 7- The machinery regulation already allows for instructions to be provided in digital format. Why is the Commission proposal not aligned with the text of the machinery regulation?
- 8- Manufacturers are now obliged to provide information digitally to the requesting authority. What if they are unwilling or unable to comply?
- 9- Instructions must remain accessible online for the expected lifetime of the product. What about products with an expected lifespan of several decades?
- 10- For lifts, where is the electronic address or machine-readable code to be placed (inside the lift, in the machine room, elsewhere)?
- 11- Digitalisation of the Declaration of Conformity (DoC) – does this mean the DoC will also need to be signed electronically?

# BULGARIA

## OMNIBUS IV – DIGITALISATION AND COMMON SPECIFICATIONS

### **General comments**

Bulgaria would like to thank the Polish Presidency for the opportunity to provide written comments on the Omnibus IV Package as a follow-up of the meeting of Working Group “Antici”, Sub-group “Simplification of legislation” held on 06.06.2025.

At this stage Bulgaria is still in a process of examining the proposed amendments in Omnibus IV Package and maintains a horizontal scrutiny reserve.

### **Specific comments**

**I. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 as regards digitalisation and common specifications**

**Article 1 – Amendments to Regulation (EU) 765/2008**

**Bulgaria strongly objects the proposed amendments in Article 1 of the Proposal for a Regulation.**

All national accreditation bodies and accredited conformity assessment bodies (CABs) perform their activities according to international standards recognised as harmonized standards. Standards setting out requirements for the national accreditation bodies and CABs lay the foundations of the international accreditation system and the conformity assessment system. They play an important role in the mutual recognition of conformity assessment results. The use of common specifications as an alternative to those standards will lead to use of different rules and application of divergent approaches to the accreditation process and in international plan this will automatically place the national accreditation bodies out of the world accreditation system.

Moreover, such an alternative is already provided in Article 13, paragraph 2 of Regulation (EU) 765/2008 - the Commission could request EA to develop sectoral accreditation schemes. We consider that the existing possibility of other means of demonstrating compliance with the requirements such as the sectoral schemes for accreditation could be used as an existing option instead of proposing new amendments. This makes the proposed common specifications absolutely unjustified. **At this stage the proposed amendments to Regulation (EU) 765/2008 are a red line for Bulgaria.**

## II. Proposal for a REGULATION and Proposal for a DIRECTIVE

### - Part „Common specifications”

- “Common specification” is defined as „a set of technical requirements“. We consider that this proposed definition should be based on the definition of „technical specification” as laid down in all NLF aligned acts and should be limited only to the specific product.

- For the quality management system provided for in some of the modules of the acts the CABs also apply international standards recognised as harmonised standards under the NLF legislation. We note that these harmonised standards could not be automatically replaced in the modules, and specifically in the provision for presumption of conformity for these systems. The provision on common specifications ensuring presumption of conformity in relation to a product could not be applicable to systems or bodies.

- The acts in the package already contain a chapter crisis-relevant common specifications based on Omnibus IMERA Package (Directive (EC) 2024/2749 and Regulation (EU) 2024/2748). We consider that one and the same term – “common specifications” cannot be used with different meaning in different parts of the act having in mind also that these common specifications are adopted on different grounds. We also note that the criteria for adoption of common specifications under the IMERA package do not consider the availability of common specifications in cases other than „emergency“ and this aspect needs to be reflected in the provisions on common specifications for “crisis relevant goods”.

- We object to the third condition empowering the Commission to adopt common specifications: „(c) where the Commission considers that there is a need to address **an urgent concern** with regard to non-compliant subsystems and safety components. – paragraph 1 (c)“. It is unclear, confusing and is absolutely unnecessary since the hypothesis of „urgent concern“ is not linked to the lack of a standard. In any case where a standard is not available the first condition in point a) could always be used.

- We object to the use of an „advisory procedure” in terms of adoption of implementing acts for common specifications. We insist on using the „examination procedure” as in the case of the Regulation (EU) 2023/1230 on machinery and the Proposal for a Regulation on toys.

- We consider that a right to “objection” should also be provided by analogy to the objection procedure laid down in Regulation (EU) 1025/2012 on standardization and in Regulation (EU) 2023/1230 on machinery and the Proposal for a Regulation on toys.

- We consider that specific provisions need to be included in the market surveillance related provisions for covering the case of shortcomings in the common specifications and the subsequent actions in such cases by analogy of the situations in NLF acts related to shortcomings in the harmonised standards – please refer to Regulation (EU) 2023/1230 on machinery and others.

## **- Part “Digitalisation”**

We have still not finalised the detailed examination of the package proposal in this aspect. However, at this stage Bulgaria considers that certain additional changes would also be necessary in the part concerning digitalisation.

Bulgaria would like to receive clarification about aspects related to the drawing up, keeping and providing on request of the Declaration of conformity (DoC):

- We would like to receive clarification how the provision “*shall keep a copy of EU Declaration of conformity*” should be interpreted and applied by taking into account that the Declaration of conformity (DoC) should be drawn up in electronic form and need to be accessible online. Does it mean that the declaration shall be kept on a paper copy or by maintaining a website and furthermore when it is included in the DPP?
- Certain provisions in conformity assessment modules refer to „*a written Declaration of conformity*”. For us it is unclear whether the term “written” is not in contradiction with „electronic form”.
- In the context of the amendments related to digitalisation of the EU Declaration of conformity (*to be drawn up in electronic form*) for us it is not clear how this declaration will be signed taking into account that the model of the declaration (as included in the annexes to the respective acts) is not changed.
- Taking into account that Directive 2000/14/EC on noise outdoors provides for **EC** Declaration of conformity while the other acts provide for **EU** Declaration of conformity, we would like to receive explanation how will the requirements for a single Declaration of conformity as well as regarding the uploading of this declaration in the Digital Product Passport be fulfilled. Is it possible to replace **EC** Declaration of conformity with **EU** Declaration of conformity in order to achieve real simplification?
- In addition, we would like to receive clarification about the reasons for not including amendments to Directive 2014/28/EU on explosives for civil uses (CIVEX) and Directive 2013/29/EU on pyrotechnical articles (PYRO).

## Simplification Omnibus IV – Digitalisation and common specifications

### CZ comments and questions

11. 6. 2025

The Czech Republic welcomes the proposals in general, as we fully support initiatives aimed at digitalisation, reducing the administrative burden for businesses and economic operators, and ensuring uniform conditions and procedures for demonstrating conformity of products across the sectors.

However, the Czech Republic raises a couple of questions and comments on the proposed provisions:

#### **1/ The provisions on the digitalisation need to be clarified to avoid misinterpretation.**

*Questions for the Commission:*

- *The following provision shall be inserted in the text of the legal acts amended by the proposed directive and regulation, specifically, for example, in the case of Regulation (EU) 2023/1230: 'Where other Union legislation applicable to machinery or related products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Parts A of Annex V to be included in the EU declaration of conformity and the instructions referred to in Article 10(7) shall be provided only in that digital product passport.' Shall we understand this provision to mean that if a product is subject to a product digital passport requirement under another EU legal act, the separate instructions or EU declaration of conformity required in this specific case, i.e. Regulation 2023/12030, shall not be required?*
- *Is a manufacturer's e-mail address understood to be a form of digital contact?*
- *If the manufacturer (including its website) ceases to exist in the future, where will the instructions and declaration of conformity be available?*
- *Must a manufacturer who manufactures machinery for his own specific use with his own know-how also ensure that the machinery is accompanied by an internet address or a machine-readable code through which the EU declaration of conformity can be accessed?*
- *When referring to a 'digital declaration of conformity' does this encompass a scanned document with a physical signature, an electronically signed document, or are both variations acceptable?*
- *We would also welcome information on the anticipated method of integration of established digital solutions into the planned structure and tools like the European Business Wallets.*

#### **2/ The common specification must remain a fallback option to the harmonised standards.**

Republic is aware of the situation in European Standardisation caused by the recent CJ EU rulings and acknowledges the need to ensure other methods to demonstrate conformity in case the harmonised standards are not available. Thus, we support the proposal as regards the introduction of the possibility to adopt the common specifications as such. However, this instrument needs to remain a fallback option to the standardisation. In that regard, the solution adopted in the Machinery Regulation should be respected as it provides a well-balanced solution agreed by the colegislators and followed in other sectorial regulation that have been adopted thereafter. The procedure adopted in the Machinery Regulation provides the Commission with the possibility to adopt the common specification if the standardisation route fails and, as a result, the harmonised standards are not available; namely in the cases when the Commission has requested to draft a harmonised standard, but the standardisation request has not been accepted or the harmonised standard was not delivered within the deadline, or the harmonised standard does not comply with the standardisation request and no reference to harmonised standards has been published in the OJ EU and no such reference is expected to be published within a reasonable period. These triggering grounds already fully cover the situation which the Commission presents as the situation that needing to be tackled, i.e. when the standardisation process is blocked.

*Questions for the Commission:*

- *Why has the Commission deviated from the procedure established under the Machinery Regulation?*
- *Why does the Commission consider the conditions set out in the Machinery Regulation for triggering the procedure of adoption of common specification to be unsuitable?*

- *Which situations are supposed to be covered by the "need to address an urgent concern with regard to non-compliance of the respective products"? Could the Commission provide us with a concrete example of an „urgent concern“ that has already occurred in any of the product sectors to better understand the reasons behind it?*
- *How will the situations be addressed when a harmonised standard covering the same essential requirements is published in the Official Journal of the EU to avoid duplicities?*

**3/ The national experts have to be adequately involved in the process of drafting the common specifications.**

The development of the harmonised standards is based on the bottom-up approach, ensuring the active participation of the relevant stakeholders. Taking into account that the common specifications will, in fact, substitute the harmonised standards, the process of their development should at least ensure the proper participation of national experts. Thus, the implementing acts should be adopted in accordance with the **examination procedure**, which ensure stronger reflection of the opinions of the national experts. The drafts of the implementing acts should also be properly **consulted with all relevant stakeholders**.



## GERMANY

German comments on the proposals for an amending regulation on digitization and common specifications (ST 9318/25 + ADD 1-2)

and an amending directive on digitization and common specifications (ST 9327/25 + ADD 1-2)

11.06.2025

General remarks:

Proposal	Description	Question/Comment
Directive 2014/31/EU, Directive 2014/32/EU, and other legislation concerning product regulation	There is no definition for “electronic form,” which is likely to cause concern, particularly among conformity assessment bodies and market surveillance authorities. We therefore kindly request the inclusion of the following comment.	To minimize confusion, we would like to ask for a definition of “electronic form” to be included in the product regulation.
General	In the definition of “digital contact,” the requirement is stated as “without the need to register or to download an application.” However, even browsers and email clients are applications that need to be installed. What form of communication would remain under such a condition? It appears that the intention is to refer specifically to “additional specific applications” or similar. This should be	<p>Please clarify the definition of “digital contact”: “... without the need to register or to download <b>additional specific</b> applications (other than a browser or email program) “.</p> <p>In addition, what is meant by the “single point” in the context of the “digital contact”? (see amendments to Article 7(2)(b)).</p>

	clarified in the text (see comment).	
general	How is it ensured that manufacturers comply with their obligation to make technical documentation available for the lifetime of the product, or at least for 10 years after it has been placed on the market? And what happens if a manufacturer ceases operations shortly after the product is placed on the market? A third-party service provider could potentially take over this function (similar to the approach with the Digital Product Passport). This question is particularly relevant for market surveillance, in-use surveillance, and end users.	Please clarify how it can be ensured that manufacturers actually make accessible any documentation for the lifetime of the product and for at least 10 years after the placing on the market. What happens if a manufacturer goes out of business and ceases operations after the placing on the market?
General		<p>Why did the Commission decide to introduce the Common Specifications individually in the respective legal acts, rather than as part of the revision of the EU Standardisation Regulation or the revision of the New Legislative Framework (NLF)?</p> <p>In principle, we welcome Common Specifications, provided that priority is given to harmonised standards.</p>
General		Why is the Commission deviating from existing legislation (e.g. the EU Machinery

		Regulation) when introducing Common Specifications in the respective sectoral legal acts?
General		Why is the specific process for developing Common Specifications, and in particular the involvement of all stakeholders, not clearly defined and made transparent in the respective sectoral legal acts?
General		

#### Non-automatic Weighing Instruments (Directive 2014/31/EU)

Proposal	Description	Question/Comment
Annex 1, No. 14, 4 <sup>th</sup> sentence		We support the Commission's efforts to eliminate references to the paper format in the product regulation. In this light we would ask that the reference to a paper printout in Dir. 2014/31/EU, Annex I No. 14, 4th sentence be amended as follows: "Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer <b>or on the customer's request be made available electronically in a standardized data format.</b> "

#### Measuring Instruments (Directive 2014/31/EU)

Proposal	Description	Question/Comment
Art. 4, No.14	Definition of common specifications	In Directive 2014/32/EU, in addition to harmonized standards, there are also normative documents. These have, as far as has been seen so far, been overlooked in one instance—namely in the definition of the “common specifications. We therefore propose the following no. 14 (a):

		<p>‘(14a) ‘common specifications’ means a set of technical requirements, other than a standard <b>or a normative document</b>, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;’.</p>
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### Regulation 2023/1542/EU, Battery regulation

Proposal	Description	Question/Comment
Art. 3, No. 23a	Definition of digital contact	Regarding the definition “digital contact”: DE understands that, in theory, a single contact point could simplify interactions with the economic operator. However, there is no obligation introduced for the economic operator to actually respond upon reasonable requests. Would it be necessary to introduce this obligation or is this covered in another way?
		Regarding the electronic form of records, correspondence and the declaration of conformity: To what extent is the protection against the counterfeiting of electronic documents ensured? Are there any additional requirements here (e.g. the requirement to use a specific system)?
Art. 38 para 1	Instructions and safety information	This amendment will change the scope of application so that only stationary battery energy storage systems will have to be accompanied by instructions and safety information. DE asks the COM for clarification of reasoning behind this change.

**Directive 2011/65/EU, RoHS Directive**

<b>Proposal</b>	<b>Description</b>	<b>Question/Comment</b>
Art. 16a		DE would like to understand better the new provisions on common specifications. What is the intention behind the change and why has this provision not been proposed in other areas, e.g., the Battery Regulation.
		DE would like to stress the importance of aligning any new digitalization requirements with the ongoing targeted amendment of the RoHS Directive.
		DE is still reviewing the changes in detail and reserves it right to comment at a later stage.

## SPAIN

- In relation to the ongoing discussions on common specifications, we would like to share the Spanish position ahead of the upcoming meeting.

From our perspective, **common specifications may be useful, but only as an exceptional measure**. Therefore, we are not in favour of introducing new or broader grounds for their use. Instead, we believe that the conditions for their application should align with those already established in other EU regulations, such as Regulation (EU) 2023/1230 on machinery and Regulation (EU) 2024/3110 on construction products. Both of these regulations provide for the same limited set of cases, which we consider appropriate:

*“Such implementing acts shall only be adopted where the following conditions are met:*  
*(a) In accordance with Article 10(1) of Regulation (EU) No 1025/2012, the Commission has requested one or more European standardisation organisations to draft a harmonised standard relating to the essential health and safety requirements set out in Annex III and:*  
*– (i) the request has not been accepted, or*  
*– (ii) the harmonised standards responding to that request have not been delivered within the deadline established under Article 10(1) of Regulation (EU) No 1025/2012, or*  
*– (iii) the harmonised standards do not comply with the request; and*  
*(b) No reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, and no such publication is expected within a reasonable period.”*

We believe maintaining these criteria ensures legal certainty, consistency with existing frameworks, and a proportionate use of common specifications, preserving the central role of harmonised standards in the EU single market.

# FRANCE

- Les autorités françaises soutiennent le principe de ce paquet de mesures visant à simplifier les règles et à réduire les charges administratives inutiles au sein du marché unique, afin de faciliter l'activité, l'innovation et la croissance des entreprises.
- **Concernant le volet du paquet Omnibus IV ayant pour objectif de soutenir la numérisation,**
  - les autorités françaises saluent l'ensemble des propositions visant à faciliter le transfert d'information entre les opérateurs économiques et les autorités et d'harmoniser ce transfert par voie électronique plutôt que par papier. Elles considèrent que ces mesures sont de nature à supprimer les redondances et créer des processus plus efficaces pour tous les acteurs.
  - Elles rappelleront toutefois qu'un tel principe ne devrait pas empêcher le législateur de prévoir des dispositions plus restrictives en faveur du format matériel (notamment papier) lorsque des enjeux de sécurité sectoriels le justifient. Elles soulignent qu'il sera essentiel de définir de manière plus précise, et selon une approche sectorielle, la notion « d'informations relatives à la sécurité », désignant les éléments devant toujours être fournis au format papier ou apposés sur le produit. Cette notion, en effet, n'est actuellement définie dans aucun texte. Par ailleurs, pour certains produits, tels que les équipements marins, des conventions internationales imposent encore la délivrance de certificats de conformité au format papier.
  - En outre, elles souhaitent que ces modalités soient rendues accessibles pour l'ensemble des textes relevant du Nouveau Cadre Législatif (NCL). Elles ont en effet identifié que certains secteurs, tels que celui des jouets ou encore le règlement sur l'écoconception des produits durables ainsi que les équipements sous pression transportables ne sont pas mentionnés dans la proposition.
- **Concernant le volet relatif à l'harmonisation des alternatives pour démontrer la conformité des produits par le recours à des spécifications communes,**
  - les autorités françaises signaleront qu'elles soutiennent la nécessité de définir de manière horizontale et transversale les conditions de recours à des spécifications communes, dès lors que ce recours constitue une solution de repli.
  - Toutefois, cette condition n'est pas formulée de manière suffisamment explicite dans la proposition d'Omnibus, contrairement à ce qui est déjà prévu dans d'autres textes (règlement éco-conception, règlement machine, règlement IA par exemple) qui prévoient déjà le recours à ces spécifications pour lesquels les autorités françaises estiment que les conditions d'encadrement sont satisfaisantes. Les autorités françaises soutiennent le recours aux spécifications communes lorsque les normes harmonisées ne répondent pas pleinement aux exigences concernées, conformément à l'article 11 du règlement (UE) n° 1025/2012, elles souhaitent cependant que le règlement Omnibus mentionne explicitement cette possibilité, afin de clarifier son application. Par ailleurs, elles demandent davantage de précisions sur la notion de situation d'urgence évoquée dans la proposition.
  - Dans ce contexte, les autorités françaises expriment leur crainte que les objectifs visés par la Commission pour cette partie de l'Omnibus ne soient pas atteints considérant que la multiplication de spécifications communes serait susceptible de progressivement i) désarticuler les exigences relatives à la conformité réglementaire européenne et les exigences de marché au niveau international et, ii) de fragmenter l'architecture normative européenne et internationale.
  - A titre d'exemple sur les technologies numériques, l'attractivité des organisations européennes de normalisation est en partie garantie par la possibilité, pour les industriels, de participer à

l'élaboration des normes harmonisées. Si cette garantie n'était plus systématique, mais soumise à un arbitrage constant, l'attractivité de ces organisations s'en verrait impactée. En outre, elles identifient que les points d'incertitude portant sur les modalités de recours (arbitrage entre spécifications communes et normes harmonisées, rôle des Etats Membres, représentativité et transparence du processus d'élaboration) ainsi que sur le positionnement même des spécifications communes comme alternative fragilisent de manière importante le *nouveau cadre législatif*.

- **Au regard du nombre important de secteurs concernés par ce volet de l'Omnibus IV, les autorités françaises formulent une réserve à ce stade et préparent une analyse plus détaillée afin d'en évaluer pleinement les implications. Elles considèrent en effet qu'une telle approche transversale nécessite un examen approfondi pour s'assurer de sa cohérence avec les cadres sectoriels existants et de ses impacts potentiels dans les secteurs concernées.**



# LITHUANIA

## **Lithuania's questions for the Commission regarding digitalisation and common specifications**

### **Digitalized communication and information exchange between institutions and businesses:**

1. How should the electronic form be interpreted? For example, is a product manual scanned in PDF format considered electronic or not?
2. Is it necessary for documents to be signed with a qualified e-signature?
3. Will the submission of scanned (e.g., in pdf format) documentation be considered sufficient, e.g., for applications for permits/licenses, or will it be necessary to ensure the submission of documentation through special IT systems (platforms, portals, e.g., in the case of LT, services through the Electronic Government Gateway)?
4. How broadly should the requirement for electronic form and electronic communication be interpreted? E.g. whether it would cover processes such as on-site inspections carried out by institutions, procedural processes, complaint handling, investigations of violations and related documentation (submission of inspection reports, collection of evidence of a possible violation, decisions on the application of sanctions or other market restriction measures)?
5. We can agree on the questions raised by other Member states in regard to “*keep copy*” and “*written*” terms.
6. How and does the upcoming NLF revision and current omnibus proposal is related. How overlaps in regulation will be overseen, E.g. implementation and application starting dates.

### **Digital manufacturer contact:**

1. On a technical level, how will this contact look like?
2. What is its relationship with the future European Business Wallet?

### **Electronic instructions:**

1. How did you decide on the one-month period, and don't you think it is too long?

### **Common specification:**

1. We see possible challenges from the recognition of products in third countries that will not be familiar with the common specifications.

2. Preliminary scrutiny regarding 765/2008. Such a change could bring chaos to the established accreditation system, which is based on EU and international standards. Would you be able to clarify if the amendment provides that the national accreditation body should comply with common specifications?
3. The adoption of common specifications in implementation acts must have strong safeguards similar to those in machinery regulations. Specifically, the term “*Urgent concern*” could be interpreted too widely.

**DPP passport.**

Could you remind us about the future of this system? What will be the practical side of the DPP? Will and how these amendments be integrated into the upcoming sectoral product amendments (as per SM strategy) integrating DPP instruments.

# NETHERLANDS

## Omnibus IV – written comments and questions NL

The Netherlands welcomes the Omnibus IV proposal on digitalisation and common specifications. In particular, the digital-by-default principle is a welcome contribution to the reduction of administrative burdens for businesses and simultaneously facilitates access to data for market surveillance authorities, consumers, and professional users.

With regard to the proposal to give the Commission the possibility to propose common specifications as a fallback option in situations where harmonised standards do not exist, are not available, or where there is urgency, the Netherlands would like to highlight the following:

- The Netherlands is not opposed to the use of (temporary) common specifications drafted by the European Commission. However, the current text in the proposal on common specifications is formulated too broadly and must be amended in order not to unintentionally disrupt the internal market and increase the burden on companies.
- We are currently observing, for example, in the context of the European Health Data Space (EHDS), a development in which the alignment of market actors with international standardisation is, in practice, being decoupled. This leads to a significant increase in administrative burdens for internationally operating market actors, as conformity would then need to be demonstrated against multiple systems.
- To prevent an increase in administrative burdens for market actors, the Commission should carefully examine the wording of the article on common specifications. Common specifications should be seen as a last-resort fallback option, in exceptional cases, where the standardisation system fails to deliver harmonised standards in a timely manner and where no other international or national standards are available as a temporary alternative.
- The Netherlands **therefore proposes to adopt the wording on common specifications as formulated in Article 20 of the Machinery Regulation** (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation, which will replace the existing Toy Safety Directive (2009/48/EC).
- To conclude, the Netherlands wishes to emphasise the importance of ensuring consistency in the substantive content of all harmonised product legislation.

### Questions:

- The Dutch parliament observes that it is sometimes difficult for consumers to distinguish between the official CE (conformité européenne) marking and the “Chinese Export” logo on products. In what way does the Commission expect this Omnibus proposal to contribute to a clearer differentiation between the CE-marking and the Chinese export logo?

## Omnibus IV (digitalisation and common specifications)

### **Art 7 Measuring Instruments Directive (MID) 2014/32/EU:**

We understand the intention of introducing the possibility of common specification. However, the MID already offers an alternative to harmonised standards with the so-called normative documents. Normative documents are based on Recommendations of the International Organisation of Legal Metrology (OIML) and are evaluated by the experts of the Working Group on Measuring Instruments. It is important for AT, that the status of all three options (harmonised standards, normative documents, common specifications) and the interconnection are sufficiently clear for economic operators, notified bodies, authorities and also standardisation organisations. As defined in Art 14a, a normative document could be a common specification. Art 8b (4) treats a normative document as a separate option. It seems unclear in Art 14a whether normative documents are treated by analogy with harmonised standards or converted into common specifications or whether the text is complete at all. AT kindly asks for further explanation of the provisions, in particular in the new Art 14a.

### **General questions concerning digitalisation:**

- **End-user might request paper instructions** or safety information at the time of purchase or up to 6 months after purchase. Does this also apply to products sold via **distance sales**? Do you anticipate problems with the adjusting to digital formats of documentation by international suppliers?
- Could you explain the rationale behind foreseeing **adoption of common specifications with the advisory procedure** (Art. 4. in Regulation (EU) No 182/2011) **and not the examination procedure** (Art. 5 in Regulation (EU) No 182/2011)?

# SLOVENIA

## Omnibus IV – Digitalisation and common specifications

### SI comments and questions

Slovenia strongly supports the goals of the simplification process in order to reduce administration burden and render our EU businesses more competitive. Slovenia therefore stresses the idea of simplification in itself and would like to avoid other initiatives in the process of simplifications that needs to be as streamlined and as fast as possible. Slovenia believes that the horizontal Working party that addresses simplification might not be best placed for discussing more complex issues particularly when the recent compromise solutions are not respected and a more indepth debate is necessary.

#### **Digitalisation**

Slovenia overall promotes digitalisation wherever that is acceptable, particularly in case of technical documentation at the level of relations between businesses and monitoring bodies. We believe that the consumer should have access to paper documents and their availability upon request might not be ideal but as long as the safety instructions are provided on paper this kind of an approximation can be acceptable.

We would like to highlight that the current NLF framework already allows for digital documents. It intentionally does not specify the form of documents in order to allow for adaptability in light of digitalisation tendencies. As this approach proved to be problematic, we are paying particular attention to the level of precision of the proposed measures as we would like to avoid legal uncertainty and provide for a more business-friendly environment and more harmonised monitoring framework.

#### **Common specifications**

**Due to the standardisation stand still we agree with the Commission that establishment of a harmonised alternative solution is crucial.** Common specifications can represent a solution also from the perspective of making them **publicly available** (an important aspect due to the recent case law of ECJ) as we expect them to be **freely accessible in all official EU languages**.

**We believe that the common specification provisions should be harmonised in line with those set out in the Machinery regulation** and later used in other pieces of legislation (ESPR, AI, batteries, toys). In our view, the **medical devices template for the delineation**

**of common specifications is not acceptable** due to the specific nature of the medical devices' domain and the introduced inconsistency with the already mentioned legislation. Slovenia also believes that triggering of common specifications on the principle of urgency is prone to different interpretations and interests which could disguise the fall-back nature of common specifications. We would therefore **avoid the idea of urgency as the possible triggering ground for common specifications.**

**The Machinery regulation model also incorporates an appropriate comitology procedure, meaning the examination procedure.** Common specifications are not harmonised standards where delegated acts are prepared and we therefore believe that the examination procedure should be applied in this context.

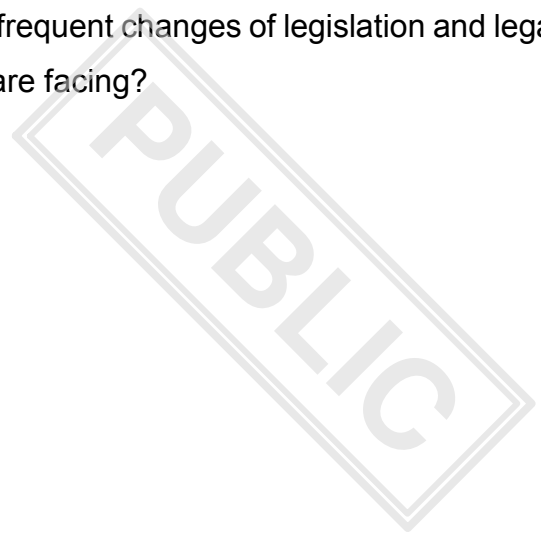
**We are concerned about the inclusion of the area of accreditation** in the given proposal as the proposed change raises many questions. Activities of national accreditation bodies are based on international standards which are also the base for the mutual recognition of accreditation documents. Introduction of common specifications into the area of accreditation raises **the issue of international recognition of EU accreditation.** As the revision of the regulation 765 is envisaged for 2026, **we propose that the issue of accreditation is excluded from the given proposal.**

We understand the need for simplification and speed related to the process but such a broad omnibus approach demands for an extensive application of national authorities that have to examine the effects of the proposed changes on very different sectors. The digitalisation and common specification proposal will also demand for a broad range of changes to the national legislation and we therefore propose the **prolongation of the implementation period from 12 to 24 months.**

As we're expecting revisions of the legislation regarding NLF and standardisation in 2026, we can hardly understand the proposed changes regarding common specifications that are included in the process of simplification as they do not seem to be based on impact assessments and do not reflect the recent compromise solution that has been systemically applied in different pieces of legislation. We are therefore reflecting on the possibility of **addressing the harmonised use of common specifications in the context of the upcoming legislative revisions** which would allow for additional debate that seems to be needed due to the nature of the Commission's relevant Omnibus proposal.

Finally, we would also like to know **how the Commission intends to deal with the possible inconsistencies between the current omnibus results concerning digitalisation and common specifications that will feed into the negotiations on the legislative revisions in 2026 and the final outcomes of the process of revision that**

**might not necessarily reflect the results of the omnibus negotiations.** How does the Commission intend to curb or prevent unnecessary frequent changes of legislation and legal uncertainty that might arise out of the situation we are facing?



# FINLAND

TEM/TTM/YLA/11.6.2025

Written preliminary comments from Finland on the IV Simplification Package, focusing on digitalization and common specifications (COM(2025) 503 and COM(2025)504.)

Please see below questions, general comments and sector-specific comments on digitalization and common specifications.

## **Finland has a general scrutiny reservation on the whole proposal.**

### **Questions:**

- How do the current and the incoming Presidency see the timeline for discussions on this proposal and next steps?
- In light of the upcoming NLF revision, we would like more information about timing of this proposal especially taking into consideration of the coherence between different proposals?
- How have the product sectors in question been selected for the proposals?

## **General comments**

- We consider this topic highly important. Simplifying rules and reducing unnecessary administrative burden is essential for a well-functioning Single Market. The European Commission's new package is a welcome step in this direction, aiming to make it easier for businesses to operate, innovate, and grow.
- In principle, we support the objectives of the package. It promotes digitalization and offers clearer, more streamlined alternatives for demonstrating product compliance.
- More broadly, we are in favour of harmonizing sectoral legislation. We believe this will benefit all stakeholders. The proposed omnibus regulation, which introduces targeted (mostly technical) updates to several sectoral laws, is a useful and pragmatic approach.

## **Some preliminary comments on common specifications**

- We can support the idea of a horizontal approach to common specifications. However, we emphasise the importance of using harmonized standards as the primary means of supporting compliance with EU legislation.
- Examination procedure should be used instead of advisory procedure, when adopting implementing acts establishing common specifications.
- When common specifications are exceptionally used, stakeholder participation must be ensured in their development process. It is critical that all relevant actors are able to



participate. The common specification should ensure a level playing field and not place different actors in unequal positions or unjustifiably favor certain stakeholders, such as large manufacturers.

- We see that the framework adopted for common specifications in the Machinery and Toys Safety Regulations would serve as a better basis for drafting the articles on common specifications.
- The criteria for developing a common specification should be clearly defined and foreseeable. The criteria in the Commission proposal is more vague compared to e.g. the agreement on the text of Toys Safety Regulation.
- There are several issues, which have not been sufficiently addressed in the Commission proposal, such as possible errors in the common specifications, making amendments to the common specifications, status of the common specification when a harmonised standard is developed later etc.
- The proposal does not mention criteria for common specifications. Common specifications should comply with the requirements of directives and regulations.

## **Some preliminary comments on safety instructions and product information in digital form**

- We would like to note that many products covered by the proposals are used by consumers. Therefore we find it important that products that are intended to be used by consumers, safety information should be available on paper.
- It should also be noted that in some cases professional products are used outside mobile networks, such as hearing protectors. Availability of safety information should be ensured in these cases.
- We would like to note It must also be clear where the safety instructions are. The proposal is not line with the locations of safety instructions in all cases. Now there is mentioned electronic form and digital product passport. There is also not clear when safety instructions should be only in DPP and also in paper format for consumers.
- We would like to also note that in many cases, the instructions are not in Finnish or Swedish. The safety instructions should be available in all EU languages. The text is also often very small and is not easy to read.

## **Some preliminary comments on transition period**

- We consider important to ensure sufficient time for transposition especially concerning package of amendments to directives (COM (2025)503). The implementation time to national legislation should be at least 24 months to implement the provisions.

## Some preliminary sector-specific comments

### COM(2025) 503

#### Art 3, Amendments to Directive 2013/53/EU .

- Finland supports the objectives of the proposals in Article 3 of the proposed Directive, concerning amendments to Directive 2013/53/EU.
- However, Finland wishes to point out that manufacturers' obligation to draw up (EU) declaration of conformity in electronic form (point 2; amendments to Article 7(2) of Directive 2013/53/EU) could constitute unnecessary administrative burden to small operators and even represent a critical barrier to the economic viability of smallest businesses.
- In Finland, smallest manufacturers produce only a few boats per year. For these entities, especially the obligation to make the DoCs accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product would in Finland's constitute an unreasonable requirement.
  - To fulfil the objective of cutting red tape, an exemption or facilitation, or at least sufficient transitional period to small manufacturers regarding Article 7(2) should be considered.

#### Art 7, amendments to Directive 2014/32/EU (Measuring Instruments Directive)

- Do we understand correctly, that the proposed article 14a would mean, that a common specification can be developed even if there is a normative document referenced in the OJ, covering the same aspects of the measuring instrument? If yes, why is the normative document not enough?
- In the proposal, common specifications have been added to modules covering the quality systems (D, D1, E1, H ja H1). Is the objective to replace also quality standards by common specifications and if yes, why is this necessary?

### COM(2025)504

#### Art 3, Amendments to regulation (EU) 2016/425 (PPE)

- The provision concerning common specifications might be missing words "common specifications", see underlined.

(10) Article 25 is replaced by the following:

'Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or common specifications or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards or common specifications? cover those requirements.'

#### Art 4 Amendments to Regulation (EU) 2016/426 (GAR)

- Finland support the general approach of the proposal concerning GAR.

- The Gas Appliances Regulation mainly applies to gas appliances used by consumers. Therefore, the proposal that instructions and safety information may be provided in an electronical form can be needless. (According to Article 2(1) of the GAD Regulation, 'appliances' means appliances burning gaseous fuels used for cooking, refrigeration, airconditioning, space heating, hot water production, lighting or washing, and also forced draught burners and heating bodies to be equipped with such burners. According to Article 3(1) of the Regulation, appliances shall only be made available on the market and put into service if, when normally used, they comply with this Regulation.)