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Interinstitutional files:

**2025/0130 (COD)
2025/0131 (COD)
2025/0133 (COD)
2025/0134 (COD)**

WK 11239/2025 INIT

LIMITE

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WORKING DOCUMENT

From: General Secretariat of the Council
To: Antici Group (Simplification)

Subject: Omnibus IV - Digitalisation & common specifications + SMC - MS compiled comments

Delegations will find enclosed compilation of MS comments as received from BE, BG, CZ, DE, IE, ES, FR, HR, IT, LV, LT, HU, NL, AT, PL, PT, RO, SI, FI and SE on the Omnibus IV - Digitalisation and common specifications + SMC proposal.

WK 11239/2025 INIT

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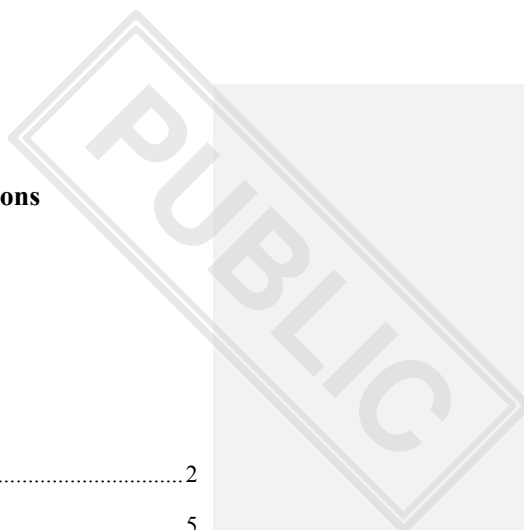
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MS comment
Omnibus IV/ digitalisation and common specifications
&
Small mis-caps

Deadline line 3rd September 2025

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BELGIUM

BE drafting suggestions regarding Omnibus IV – Digitalisation & Common specification, and their justifications

Drafting suggestion 1

(8) **Instructions and safety information provided in digital format should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the instructions and safety information. This is in line with the overarching vision of digital inclusion, as set out in *the European Declaration on Digital Rights and Principles for the Digital Decade, notably chapter II on Solidarity and inclusion.***

Justification

Alignment of this piece of legislation with a very relevant joint declarant, adopted recently by the co-legislators.

Chapter II reads as follows:

Solidarity and inclusion

Technology should be used to unite, and not divide, people. The digital transformation should contribute to a fair and inclusive society and economy in the EU.

We commit to:

- a) making sure that the design, development, deployment and use of technological solutions respect fundamental rights, enable their exercise and promote solidarity and inclusion;
- b) a digital transformation that leaves nobody behind. It should benefit everyone, achieve gender balance, and include notably elderly people, people living in rural areas, persons with disabilities, or marginalised, vulnerable or disenfranchised people and those who act on their behalf. It should also promote cultural and linguistic diversity;
- c) developing adequate frameworks so that all market actors benefiting from the digital transformation assume their social responsibilities and make a fair and proportionate contribution to the costs of public goods, services and infrastructures, for the benefit of all people living in the EU.

Drafting suggestions 2 & 3

*'(16a) 'digital contact' means any up-to-date and **freely** accessible online communication channel **of which at least one email address** through which economic operators can be reached without the need to register or to use an application;'*

*'(16a) 'digital contact' means any up-to-date and **freely** accessible online communication **channel of which at least one email address** through which economic operators can be reached without the need to register or to use an application **specific for the economic operator;**'*

Justification

We would like the definition of "digital contact" to be clarified to avoid it referring to a simple webpage or to other elements that do not allow for direct, effective, and traceable communication. Instead, it should imply a truly functional means of communication — an email address being one of the most illustrative examples.

This would also help prevent confusion regarding acceptable formats or communication channels. As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and potentially inaccessible or unavailable due to changes to the relevant website.

A mere mention of a website compels consumers or Market Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should for instance take the form of an email address that is directly accessible without intermediate steps.

This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address.

With regards to the "*without the need ... to use an application*", we believe that it creates confusion as a user still must download and/or use a browser application to access the webpage. The intention is that no user should download or use a "specific app with the sole purpose to communicate with the economic operator". Hence, we propose to nuance this by adding "**specific for the economic operator**".

Drafting suggestion 4

Art 11 (2): 'Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, **in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device** with all the information and documentation necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority.;

Justification

Chfr. recital 11 : "Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device." Also cfr. article 11 (2) (d) where this is implemented for consumers: "When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times."

It makes sense to make the adaptation now, in a uniform manner which is more efficient for enterprises than to potentially adapt their processes again and make additional costs.

Proposal to amend articles 11 (3), 11 (4) (b) & 11 (5) in an identical way.

BULGARIA



Brussels, 27 August 2025
(OR. en)

12227/25

**Interinstitutional File:
2025/0134 (COD)**

LIMITE

SIMPL 90	TELECOM 266
ANTICI 100	POLCOM 192
EF 268	COMPET 817
ECOFIN 1107	ENV 771
MI 597	CLIMA 310
ECO 23	TRANS 338
ENT 143	ENER 407
IA 106	CODEC 1157
IND 313	

NOTE

From: General Secretariat of the Council

To: Delegations

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 76512008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 202311542 and (EU) 2024/1781 as regards digitalisation and common specifications
- Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal, for examination at the meeting of the Antici Group (Simplification) on 1 September 2025.
Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strike through~~.

2025/0134 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil their intended purpose and to limit the administrative burden, it is important to streamline those requirements.
- (2) In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’⁶, the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.

¹ OJ C, , p. .

- (3) In its Better regulation Guidelines ², the Commission promotes the ‘digital by default’ principle to support digital transformations, by facilitating digital-ready policies which consider the fast-evolving world of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.
- (4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators’ obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators’ obligations when they do not affect protection and safety of consumers **or require an excessive burden for the economic operators**. Embracing digitalisation will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike. **A smooth transition should be pursued.**
- (5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it into service. Such legal acts include Regulations (EU) 2016/424³, (EU) 2016/425⁴, (EU) 2016/426⁵, (EU) 2023/1230⁶, (EU) 2023/1542⁷ and (EU) 2024/1781⁸ of the European Parliament and of the Council (the ‘Regulations concerned’). The Regulations concerned are based on the principles of the ‘new approach’ to technical harmonisation and are aligned with the

² https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

³ Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/424/oj>).

⁴ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51, ELI: <http://data.europa.eu/eli/reg/2016/425/oj>).

⁵ Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99, ELI: <http://data.europa.eu/eli/reg/2016/426/oj>).

⁶ Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and amending Directive (EU) 2021/647 (OJ L 165, 29.6.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1230/oj>).

⁷ Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).

⁸ Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L 281, 28.6.2024, p. 1, ELI: <http://data.europa.eu/eli/reg/2024/1781/oj>).

reference provisions laid down in Decision No 768/2008/EC of the European Parliament and of the Council⁹.

- (6) In accordance with the Regulations concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Regulations has been demonstrated. In order to enable seamless electronic processes, the EU declaration of conformity should be drawn up only in electronic form.
- (7) Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, and (EU) 2023/1230 require that a copy of the EU declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity electronically accompany the product. The manufacturer will ~~make sure~~ ensure that the EU declaration of conformity is **directly** accessible through an internet address or a machine-readable code, **free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the EU declaration of conformity.**
- (8) Taking into account that in 2024 no less than 94% of EU households had access to internet¹⁰, the paper format of the instructions accompanying the products under the scope of the Regulations concerned is ~~outdated~~ **becoming less important** and not aligned with ~~the~~ current technologies, the ~~practice~~ **practices** of consumers ~~not with~~ the green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Regulations concerned. This will allow manufacturers to provide instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to ~~still~~ protect the safety of consumers, the safety information, including instructions having **an** impact on product safety, should be provided in paper format or marked on the product. **Instructions and safety information provided in digital format should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the instructions and safety information.** Moreover, end-users should be able to obtain a

⁹ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82, ELI: [http://data.europa.eu/eli/dec/2008/768\(1\)/oj](http://data.europa.eu/eli/dec/2008/768(1)/oj)).

¹⁰ [1] Source: Digital economy and society statistics - households and individuals - Statistics Explained.

paper copy of the instructions for use or safety information, upon request – at the time of the purchase and for a certain period of time after their purchase.

- (-9) **Regulation (EU) 2016/425 contains certain sectoral specificities, including the fact that the entirety of the instructions and information set out in point 1.4 of Annex II are related to the safe use of the product. Thus, in order to protect the safety of consumers, where the product is intended for, or can be reasonably foreseen to be used by, consumers, all the instructions and information set out in point 1.4 of Annex II should be provided in a paper format or made visible on the packaging**
- (9) In order to facilitate communication between economic operators and national competent authorities and end-users, the indication of a digital contact of the manufacturer on the product and in the EU declaration of conformity is necessary to enhance the effectiveness of market surveillance and to expedite the process of tracing non-compliant products. Currently, economic operators are required to indicate their postal address on the product, but this is not always sufficient to ensure that competent authorities can establish rapid contact. It is therefore necessary to require economic operators to provide both a postal address and a digital contact on the product and in the EU declaration of conformity. Such a digital contact should be defined in the Regulations concerned. **The digital contact should allow consumers and competent authorities to communicate with economic operators directly, and should be accessible free of charge, without the obligation to provide personal data, download additional specific applications or the obligation to register solely to contact the economic operator. Such digital contact may include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines. The term ‘digital contact’, similarly to the term ‘electronic address’ in Regulation (EU) 2023/988 on general product safety, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.**
- (10) The Regulations concerned require that economic operators provide, ~~on~~**upon** a reasoned request from a competent national authority, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Regulations, in paper or electronic form. The paper-based form is ~~an outdated requirement~~**becoming less important**, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to

achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the necessary information and documentation in electronic form only. Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device.

- (11) The current Union standardisation framework, which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹¹, represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation**. However, ~~where no~~ **in the absence of relevant references to** harmonised standards ~~exist or where they are insufficient~~, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation, provided that in doing so it duly respects the role and functions of the European standardisation organisations**, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation**.
- (12) As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542¹², it is essential to require economic operators to store the information contained in the EU declaration of conformity and instructions in the digital product passport where a product is covered by multiple pieces of legislation. This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents - **such as declarations of conformity - required under the various pieces of product legislation that may apply to the same product, thereby upholding the principle of a single declaration of conformity. In addition, instructions provided in electronic form would be stored together with the declaration of conformity**. By storing the documentation in one place,

¹¹ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: <http://data.europa.eu/eli/reg/2012/1025/oj>).

¹² **Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).**

all necessary documents demonstrating product compliance would be easily accessible, ensuring transparency and facilitating compliance. This streamlined approach would enhance the overall efficiency of the regulatory framework, and it aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or other economic operator, where appropriate, should provide a single EU declaration of conformity.

- (13) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as this Regulation amends Regulations which are harmonising products legislations but can rather by reason of better harmonisation of EU applicable rules to products, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (14) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements amendments to Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.
- (15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations (EU) ~~765/2008~~, ~~(EU) 2016/424~~, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with those Regulations in their version applicable before that date.
- (16) Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 765/2008

Regulation (EU) 765/2008 is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (9a) is inserted:

~~'(9a) 'a common specification' means a set of technical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a product, device, service, process or system;'~~²

(b) paragraph 10 is replaced by the following:

~~'10. 'accreditation' shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards or common specifications and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;'~~²

(2) in Article 10, paragraph 5 is replaced by the following:

~~'5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account the relevant harmonised standards or common specifications referred to in Article 11;'~~²

(3) in Article 11, paragraph 1 is replaced by the following:

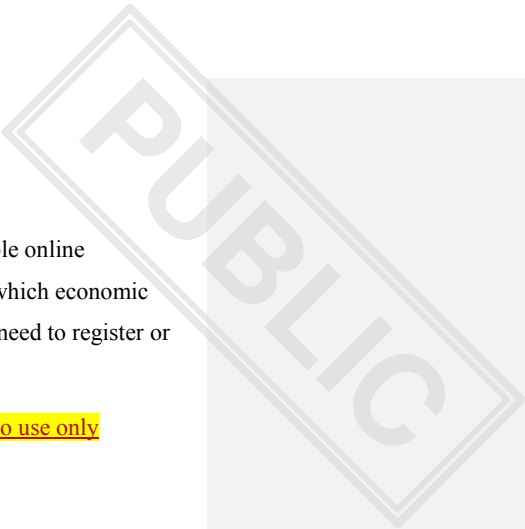
~~'1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, or with the criteria laid down in common specifications, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.'~~²

Article 2

Amendments to Regulation (EU) 2016/424

Regulation (EU) 2016/424 is amended as follows:

(1) Article 3 is amended as follows:



- (a) the following point (17a) is inserted:

‘(17a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted** ~~or engaged~~ without the need to register or to ~~download~~**use** an application;’²

Justification: The meaning of “engaged” is not clear. It is sufficient to use only “contacted” here and in all other relevant provisions.

- (b) the following point (19a) is inserted:

‘(19a) ‘common specifications’ means a ~~set of technical requirements~~**specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex II of this Regulation** applicable to a ~~product, device, service, process or system;~~**subsystem or safety component;**’

Justification: The definition needs to be in singular which is a usual legal technique.

In Article 2 of Regulation (EU) No 1025/2012 we have a definition of “technical specification”, “ICT specification” and the same approach should be used in respect of “common specification”

- (2) Article 11 is amended as follows:

- (a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity **referred to in Article 19**, in electronic form, and affix the CE marking- **referred to in Article 20;**’

- (b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.’

- (c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the subsystem or safety component. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted** ~~or engaged.~~’

- (d) paragraph 7 is replaced by the following:

7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly** and by the instructions and safety information, in a language which can be easily understood by ~~end-users~~**users**, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable ~~end-user~~**user** of the **product-subsystem or the safety component** when deciding the specific format for the instructions and safety information. When drafting **instructions and** the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the ~~end-user~~**user**, as well as the role which the instructions play for ensuring safety.

However, where a large number of subsystems or safety components are delivered to a single economic operator or ~~end-user~~**user**, the batch or consignment concerned may be accompanied by a single **document containing the** internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly**.

Justification: The internet address is the same for all products in the batch but it is provided by a certain carrier – document, so it is enough that the batch is accompanied by only one such carrier – single document.

When the instructions **and safety information**, referred to in the first subparagraph, are provided in electronic form the manufacturer shall:

- (a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to access them **directly** and how to request them in paper format;
- (b) present them in a format that makes it possible for the ~~end-user~~**user** to print and download the instructions **and safety information** and save them on an electronic device so that the ~~end-user~~**user** can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions **and**

safety information are embedded in the software of the subsystem or the safety component;

- (c) make them accessible online during the expected lifetime of the subsystem or the safety component and for at least 30 years after the placing on the market of the subsystem or the safety component.

However, the ~~end-user~~ may, at time of the purchase of the ~~product~~ **subsystem or the safety component**, or up to six months after that purchase, request the instructions or safety information in paper format. Where the ~~end-user~~ requests those instructions or safety information, the manufacturer shall provide them to the ~~end-user~~, free of charge, within one month of receiving the request.;

- (e) paragraph 9 is replaced by the following:

‘9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.;

- (3) in Article 12(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component.;

- (4) Article 13 is amended as follows:

- (a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly** and ~~by the instructions and safety information and~~, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).;

- (b) in paragraph 3, first subparagraph, the first sentence is replaced by the following:

‘Importers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the subsystem or safety component.’

(b1) paragraph 4 is replaced by the following:

‘4. Importers shall ensure that the subsystem or the safety component is accompanied by instructions and safety information in accordance with Article 11(7), in a language which can be easily understood by users, as determined by the Member State concerned.’;

Justification: Reference to Article 11(7) is necessary, as the instructions and safety information accompany the product either on paper or in electronic form in accordance with the rules established in Article 11(7).

(c) paragraph 9 is replaced by the following:

‘9. Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.’

(5) Article 14 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a subsystem or a safety component available on the market, distributors shall verify that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed directly and by the instructions and safety information in accordance with Article 11(7) and, where appropriate, by other required documents, in a language which can be easily understood by end-users as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 11(5) and (6) and Article 13(3) respectively.’

(b) paragraph 5 is replaced by the following:

‘5. Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have made available on the market.’

(6) the following Article 17a is inserted:

‘Article 17a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~**adopt** implementing acts ~~adopt~~**establishing** common specifications ~~that enable compliance with the essential covering requirements set out in Annex II in any of~~**that provide a means to comply with the applicable essential safety requirements set out in Annex II.** Those implementing acts shall only be adopted where the following ~~cases~~**conditions are fulfilled:**

Justification: The text “common specifications that provide a means to comply with the essential requirements set out in Annex II” uses the wording of the definition of common specification.

- (a) **there is no harmonised standard covering those the relevant essential requirements set out in Annex II** ~~are not covered by harmonised standards, or parts thereof, the references~~**the reference** of which ~~have been~~**is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
- (b) ~~requirements set out in Annex II are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of a product with the essential for those the relevant essential requirements set out in Annex II** ~~set out in Annex II;~~**or**

Justification: It is not clear to which requirements refers the phrase “those requirements”. The proposed phrase “the relevant essential requirements” refers to the essential requirements which the common specification intends to cover.

- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

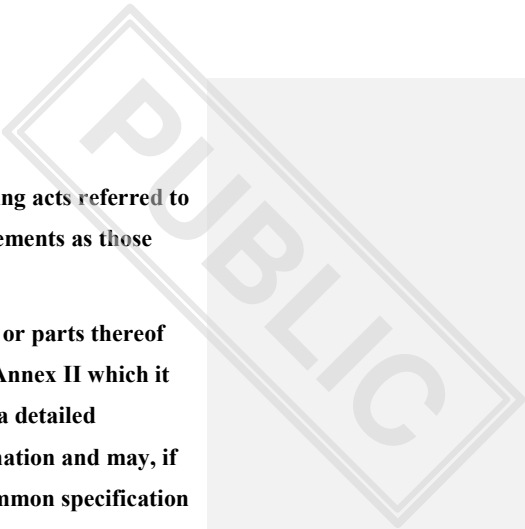
- (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
- (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article ~~44(2)~~44(3).

2. Subsystems and safety components that are in conformity with common specifications **referred to in paragraph 1** or parts thereof shall be presumed to be in conformity with essential requirements **set out in Annex II** covered by those **common** specifications or parts thereof; ~~set out in Annex II.~~

Justification: Reference to paragraph 1 is necessary to avoid confusion that the presumption of conformity applies also for common specifications adopted under the internal market emergency mode activated under IMERA Regulation. There are specific provisions on the validity of the presumption of conformity related to common specifications adopted under IMERA emergency mode.

3. **Before preparing the draft of the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the**



European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(7) in Article 18, paragraph 3 is replaced by the following:

‘3. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(8) ~~in Article 19, the following paragraph 5 is added~~ is amended as follows:

(a) in paragraph 2, the second sentence is replaced by the following:

‘It shall accompany the subsystem or the safety component and shall be translated into the language or languages required by the Member State in which the subsystem or the safety component is placed or made available on the market. The subsystem and the safety component shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be directly accessed.’;

Justification: The EU declaration of conformity is in electronic form and does not accompany the product.

(b) the following paragraph 5 is added:

‘5. Where other Union legislation applicable to ~~the~~ subsystem or ~~a~~ safety ~~component~~ **components** 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 ~~in~~ Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 19, and the instructions and safety information**



~~and~~ referred to in Article 11(7) ~~shall~~ may be provided only in that digital product passport.

Where the information required in Annex IX to be included in the EU declaration of conformity or, as appropriate, the EU declaration of conformity required in Article 19, is provided in the digital product passport economic operators shall be deemed to comply with their obligations related to drawing up and keeping the EU declaration of conformity under this Regulation.;'

Justification:

The text of the Toys Regulation, which is currently subject to legal-linguistic revision, as sent to the Member States on 25 August 2025 contains the following:

“(54) Manufacturers should create a digital product passport to provide information on the compliance of toys with this Regulation and with other Union law applicable to toys. They should keep the digital product passport up to date and make any necessary changes when required. The digital product passport should replace the EU declaration of conformity pursuant to Directive 2009/48/EC and include the elements necessary to assess the conformity of the toy with the applicable requirements and harmonised standards or other specifications. Furthermore, in order to reduce the administrative burden, it should be possible to use the digital product passport pursuant to this Regulation to comply with the obligation to draw up an EU declaration of conformity for toys which fall within the scope of other Union law requiring an EU declaration of conformity. Where the digital product passport is used as an EU declaration of conformity pursuant to other Union law applicable to the toy, manufacturers and other economic operators should be deemed to comply with their respective obligations in relation to the EU declaration of conformity pursuant to that other Union law.

Article 19

Digital product passport

5. *Where the digital product passport created in accordance with this Regulation for a toy includes all the information required for the declaration of conformity in accordance with, as applicable, Regulation (EU) 2024/1689 or (EU) 2024/2847, Directive 2011/65/EU¹³,*

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¹³ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88, ELI: <http://data.europa.eu/eli/dir/2011/65/oj>).

2014/30/EU¹⁴, 2014/35/EU¹⁵ or 2014/53/EU of the European Parliament and of the Council or Commission Delegated Regulation (EU) 2019/945¹⁶, the following provisions shall apply:

(a) manufacturers and, where applicable, providers of high-risk AI systems, shall be deemed to comply with the obligation to draw up an EU declaration of conformity in accordance with, as applicable, Article 16, point (g), of Regulation (EU) 2024/1689, Article 13(12) of Regulation (EU) 2024/2847, Article 7, point (c), of Directive 2011/65/EU, Article 7(2) of Directive 2014/30/EU, Article 6(2) of Directive 2014/35/EU, Article 10(3) of Directive 2014/53/EU or Article 6(2) of Delegated Regulation (EU) 2019/945;

(b) manufacturers shall also be deemed to comply, where applicable, with the obligation set out in Article 13(20) of Regulation (EU) 2024/2847, Article 10(9) of Directive 2014/53/EU or Article 6(8) of Delegated Regulation (EU) 2019/945;

(c) by drawing up the digital product passport, manufacturers shall assume responsibility for the compliance of the toy with the requirements laid down in the applicable Regulations or Directives;

(d) economic operators and, where applicable, providers of high-risk AI systems shall use the digital product passport to fulfil their obligations related to the declaration of conformity in accordance with, as applicable, Article 18(1), point (e), Article 22(3), points (a) and (b), Article 23(1), point (c), Article 23(5) and Article 24(1) of Regulation (EU) 2024/1689, Article 13(13), Article 18(3), point (a), and Article 19(2) and (6) of Regulation (EU) 2024/2847, Article 7, points (c) and (d), Article 8, point (b), and Article 9, point (g), of Directive 2011/65/EU, Article 7(2) and (3), Article 8(2), point (a), and Article 9(7) of Directive 2014/30/EU, Article 6(2) and (3), Article 7(2), point (a), and Article 8(8) of Directive 2014/35/EU, Article 10(3) and (4), Article 11(2), point (a), and Article 12(8) of Directive 2014/53/EU or

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¹⁴ Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79, ELI: <http://data.europa.eu/eli/dir/2014/30/oj>).

¹⁵ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357, ELI: <http://data.europa.eu/eli/dir/2014/35/oj>).

¹⁶ Commission Delegated Regulation (EU) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems (OJ L 152, 11.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg_del/2019/945/oj).

Article 6(3) and (4), Article 7(2), point (a), and Article 8(8) of Delegated Regulation (EU) 2019/945.

As explained in Recital (54), Article 19(5) of the Toys Regulation provides for optional use of the DPP where the toy is covered also by Directives 2011/65/EU, 2014/30/EU, 2014/35/EU and 2014/53/EU. These directives are also covered by the Digitalisation and CS Omnibus. If those directives provide for obligation to use the DPP required by other applicable Union legislation this will create legal uncertainty and confusion for economic operators. It is necessary to ensure coherence between the Toys Regulation and the amendments to those directives and other acts covered by the Digitalisation and CS Omnibus proposals – optional use of DPP required under other applicable Union legislation.

(9) in Article 26, paragraph 7, point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards ~~or~~ and common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’

(10) in Article 34, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(10a) in Article 40(5) the following point (c) is added:

‘(c) shortcomings in the common specifications referred to in Article 17a conferring a presumption of conformity.’;

(10b) in Article 41, paragraph 3 is replaced by the following:

‘3. Where the national measure is considered justified and the non-compliance of the subsystem or safety component is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Regulation or the common specifications referred to in point (c) of Article 40(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 17a(6) of this Regulation respectively.’;

(11) in Article 43(1), point (d) is replaced by the following:

‘(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’

(12) Annexes III to IX are amended in accordance with Annex I to this Regulation.

Article 3

Amendments to Regulation (EU) 2016/425

Regulation (EU) No 2016/425 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (8a) is inserted:

‘(8a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted or engaged** without the need to register or to ~~download-use~~ an application;’

(b) the following point (10a) is inserted:

‘(10a) ‘common specifications’ means a ~~set of~~ technical ~~requirements~~**specifications**, other than a standard, that provides a means of complying with the essential **health and safety** requirements **set out in Annex II of this Regulation** applicable to a ~~product, device, service, process or system~~**PPE**;’

(2) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, in electronic form, and affix the CE marking referred to in Article 16;’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in the design or characteristics of the PPE and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account;’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the PPE. The postal

address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted or engaged**;

(d) paragraphs 7 and 8 are replaced by the following:

‘7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the PPE when deciding the specific format for the instructions and information set out in point 1.4 of Annex II.

In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make ~~them~~ visible on the packaging, the instructions and information set out in point 1.4 of Annex II-, **which are related to the safe use of the PPE**. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information set out in point 1.4 of Annex II, **which are related to the safe use of the PPE**, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

When the instructions **and information**, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the PPE, or, where that is not possible, on its packaging or in an accompanying document, how to access them **directly** and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions **and information** and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the PPE; this requirement also applies where the instructions **and information** are embedded in the software of the PPE;

- (c) make them accessible online during the expected lifetime of the PPE and for at least 10 years after the placing on the market of the PPE.

However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.

8. The manufacturer shall ~~provide~~ **ensure that the PPE is accompanied by the** internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed ~~with the PPE.;~~’

- (e) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority.;

- (3) in Article 9(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE;;’

- (4) Article 10 is amended as follows:

(a0) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be directly accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).;’

Justification: Align the obligation of the importer as proposed in relation to Article 13(2) of Regulation (EU) 2016/424.

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be ~~reached~~ **contacted or engaged** or, where that is not possible, on its packaging or in a document accompanying the PPE.;

(a1) paragraph 4 is replaced by the following:

‘4. Importers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in accordance with Article 8(7) in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.’;

(b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of PPE **with this Regulation** in a language which can be easily understood by that authority.’;

(5) in Article 11(5) the first sentence is replaced by the following is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making PPE available on the market, distributors shall verify that it bears the CE marking, that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be directly accessed, by the instructions and information in accordance with Article 8(7) and, where appropriate, by other required documents, in a language which can be easily understood by consumers and other end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.’;

Justification: Align the obligation of the distributor as proposed in relation to Article 14(2) of Regulation (EU) 2016/424.

(b) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE.’;

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications ~~that enable compliance with essential covering requirements set out in Annex II in any of~~ **that provide a means to comply with the applicable essential health and safety requirements set out in Annex II. Those implementing acts shall only be adopted where the following conditions are fulfilled:**

(a) **there is no harmonised standard covering those the relevant essential health and safety requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the reference** ~~the reference~~ **of which**

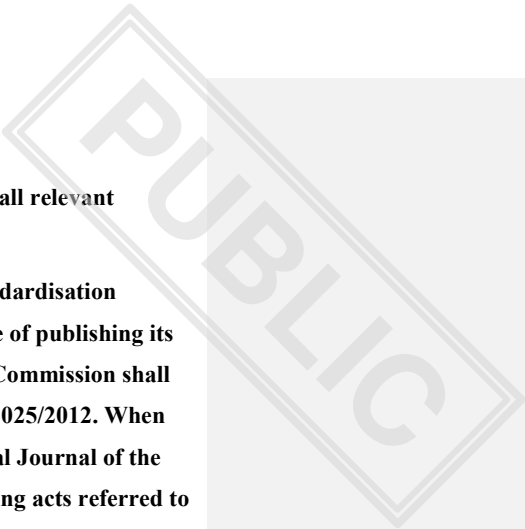
~~have been~~ published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

- (b) requirements set out in Annex II are covered by harmonised standards ~~the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of PPE with the for those the relevant essential health and safety requirements set out in Annex II~~ ~~set out in Annex II,~~ **and:**

- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
- (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant PPE.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article ~~44(2)~~**44(3)**.

2. PPE that is in conformity with common specifications referred to in paragraph 1 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof, ~~set out in Annex II;~~
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group**



as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.

5. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.
6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential **health and safety** requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.”

(7) in Article 15, the following paragraph 5 is added:

- ‘5. Where other Union legislation applicable to the PPE 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 Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 15**, and the instructions referred to in Article 8(7) ~~shall~~may be provided only in that digital product passport.

Where the information required in Annex IX to be included in the EU declaration of conformity or, as appropriate, the EU declaration of conformity required in Article 15, is provided in the digital product passport economic operators shall be deemed to comply with their obligations related to drawing up and keeping the EU declaration of conformity under this Regulation.’

Justification:

See the explanation under Article 2, point (8)(b) of this Regulation

(8) in Article 19, the following paragraph is added:



‘Where applicable, the manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and documentation relating to conformity assessment procedures in electronic form.’

(9) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards ~~or~~ and common specifications, and of the relevant provisions of Union harmonisation legislation and of national legislation;’

~~(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 *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.’~~

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Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to conformity assessment bodies.

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(11) In Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(11a) in Article 38(5) the following point (c) is added:

‘(c) shortcomings in the common specifications referred to in Article 14a conferring a presumption of conformity.’;

(11b) in Article 39, paragraph 3 is replaced by the following:

‘3. Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation or the common specifications referred to in point (c) of Article 38(5) of this

Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 14a(6) of this Regulation respectively.

- (12) Annexes II, III, V, VII, VIII, and IX are amended in accordance with Annex II to this Regulation.

Article 4

Amendments to Regulation (EU) 2016/426

Regulation (EU) No 2016/426 is amended as follows:

- (1) Article 2 is amended as follows:

- (a) the following point (21a) is inserted:

‘(21a) digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted or engaged** without the need to register or to ~~download~~**use** an application;’

- (b) the following point (23a) is inserted:

‘(23a) ‘common specifications’ means a ~~set of~~**set of** technical ~~requirements~~**specifications**, other than a standard, that provides a means of complying with the essential requirements **set out in Annex I of this Regulation** applicable to a ~~product, device, service, process or system~~**; an appliance or a fitting**;’

- (2) Article 7 is amended as follows:

- (a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of an appliance or a fitting with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’

- (b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in appliance or fitting design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.’

- (c) paragraphs 6 and 7 are replaced by the following:

‘6. Manufacturers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or,

where that is not possible, on the packaging or in a document accompanying the appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted** ~~or engaged~~. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Manufacturers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted** ~~or engaged~~. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.

7. Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in an electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

Manufacturers shall take into account the intended use and the foreseeable end-user of the ~~product~~**appliance** when deciding the specific format for the instructions and safety information.

In the case of appliance ~~or fitting~~ intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the ~~equipment~~**appliance**, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

Manufacturers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of

conformity can be accessed **directly** and that it contains, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned. ~~The instructions may be provided in electronic form.~~

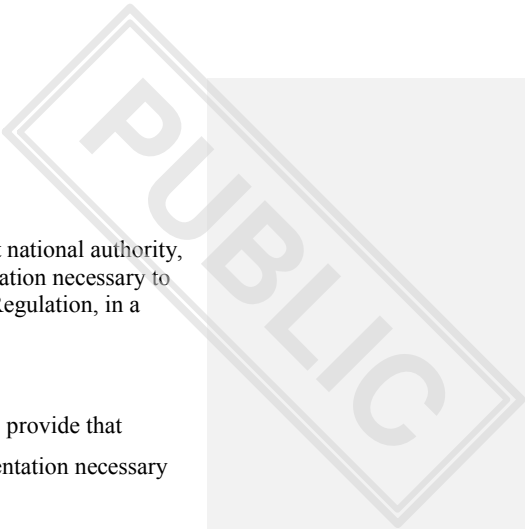
However, where a large number of fittings are delivered to a single end-user, the batch or consignment concerned may be accompanied by a single document containing the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.

When the instructions and safety information, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the appliance ~~or fitting~~, or, where that is not possible, on its packaging or in an accompanying document, how to **directly** access them and how to **directly** request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions **and safety information** and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the appliance ~~or fitting~~;
- (c) make them accessible online during the expected lifetime of the appliance ~~or fitting~~ and for at least 10 years after the placing on the market of the appliance ~~or fitting~~.

However, the end-user may, at time of the purchase of the appliance ~~or fitting~~, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;’

Justification: Instructions and safety information are required only for appliances – subparagraphs 1, 2, 3, 4, 7 and 8 of this paragraph. In those provisions the words “or fitting” are not relevant and should be deleted. Instructions for incorporation are required only for fittings (subparagraphs 5 and 6) and they are not a separate document but are included in the EU declaration of conformity.



(d) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting with this Regulation, in a language which can be easily understood by that authority.’

(3) in Article 8(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting;’

(4) Article 9 is amended as follows:

(a) ~~in paragraph 2, second subparagraph, the second sentence is replaced by the following~~ is amended as follows:

(i) in the first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the appliance bears the CE marking and is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).’;

Justification: The deleted text is covered by paragraph 4 with the amendments proposed below.

(ii) in the second subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking and is accompanied by the internet address and machine readable code through which the EU declaration of conformity can be accessed directly and by, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).’

Justification: The deleted text is covered by paragraph 4 with the amendments proposed below.

(b) paragraph 3 is replaced by the following:

‘3. Importers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the appliance. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.’

Importers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the fitting. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.;

- (c) ~~in~~ paragraph 4, ~~the second subparagraph~~ is replaced by the following:

‘Importers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I Article 7(7), in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Importers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly** and ~~by that it contains~~, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.;

- (d) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting in a language which can be easily understood by that authority.;

- (5) Article 10 is amended as follows:

- (a) in paragraph 2, the ~~first and~~ second subparagraphs ~~is-are~~ replaced by the following:

‘Before making an appliance available on the market, distributors shall verify that the appliance bears the CE marking and that it is accompanied by instructions and safety information in accordance with point 1.5 of Annex I Article 7(7), in a language which can be easily understood by consumers and other end-users, as determined by the Member State in which the appliance is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly**, and ~~by that it contains~~, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.;

Justification: The first subparagraph of paragraph 2 must be amended in order to avoid contradictions with Article 7(7). The second subparagraph must be modified to clarify that the instructions for incorporation are included in the EU declaration of conformity.

(6) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting.’

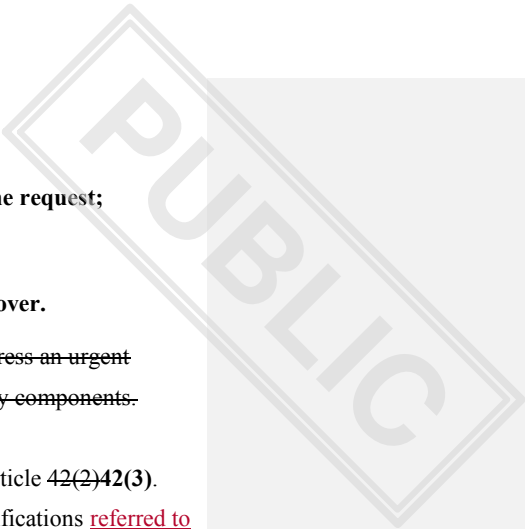
(7) the following Article 13a is inserted:

‘Article 13a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications ~~that enable compliance with essential covering requirements set out in Annex I in any of~~ **that provide a means to comply with the applicable essential safety requirements set out in Annex I.** **Those implementing acts shall only be adopted where the following conditions are fulfilled:**

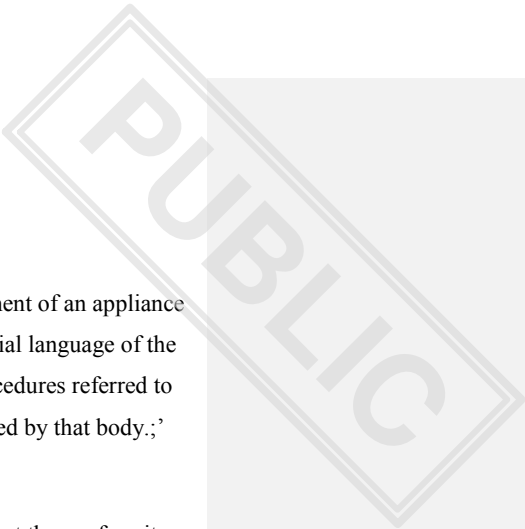
- (a) **there is no harmonised standard covering ~~those the relevant essential~~ requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
- (b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of appliances and fittings with the for ~~those the relevant essential~~ requirements set out in Annex I set out in Annex I, and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**



- (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination procedure as provided for~~ referred to in Article 42(2)42(3).

2. Appliances and fittings that are in conformity with common specifications referred to in paragraph 1 or parts thereof shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those **common** specifications or parts thereof; ~~set out in Annex I.~~
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**



(8) Article 14 is amended as follows:

(a) paragraph 4 is replaced by the following:

‘4. Records and correspondence relating to conformity assessment of an appliance or a fitting shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraphs 2 and 3 is established or in a language accepted by that body.’

(b) the following paragraph 5 is added:

‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(9) Article 15 is amended as follows:

(a) paragraph 6 is replaced by the following:

‘6. The fitting shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly**.’

(b) the following paragraph 7 is added:

‘7. Where other Union legislation applicable to an appliance or a fitting 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 Annex ~~H~~V to be included in the EU declaration of conformity, **or as appropriate, the EU declaration of conformity required in Article 15**, and the instructions **and safety information** referred to in Article 7(7) ~~shall~~may be provided only in that digital product passport. **This does not affect the obligation to provide the safety information in paper format according to Article 7(7)**

Where the information required in Annex V to be included in the EU declaration of conformity or, as appropriate, the EU declaration of conformity required in Article 15, is provided in the digital product passport economic operators shall be deemed to comply with their obligations related to drawing up and keeping the EU declaration of conformity under this Regulation.’

Justification:

[See the explanation under Article 2, point \(8\)\(b\) of this Regulation](#)

(10) in Article 23(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards ~~or~~and common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’

(11) in Article 31, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(11a) in Article 37(5) the following point (c) is added:

‘(c) shortcomings in the common specifications referred to in Article 13a conferring a presumption of conformity.’;

(11b) in Article 38, paragraph 3 is replaced by the following:

‘3. Where the national measure is considered justified and the non-compliance of the appliance or fitting is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Regulation or the common specifications referred to in point (c) of Article 37(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 13a(6) of this Regulation respectively.’;

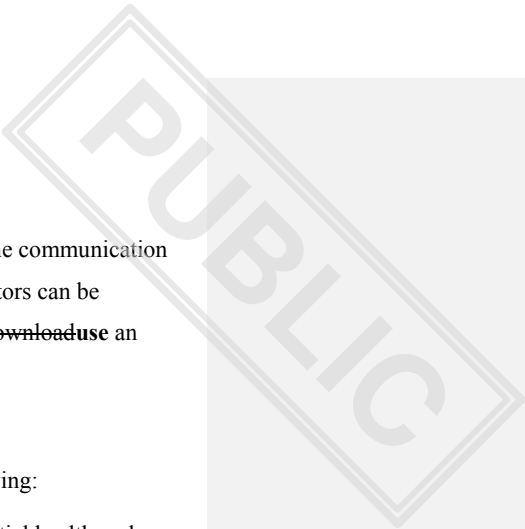
(12) in Article 40(1), point (f) is replaced by the following:

‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’

(13) Annexes III and V are amended in accordance with Annex III to this Regulation.

*Article 5***Amendments to Regulation (EU) 2023/1230**

Regulation (EU) 2023/1230 is amended as follows:



(1) in Article 3, the following point (22a) is inserted:

‘(22a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted or engaged** without the need to register or to ~~download~~**use an** application.’

(2) Article 10 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.’

(b) in paragraph 8, the first subparagraph is replaced by the following:

‘Manufacturers shall ensure that the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity set out in Part A of Annex V can be accessed **directly**.’

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority.’

(3) Article 11 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Part B, of Annex IV, manufacturers shall draw up the EU declaration of incorporation, in digital format, in accordance with Article 22.’

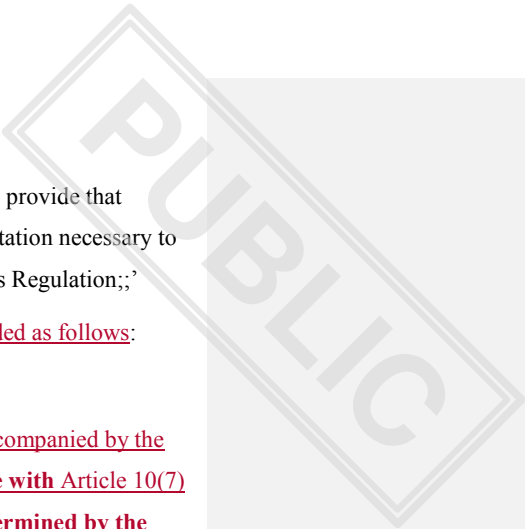
(b) in paragraph 8, the first subparagraph is replaced by the following:

‘Manufacturers shall ensure that the partly completed machinery is accompanied by the internet address or machine-readable code through which the EU declaration of incorporation set out in Part B of Annex V can be accessed **directly**.’

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority.’

(4) in Article 12(2), point (b) is replaced by the following:



‘(b) further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation;’

(5) ~~in Article 13(9), the first sentence is replaced by the following is amended as follows:~~

~~(a) paragraph 4 is replaced by the following:~~

~~‘4. Importers shall ensure that the machinery or related product is accompanied by the instructions for use and the information referred to in accordance with Article 10(7) in a language which can be easily understood by users, as determined by the Member State concerned.’;~~

Justification: Paragraph 4 must be amended to avoid contradictions with Article 10(7).

~~(b) in paragraph 9, the first sentence is replaced by the following:~~

‘9. Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority.’

(6) ~~in Article 14(8), the first sentence is replaced by the following is amended as follows:~~

~~(a) paragraph 4 is replaced by the following:~~

~~‘4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions referred to in accordance with Article 11(7) in a language which can be easily understood by the person who incorporates the partly completed machinery, as determined by the Member State concerned.’;~~

Justification: Paragraph 4 must be amended to avoid contradictions with Article 11(7).

~~(b) in paragraph 8, the first sentence is replaced by the following:~~

‘Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority.’

(7) Article 15 is amended as follows:

(a) in paragraph 2, points ~~(b) and (c) are~~ replaced by the following:

(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be accessed directly;

(c) the machinery or related product is accompanied by the instructions for use and the information referred to in accordance with Article 10(7), and that they are in a language which can be easily understood by users, as determined by the Member State in which the machinery or related product is to be made available on the market;²

Justification: Article 15(2), point (c) must be modified to avoid contradictions with Article 10(7).

(b) in paragraph 6, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority.’

(8) ~~in Article 16(6), the first sentence is replaced by the following is amended as follows:~~

(a) in paragraph 2, points (a) and (b) are replaced by the following:

(a) the partly completed machinery is accompanied by the internet address or machine-readable code through which the EU declaration of incorporation referred to in Article 11(8) can be accessed directly;

(b) the partly completed machinery is accompanied by the assembly instructions referred to in accordance with Article 11(7), and that they are in a language which can be easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market;

Justification: Article 16(2), points (a) and (b) must be modified to take account of electronic EU declaration of conformity and to avoid contradictions with Article 11(7).

(b) in paragraph 6, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation.’



(9) in Article 21, the following paragraph 5 is added:

‘5. 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 **or, as appropriate, the EU declaration of conformity required in Article 21, and the instructions for use, and safety-the information? set out in Annex III and the safety information** referred to in Article 10(7) ~~shall~~**may** be provided only in that digital product passport. **This does not affect the obligation to provide the safety information in paper format according to Article 10(7)**

Where the information required in Annex V to be included in the EU declaration of conformity or, as appropriate, the EU declaration of conformity required in Article 21, is provided in the digital product passport economic operators shall be deemed to comply with their obligations related to drawing up and keeping the EU declaration of conformity under this Regulation.;

Justification:

The text “instructions for use, the information set out in Annex III and the safety information” is used in the last subparagraph of Article 10(7).

For the optional use of DPP see the explanation under Article 2, point (8)(b) of this Regulation

~~(10) in Article 22, the following paragraph 5 is added:~~

~~‘5. 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 incorporation or instructions in a digital product passport, the information required in Parts B of Annex V to be included in the EU declaration of incorporation **or, as appropriate, the EU declaration of incorporation required in Article 22, and the instructions referred to in Article 11(7) shall be provided only in that digital product passport.;**~~

Justification: The use of digital product passport for partly completed machinery which is not a final product and is subject to additional production process is not relevant. The EU

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declaration of incorporation for the partly completed machinery is included in the technical documentation of the machinery.

- (11) in Article 25, the following paragraph 6 is added:
- ‘6. Where applicable, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in digital format.’
- (12) Annexes III, V, VII, IX, and X are amended in accordance with Annex IV to this Regulation.

Article 6

Amendments to Regulation (EU) 2023/1542

Regulation (EU) 2023/1542 is amended as follows:

- (1) in Article 3 the following point (23a) is inserted:
- ‘(23a) ‘digital contact’ means any up-to-date and ~~such as email addresses freely~~ accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted or engaged** without the need to register or to ~~download~~**use** an application.’

- (1a) in Article 16 the following paragraph 4 is added:

‘4. When a Member State considers that a common specification or parts thereof does not entirely satisfy the requirements laid down in Articles 9, 10, 12, 13, 14 and 78 which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

Justification: This provision is part of the “Machinery Regulation model” for common specifications and must be included also in Batteries Regulation.

- (2) Article 17 is amended as follows:
- (a) paragraph 4 is replaced by the following:
- ‘4. Records and correspondence relating to the conformity assessment procedures of batteries shall be drawn up, in electronic form, in the official language or languages of the Member State where the notified body carrying out the

conformity assessment procedures is established, or in one or more languages accepted by that body.;

(b) the following paragraph 5 is added:

‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.;

(3) in Article 18(2), the third sentence is replaced by the following:

‘It shall be drawn up in electronic form.;

(4) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. When placing a battery on the market or putting it into service, including for the manufacturers’ own purposes, manufacturers shall ensure that the battery:

- (a) has been designed and manufactured in accordance with Articles 6 to 10 and Articles 12 and 14, and is, for stationary battery energy storage systems, accompanied by clear, understandable and readable instructions and safety information in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be placed on the market or put into service; and
- (b) is marked and labelled in accordance with Article 13.

The instructions and safety information for stationary battery energy storage systems may be provided in electronic form. In the case of stationary battery energy storage systems intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information.

When the instructions **and safety information** are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

The end-user may, at time of the purchase of the stationary battery energy storage systems, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests

those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

(b) in paragraph 7, the first sentence is replaced by the following:

‘Manufacturers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.;

(c) in paragraph 10, the second sentence is replaced by the following:

‘That information and documentation shall be provided in electronic form.;

(5) in Article 39, the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, free of charge.;

(6) in Article 40(3), point (b) is replaced by the following:

‘(b) further to a reasoned request from a national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the battery.;

(7) Article 41 is amended as follows:

(a0) in paragraph 2, first subparagraph, point (c) is replaced by the following:

‘(c) the battery is accompanied by the documents required pursuant to Articles 6 to 10 and Articles 12, 13 and 14, and for stationary battery energy storage systems - by instructions and safety information in accordance with Article 38(1) in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be made available on the market; and’;

Justification: As the obligation for the manufacturer in relation to instructions and safety information is limited to stationary battery energy storage systems, the same obligation of the importer must be also limited to such batteries.

(a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.;

(b) in paragraph 8, the second sentence is replaced by the following:

‘That information and the documentation shall be provided in electronic form.;

(8) ~~in Article 42(6), the second sentence is replaced by the following is amended as follows:~~

(a) in paragraph 2, point (c) is replaced by the following:

‘(c) the battery is accompanied by the documents required pursuant to Articles 6 to 10 and Articles 12, 13 and 14, and for stationary battery energy storage systems - by instructions and safety information in accordance with Article 38(1) in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be made available on the market or put into service; and’;

Justification: As the obligation for the manufacturer in relation to instructions and safety information is limited to stationary battery energy storage systems, the same obligation of the distributor must be also limited to such batteries.

(b) in paragraph 6, the second sentence is replaced by the following:

‘That information and the documentation shall be provided in electronic form.’;

- (9) Annexes VIII, IX and XIII are amended in accordance with Annex V to this Regulation.

Article 7

Amendments to Regulation (EU) 2024/1781

Regulation (EU) 2024/1781 is amended as follows:

- (1) in Article 2, the following point (46a) is inserted:

‘(46a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted or engaged** without the need to register or to ~~download~~**use** an application.’;

- (2) in Article 24(2), the second sentence is replaced by the following:

‘Such information and documentation shall be provided, in electronic form, within 30 days of receipt of the request.’;

- (3) in Article 27(10), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’;

- (4) in Article 28(2), point (c) is replaced by the following:

‘(c) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product, in a language that can be easily understood by that authority as soon as possible and in any event within 15 days of receipt of such a request; and’;

- (5) in Article 29(8), the second sentence is replaced by the following:
‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’
- (6) in Article 30(5), first subparagraph, the second sentence is replaced by the following:
‘That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority.’
- (-7) **in Article 36(2), second subparagraph, the second sentence is replaced by the following: ‘That information shall be provided in electronic form within 15 days of receipt of a request by the market surveillance authority’.**
- (7) in Annex V, point 2 is replaced by the following:
‘2. Name, postal address and digital contact of the manufacturer and, where applicable, the manufacturer’s authorised representative..’

Article 8

Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1542 and (EU) 2024/1781 before [OP: please insert 24 months after entry into force of this amending Regulation)].

Article 9

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 5 and Annex IV shall apply from 20 January 2027.

The following provisions shall apply from [OP: please insert 24 months after entry into force of this amending Regulation]:

- (a) Article 2, point(1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);
- (b) Article 3, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);
- (c) Article 4, point (1)(a), points (2)(a), (c) and (d), and points (3), (4), (5), (6), (8), (9) and (12);

- (d) Articles 6 and 7;
- (e) Annex I, point (1)(a) and (c), point (2)(a), point (3)(a), point (4)(a), point (5)(a), (d) and (e), and point (7)(a);
- (f) Annex II, point (1)(a), point (3)(a), (c)(i) and (d)(i), point (4)(a), point (5)(a) and point (6)(a);
- (g) Annex III, point (1)(a)(i), (c), (e) and (g) and point (2)(a);
- (h) Annex V.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Annexes III to IX to Regulation (EU) 2016/424 are amended as follows:

- (1) Annex III is amended as follows:
- (a) in point 3, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (b) in point 4, points 4.2 and 4.3 are replaced by the following:
 - ‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;
 - 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;;
 - 4.3a. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation’**
 - (c) in point 6, first subparagraph, the second sentence is replaced by the following:
 - ‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning.;;’
- (2) Annex IV is amended as follows:
- (a) in point 3.1., point (a) is replaced by the following:

(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

~~(b) in point 3.3., first subparagraph, the second sentence is replaced by the following:~~

~~‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’~~

Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to the quality system of the manufacturer.

(3) Annex V is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) point 4.1 is replaced by the following:

‘4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’

(c) point 5.2. is replaced by the following:

‘5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of

this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(4) Annex VI is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.2., paragraph 1 is replaced by the following:

‘The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the subsystem or the safety component with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.;

(5) Annex VII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.2., point (b) is replaced by the following:

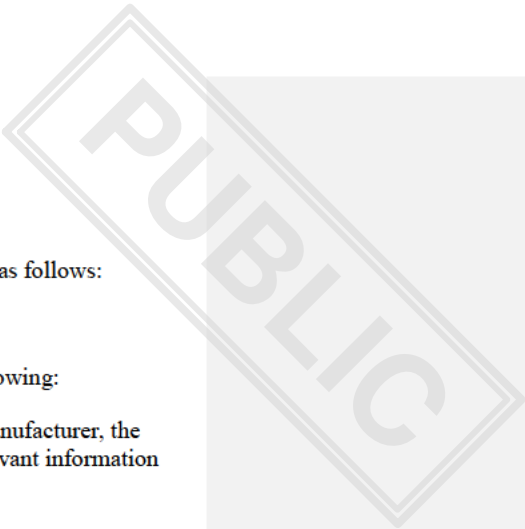
‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;’

~~(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:~~

~~‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;~~

Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to the quality system of the manufacturer.

- (d) in point 3.6.2., point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer;;’
- (e) in point 3.6.3, first subparagraph, the second sentence is replaced by the following:
 - ‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’
- (6) in Annex VIII, point 2, point (c) is replaced by the following:
 - ‘(c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, ~~and~~ a list of common specifications **referred to in Article 17a**, applied in full or in part, and where those harmonised standards or common specifications, have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;;’
- (7) Annex IX is amended as follows:
 - (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;;’
 - (b) point 6 is replaced by the following:
 - ‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’



ANNEX II

Annexes II, III, V, VII, VIII, and IX to Regulation (EU) 2016/425 are amended as follows:

- (1) in Annex II, point 1.4 is amended as follows:
 - (a) in the first subparagraph, the first sentence is replaced by the following:

‘In addition to the name, postal address and digital contact of the manufacturer, the instructions ~~that must be supplied with the PPE~~ must contain all relevant information on:’
 - ~~(b) points (k) and (l) are replaced by the following:~~
 - ~~(b) in the first subparagraph, points (i) to (k) are deleted:~~
 - ~~‘(k) references to the relevant harmonised standard(s) or common specification(s) used, including the date of the standard(s) or specification(s), or references to the other technical specifications used;~~
 - ~~(b1) in the first subparagraph, point (l) is replaced by the following:~~
 - ~~‘(l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed directly;’~~
 - ~~(b2) the second subparagraph is deleted:~~

Justification: The present text of point 1.4 of Annex II to Regulation (EU) 2016/425 reads:

“1.4. Manufacturer's instructions and information
In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:
 ...
(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
(l) the internet address where the EU declaration of conformity can be accessed.
The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.”
 As the EU declaration of conformity will be directly accessible, it is not necessary to duplicate part of its content in the instructions. Information under points (i), (j) and (k) above is included also in the EU declaration of conformity and must be deleted in point 1.4 of

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Annex II. The second subparagraph of point 1.4 must be deleted as the EU declaration of conformity will be only in electronic form.

- (2) in Annex III, points (f) and (g) are replaced by the following:
- ‘(f) the references of the harmonised standards referred to in Article 14 ~~or~~ and the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;
 - (g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;;’
- (3) Annex V is amended as follows:
- (a) in point 3., point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;;’
 - (b) in point 4, points (d) to (f) are replaced by the following:
 - ‘(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed in accordance with other technical specifications;
 - (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;
 - (f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet

the corresponding essential health and safety requirements and have been applied correctly.;

(c) point 6.2., is amended as follows:

(i) point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, the latter's name, postal address and digital contact;;’

(ii) point (e) is replaced by the following:

‘(e) where harmonised standards or common specifications have been fully or partially applied, the references of those standards or specifications or parts thereof;;’

(d) point 7.6. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) his name, postal address and digital contact and data identifying the EU type-examination certificate concerned;;’

(ii) point (b) is replaced by the following:

‘(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications or other technical specifications applied;;’

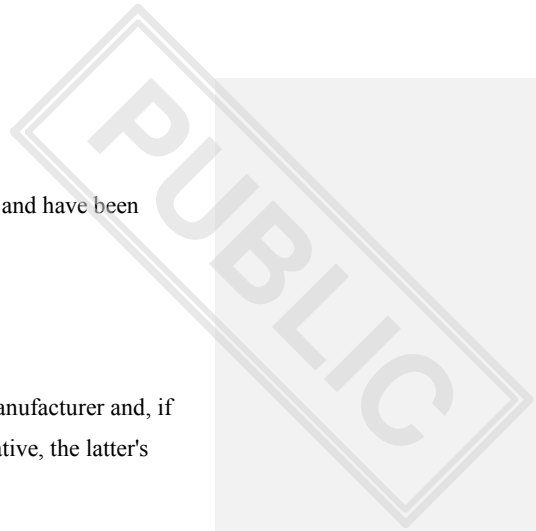
(4) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact;;’

(b) point 4.3. is replaced by the following:

‘4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or



equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.;

(5) Annex VIII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

~~(b) in point 3.3., the second subparagraph is replaced by the following:~~

~~‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’~~

Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to the quality system of the manufacturer.

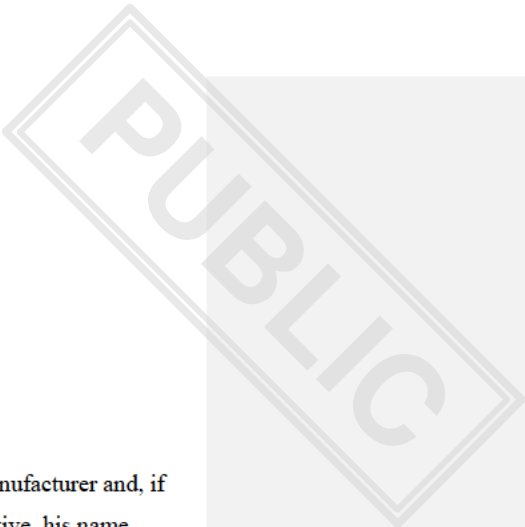
(6) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;.’

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard **or common specification**, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared.’



ANNEX III

Annexes III and V to Regulation (EU) 2016/426 are amended as follows:

(1) Annex III is amended as follows:

(a) point 1.3.1. is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(ii) in point (c), point (4) is replaced by the following:

‘(4) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union ~~and~~ a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’

(iii) in point (e), the second sentence is replaced by the following:

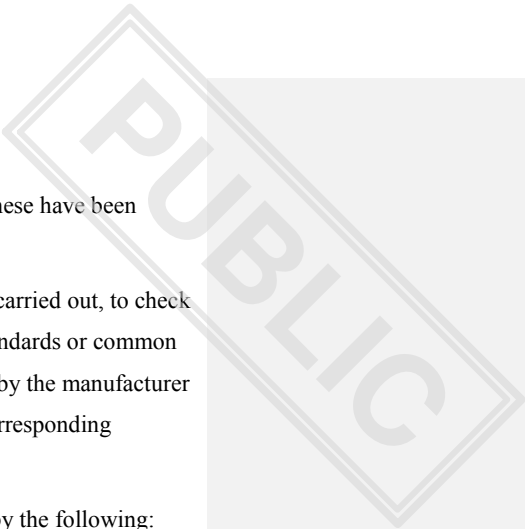
‘(e) This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full;’

(b) in point 1.4., points 1.4.2., 1.4.3. and 1.4.4. are replaced by the following:

‘1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards **or common specifications**, as well as the elements which have been designed in accordance with other relevant technical specifications;’

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1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the



relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;’

(c) in point 1.6., first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning;’

(d) In point 2.3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation;’

~~(d1) in point 2.4.2, second subparagraph the second sentence is deleted;~~

Justification: In point 2.4.2, second subparagraph the second sentence reads:

“A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

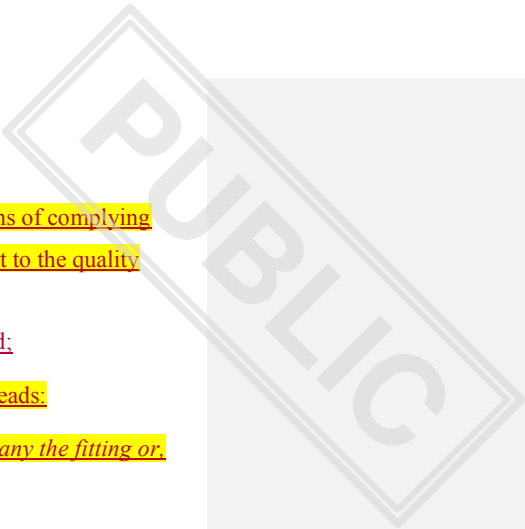
As the EU declaration of conformity of the fitting is in electronic form, the above sentence is no longer adequate and must be deleted.

(e) in point 3.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

~~(f) in point 3.3.3., the second subparagraph is replaced by the following:~~

~~‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification;’~~



Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to the quality system of the manufacturer.

~~(f1) in point 3.5.2, second subparagraph the second sentence is deleted;~~

Justification: In point 3.5.2, second subparagraph the second sentence reads:

“A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

As the EU declaration of conformity of the fitting is in electronic form, the above sentence is no longer adequate and must be deleted.

(g) in point 4.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

~~(h) in point 4.3.3., the second subparagraph is replaced by the following:~~

~~‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’~~

Justification: According to the definition, common specifications provide a means of complying with the essential requirements which are applicable to products and not to the quality system of the manufacturer.

~~(h1) in point 4.5.2, second subparagraph the second sentence is deleted;~~

Justification: In point 4.5.2, second subparagraph the second sentence reads:

“A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

As the EU declaration of conformity of the fitting is in electronic form, the above sentence is no longer adequate and must be deleted.

(i) point 5.4.1. is replaced by the following:

‘5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the

approved type described in the EU type-examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(j) point 5.5.2. is replaced by the following:

‘5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(j1) in point 5.6.2, second subparagraph the second sentence is deleted;

Justification: In point 5.6.2, second subparagraph the second sentence reads:

“A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

As the EU declaration of conformity of the fitting is in electronic form, the above sentence is no longer adequate and must be deleted.

(k) in point 6.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, ~~and~~ a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.;

(l) in point 6.4., the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’

(1) in point 6.5.2, second subparagraph the second sentence is deleted:

Justification: In point 6.5.2, second subparagraph the second sentence reads:

“A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

As the EU declaration of conformity of the fitting is in electronic form, the above sentence is no longer adequate and must be deleted.

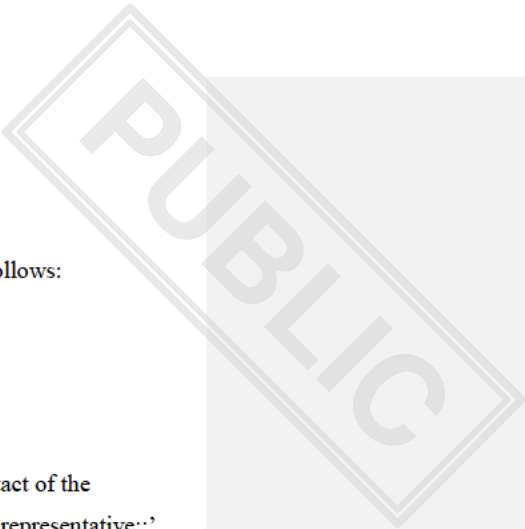
(2) Annex V is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;’

(b) paragraph 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’



ANNEX IV

Annexes III, V, VII, IX, and X to Regulation (EU) 2023/1230 are amended as follows:

(1) Annex III is amended as follows:

(a) in point 1.7.4.2., point 1 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the business name, full postal address and digital contact of the manufacturer and, where applicable, of its authorised representative;’

(ii) point (c) is replaced by the following:

‘(c) ~~the EU declaration of conformity, or~~ the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);’

Justification: Direct access to the EU declaration of conformity is sufficient.

No need to repeat the content of the declaration.

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(b) point 4.3.1. is amended as follows:

(i) the first subparagraph is replaced by the following:

‘Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name, postal address and digital contact of the manufacturer and the identifying reference of the relevant certificate.’

(ii) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’

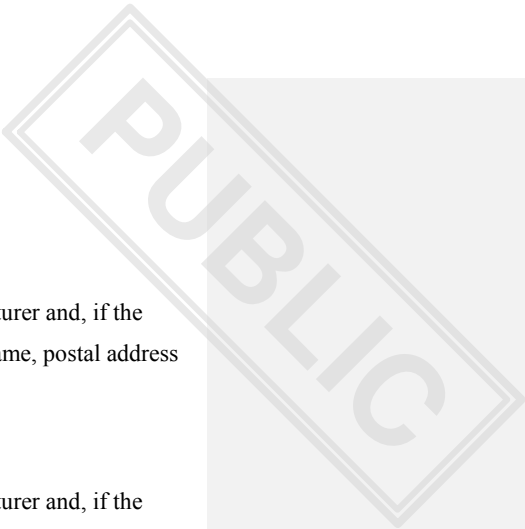
(2) Annex V is amended as follows:

(a) in Part A, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’

(b) in Part B, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’



(3) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’

(b) in point 6.2., point (b) is replaced by the following:

‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’

(c) in point 7.6., point (a) is replaced by the following:

‘(a) its name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’

(4) in Annex IX, point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’

(5) Annex X is amended as follows:

(a) in point 2., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’

ANNEX V

Annexes VIII, IX and XIII to Regulation (EU) 2023/1542 are amended as follows:

- (1) in Annex VIII, Module D1: Quality assurance of the production process, point 5.1, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the manufacturer’s authorised representative, its name, postal address and digital contact as well;’
- (2) in Annex IX, point 2 is replaced by the following:

‘Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative;’
- (3) in Annex XIII, point 1, the following point (t) is added:
 - ‘(t) ‘clear, understandable and readable instructions ~~for use and safety information~~ in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).’

PUBLIC

CZECHIA

Omnibus IV – digitalization and common specifications

CZ comments

- **Documents ST 12226/25 and ST 12227/25**

The Czech Republic maintains a positive scrutiny reservation to the submitted compromise proposals. However, it is necessary to technically refine the text and ensure that the made amendments are consistent with the wording of the individual legal acts to which they apply. See the proposed specific amendments below.

Provisions on common specifications should be amended as follows to be in line with the legal framework of machinery regulation and toy safety regulation:

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of adopt~~ **adopt** implementing acts, ~~adopt establishing~~ **establish** common specifications ~~that enable compliance with the essential covering requirements set out in in any of that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following cases-conditions are fulfilled:~~

(a) ~~there is no harmonised standard covering those requirements set out in are not covered by harmonised standards, or parts thereof, the references-the reference of which have been-~~ **there is no reference of which has been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period; and....**

.....

5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**

Transitional provisions, Entry into force and application

The Czech Republic **is proposing** that the transitional periods for both proposals be the same, at a minimum of two years. This period is considered sufficient for relevant parties and entities to implement the new digital obligations and make the required adjustments to their internal systems, tools, and communication channels. In this context, the Czech Republic also **notes** that the draft regulation's relevant article (Article 9 - Entry into force and application) fails to specify its effective date—the date from which the regulation will be applied.

Document ST 12 226/26 should be amended as follows:

Article 8

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(1) Article 2 is amended as follows:

(a)

(b) the following point (13a) is inserted:

‘(13a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements ~~set out in Annex II Annex I of this Directive~~ applicable to a product, device, service, process or system;’

.....
(7) the following Article 14a is inserted:

‘Article 14a

Common Specifications

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in ~~Annex II Annex I~~ which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

Essential requirements are listed in Annex I of the Directive 2014/33/EU.

.....
(10) in Article 17, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to lifts or safety components for lifts 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 Annex II to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions ~~and safety information~~ referred to in Articles 7(7) and 8(7) shall be provided only in that digital product passport.’

Due to the nature of the products, lifts are provided only with the instructions for use, not with safety information.

Article 11

Amendments to Directive 2014/53/EU

.....
(6) the following Article 16a is inserted: ‘Article 16a

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of adopt~~ **adopt** implementing acts, ~~adopt~~ **establishing** common specifications ~~that enable compliance with the essential covering~~ requirements set out in Article 3 in any of **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following ~~eases~~ conditions are fulfilled:....**

The current text of Directive 2014/53/EU does not include the term 'essential safety requirements'; it only refers to 'essential requirements'.

• **EK compromise text on common specifications**

The Czech Republic maintains a scrutiny reservation regarding the proposed text of “urgency clause”. The Czech Republic is aware of the situation in European standardization that is leading the Commission to introduce an additional reason for adopting a common specification and is open to

further discussion. The Czech Republic remains open to further discussion, particularly regarding the specific situations in which the Commission's empowerment should be exercised. In any case, maintaining the examination procedure for the adoption of the respective implementing acts is our redline.

If the purpose is to allow the Commission to avoid fulfilling the requirement to ask ESOs to create a European standard or revise a harmonized European standard in situations where it is clear that the ESOs are unable to create or revise that EN, then the text of paragraph 1b should refer to the conditions set out in paragraph 1(a) and (b), and not to conditions 1a and 1b – see the amendments proposed below.

1b. In exceptional cases, where it has received information on urgent market concerns about the application of essential health and safety requirements due to the absence of harmonised standards or parts thereof published in the Official Journal, the Commission may adopt an implementing act referred to under paragraph 1 even if conditions **set in the paragraph 1 letters ~~1(a)~~ and ~~1(b)~~** are not fulfilled.

Comments by the Czech Republic to Omnibus IV: the mid-cap definition

1. MiFID II

Art. 3 of the Directive

CZ must maintain the position on the transposition deadline, which is too short for our national legislative process. Not to mention the forthcoming elections, which will also have an impact on the length of the process. For this reason, we would like to repeat our request for **at least 18-month deadline for transposition**.

2. GDPR

Recital 8 of the Regulation

CZ does not support specific new reference to smaller “enterprises” in the second sentence but can accept the whole text of recital 8 in the spirit of compromise since the “organizations” are covered at the end of the sentence and in the operative text.

Recital 9 of the Regulation

CZ believes that the words “upon assessment” require a qualification. As Danish Presidency explained in WK 10598/25, this should lead enterprises and organizations to assess whether a processing activity is high risk, in order to benefit from the derogation.

However, Article 35 does not require data that controller carries out protection impact assessment (DPIA) regarding every processing but is limited to situations when the processing reasonably may lead to high risk. Article 35(5) even provides for official lists of processing operations for which DPIA is not required.

Because DPIA is more burdensome than maintaining the record of processing activities¹ in many situations, this condition might demotivate SMEs and SMCs from even trying to benefit from this derogation.

CZ understands that there are legitimate concerns about complex processing situations where DPIA is due. But duty to provide DPIA is already established by Article 35, which provides for examples and positive and negative lists. Recital 9 should not extend this obligation to new situations.

CZ therefore asks for qualification to ensure that DPIA is carried out only where required, that is, when it is reasonably expected that processing may result in high risk pursuant to Article 35(1)-(5)(10)(11) of the GDPR.

While CZ can support the remainder text as it stands, we propose minor **changes** in the **last** sentence:

- “**should be**” instead of “is” to keep up with the language appropriate in preambles (clarification itself, as CZ understands it, is actually in the words “and to the extent that” in Article 30(5)).
- “**such**” to indicate very clearly that the last sentence is limited to entities below 750 employees.

Whole text of recital 9 would read:

(9) In order to reflect the above, it is necessary to amend Article 30(5) of Regulation (EU) 2016/679, by extending the scope of the derogation from the record-keeping obligation to ~~SMC~~enterprises and

¹ See Article 35(7) GDPR. EDPB Guidelines for DPIA are more than 20 pages long; EDPB position on Article 30(5) has two pages.

organisations with fewer than 750 employees to allow ~~also~~ them to ~~profit~~ **also benefit** from that derogation and by providing that the derogation applies unless the processing, **upon assessment where required (by Article 35 of Regulation (EU) 2016/679)**, is likely to result in a 'high risk' to data subjects' rights and freedoms, within the meaning of Article 35 of Regulation (EU) 2016/679. In particular the processing of personal data referred to in paragraph 3 of that provision should be considered as requiring the data controller or the processor to maintain records of ~~those~~ processing activities. **Furthermore, it should be clarified that such enterprises and organisations carrying out high-risk processing of personal data are only required to maintain a record of the specific processing activities likely to result in a 'high-risk' to data subjects' rights and freedoms within the meaning of Article 35 of Regulation (EU) 2016/679.**

Recital 10 of the Regulation

While CZ observes that the changes narrow down the original intention of the Commission, we may accept the text in the spirit of compromise. (CZ would welcome if at least the processing mandated by Union or Member State law or by a collective agreement in the field of employment and social security and social protection law (such as evidence of sick leaves, professional health fitness, protection of pregnant women etc.) would be clearly excluded.)

Recital 11 of the Regulation

CZ is afraid that the last sentence reduces the room for manoeuvre of industry associations and businesses that prepare these codes of conducts (but not certification mechanisms and privacy seals). Nevertheless, we may accept the text in the spirit of compromise.

Article 1(2) of the Regulation

CZ believes that the added words "and to the extent that" provide clarification (mentioned in recital 9) that only the assessed high-risk processing activities require keeping the records of processing activities. That is, even the controller that has assessed that one of its processing activities is likely to result in high risk, shall be obliged to maintain record only in relation to such high-risk processing activity and not in relation to the others. Therefore, CZ supports the text as it currently stands.

However, CZ would have a problem with attempts to duplicate the ideas in recitals 9 or 10 in the operative text at this stage.

3. Batteries

Art. 5 (2a) a recital 19a of the Regulation

CZ firmly opposes the proposed inclusion of Article 5(2a) and Recital 19a, which would remove Article 74(5) from the Batteries Regulation. This provision is key to preventing freeriding by ensuring manufacturers disclose recycling costs. While consumer protection is important, CZ stresses that transparency throughout the distribution chain is essential. Full deletion of Article 74(5) would undermine efforts against freeriding and limit Member States' ability to enforce their own measures. From the CZ perspective, it may be possible to amend the Article 74(5). CZ believes that costs should be stated on sales documents throughout the entire distribution chain, from manufacturer to end user. If it is not feasible to omit the Art. 5 (2a) and recital 19a from the proposal, CZ recommends converting the requirement into an optional provision as follows:

PUBLIC

Member states may determine that the costs covered by the producer under Article 56(4), points (a) to (d), shall be shown separately to the end-user at the point of sale of a new battery.

GERMANY



Brussels, 27 August 2025
(OR. en)

12226/25

**Interinstitutional File:
2025/0133 (COD)**

LIMITE

SIMPL 89	TELECOM 265
ANTICI 99	POLCOM 191
EF 267	COMPET 816
ECOFIN 1106	ENV 770
MI 596	CLIMA 309
ECO 22	TRANS 337
ENT 142	ENER 406
IA 105	CODEC 1156
IND 312	

NOTE

From: General Secretariat of the Council

To: Delegations

Subject: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/1301/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications
- Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal, for examination at the meeting of the Antici Group (Simplification) on 1 September 2025.
Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strike through~~.

2025/0133 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 110(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

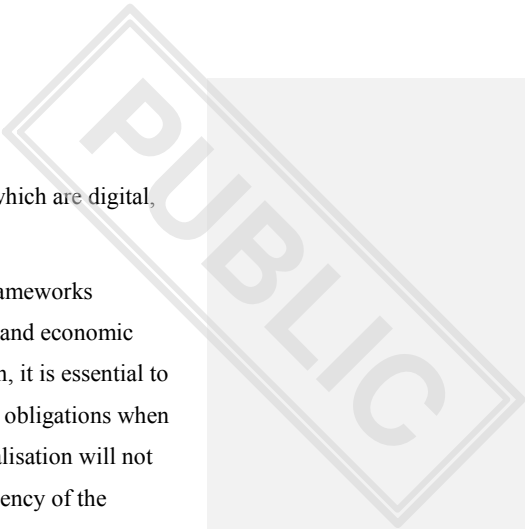
Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil the purpose for which they were intended and to limit the administrative burden, it is important to streamline those requirements.
- (2) In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’, the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.
- (3) In its Better Regulation Guidelines, the Commission promotes the ‘digital by default’ principle to support digital transformations by facilitating digital-ready policies which



consider the fast-evolving world of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.

- (4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators' obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators' obligations when they do not affect protection and safety of consumers. Embracing digitalisation will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike.
- (5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it into service. Such legal acts include Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council ('the Directives concerned'). Most of the Directives are based on the principles of the 'new approach' to technical harmonisation and are also aligned ~~to~~**with** the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council.
- (6) In accordance with the Directives concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Directives has been demonstrated. In order to enable seamless electronic processes, the EU declaration of conformity should be drawn up only in electronic form.
- (7) Moreover, Directives 2000/14/EC, 2013/53/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU and 2014/53/EU require that a copy of the EU declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity accompany the product in electronic form. The manufacturer should therefore ~~make sure~~**ensure** that the EU declaration of conformity is **directly** accessible through an internet address or a machine-readable code, **free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the EU declaration of conformity.**
- (8) Taking into account that in 2024 no less than 94% of EU households had access to internet, the paper format of the instructions for use accompanying the products under the scope of the Directives concerned is ~~outdated~~**becoming less important** and is not aligned with ~~the~~

current technologies, the ~~practice~~**practices** of consumers ~~not with~~ green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Directives. This will allow manufacturers to **provide** instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to ~~still~~ protect the safety of consumers, the safety information, including instructions having **an** impact on product safety, should be provided in paper format or marked on the product. **Instructions and safety information provided in digital format should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the instructions and safety information.** Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of ~~the~~ purchase and for a certain period of time after their purchase.

- (9) Directive 2014/53/EU provides for the possibility for manufacturers to provide a simplified EU declaration of conformity in an electronic form. Considering that this proposal is introducing a digital by default format of the EU declaration of conformity, the provisions on the simplified EU declaration of Conformity become redundant. It is therefore necessary to remove such provisions from Directive 2014/53/EU.
- (10) In order to facilitate communication between economic operators and national competent authorities and end-users, the indication of a digital contact of the manufacturer on the product and in the EU declaration of conformity is necessary to enhance the effectiveness of market surveillance and to expedite the process of tracing non-compliant products. Currently, economic operators are required to indicate their postal address on the product, but this is not always sufficient to ensure that competent authorities can establish rapid contact. It is therefore necessary to require economic operators to provide both a postal address and a digital contact on the product and in the EU declaration of conformity. Such digital contact should be defined in the Directives. **The digital contact should allow consumers and competent authorities to communicate with economic operators directly, free of charge, without the obligation to provide personal data, downloading additional specific applications or the obligation to register solely to contact the economic operator. Such digital contact may include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing static websites, automatic replies to queries, chatbots, fax numbers, or telephone lines. The term ‘digital contact’, similarly to the term ‘electronic address’**

in Regulation (EU) 2023/988 on general product safety, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.

- (11) The Directives concerned require that economic operators provide, ~~on~~**upon** a reasoned request from a competent national authority or the European Commission, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Directives, in paper or electronic form. The paper-based form is ~~an outdated requirement~~**becoming less important**, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the necessary information and documentation in electronic form only. Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device.
- (12) Directive 2014/90/EU contains certain sectoral specificities, including the unique requirements for ensuring the safety of marine equipment on board EU ships. Due to those specificities, that Directive differs from other NLF-aligned legislation. Specifically, it foresees the obligation for a paper copy of the declaration of conformity to be on board an EU ship until the marine equipment is removed. However, given the availability of the European Maritime Safety Agency's database to Member State flag states and market surveillance authorities, the obligation should be satisfied by uploading a copy of the declaration of conformity to this database. This would enable the necessary checks and controls of the marine equipment on the ship to be carried out electronically and ensure uniform application and practices under this legislation.
- (13) The current Union standardisation framework which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety requirements ~~or with other requirements~~ **of the Directives amended by this Directive**. However, ~~where no~~**in the absence of relevant references to** harmonised standards ~~exist or where they are insufficient~~, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety or other requirements **of the Directives amended by this**

Directive, provided that in doing to it duly respects the role and functions of the European standardisation organisations, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety or other requirements **of the Directives amended by this Directive**.

- (14) As the digital product passport is foreseen in certain Union legislations, such as Regulation (EU) 2023/1542 ~~of the European Parliament and of the Council~~, it is essential to require the economic operators to store the information contained in the EU declaration of conformity and instructions for use in the digital product passport where a product is covered by multiple pieces of legislation. This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents - **such as declarations of conformity - required under the various pieces of product legislation that may apply to the same product, thereby upholding the principle of a single declaration of conformity. In addition, instructions provided in electronic form would be stored together with the declaration of conformity.** By storing the documentation in one place, all necessary documents demonstrating product compliance would be easily accessible, ensuring transparency and facilitating compliance. This streamlined approach would enhance the overall efficiency of the regulatory framework and aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or any other economic operator, where appropriate, should provide a single EU declaration of conformity.
- (15) Since the objectives of this Directive cannot be sufficiently achieved by the Member States as this Directive amends Directives which are harmonising products legislations but can rather, by reason of harmonisation of EU applicable rules, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (16) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of the national measures transposing this Directive, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the

market in accordance with the Directives concerned before the date of application of the national measures transposing this Directive.

- (17) To ensure a smooth and effective transition, to ~~minimize~~**minimise** disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements, application of transposition measures concerning digitalisation should be deferred.
- (18) Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2000/14/EC

Directive 2000/14/EC is amended as follows:

- (1) in Article 3, the following point (g) is added:
- ‘(g) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~**use** an application.’
- (2) in Article 4(1), the third indent is replaced by the following:
- ‘the equipment bears CE marking and the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the ~~ECEU~~ declaration of conformity can be **directly** accessed.’
- (3) in Article 5, paragraph 1 is replaced by the following:
- ‘1. Member States shall take appropriate measures to ensure that equipment referred to in Article 2(1) may be placed on the market or put into service only if it conforms to the provisions of this Directive, bears the CE marking and the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the ~~ECEU~~ declaration of conformity can be **directly** accessed.’
- (4) in Article 6, paragraph 1 is replaced by the following:
- ‘1. Member States shall not prohibit, restrict or impede the placing on the market or putting into service in their territory of equipment referred to in Article 2(1) which

complies with the provisions of this Directive, bears the CE marking, the indication of the guaranteed sound power level and is accompanied by the internet address or machine-readable code through which the ~~ECEU~~ declaration of conformity can be **directly** accessed.;

(5) Article 7 is replaced by the following:

‘Presumption of conformity

Member States shall presume that equipment referred to in Article 2(1) bearing the CE marking and the indication of the guaranteed sound power level and which is accompanied by the internet address or machine-readable code through which the ~~ECEU~~ declaration of conformity can be **directly** accessed conforms to all the provisions of this Directive.;

(6) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The manufacturer, or his authorised representative established in the Community, of equipment referred to in Article 2(1) shall, in order to certify that an item of equipment is in conformity with the provisions of this Directive, draw up an ~~ECEU~~ declaration of conformity, in electronic form, for each type of equipment manufactured; the minimum content of this declaration of conformity is laid down in Annex II.;

(b) the following paragraph 4 is added:

‘4. Where other Union legislation applicable to the equipment 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 ~~ECEU~~ declaration of conformity or instructions in a digital product passport, the information required in Annex II to be included in the ~~ECEU~~ declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 11(5) shall be provided only in that digital product passport.;

(7) Article 14 is amended as follows:

(a) paragraph 3 is replaced by the following:

‘3. Member States shall ensure that the Commission and any other Member State may, on a reasoned request, obtain all information, in electronic form, used

during the conformity assessment procedure concerning a type of equipment and in particular the technical documentation provided for in Annex V item 3, Annex VI item 3, Annex VII item 2, Annex VIII items 3.1 and 3.3.;

(b) the following paragraph 4 is added:

‘4. Where appropriate, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(8) Annexes II and V to VIII are amended in accordance with Annex I to this Directive.

Article 2

Amendments to Directive 2011/65/EU

Directive 2011/65/EU is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (6a) is inserted:

‘(6a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ **use** an application.’

(b) the following point (13a) is inserted:

‘(13a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provides means of complying with the requirements **set out in Article 4 of this Directive** applicable to ~~a product, device, service, process or system;~~ **an EEE;**’

(2) Article 7 is amended as follows:

(a) in point (c), the first sentence is replaced by the following:

‘(c) Where compliance of EEE with the applicable requirements has been demonstrated by the procedure referred to in point (b), manufacturers draw up an EU declaration of conformity, in electronic form, and affix the CE marking on the finished product.’

(b) in point (e), the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards, in the common specifications or in technical specifications by reference to which conformity of EEE is declared shall be adequately taken into account;’

(c) point (h) is replaced by the following:

‘(h) manufacturers indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. The postal address and digital contact must indicate a single point through which the manufacturer can be reached. Where other applicable Union legislation contains provisions for the affixing of the manufacturer’s name, postal address and digital contact which are at least as stringent, those provisions shall apply;’

(d) point (j) is replaced by the following:

‘(j) manufacturers, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the EEE with this Directive, in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market;’

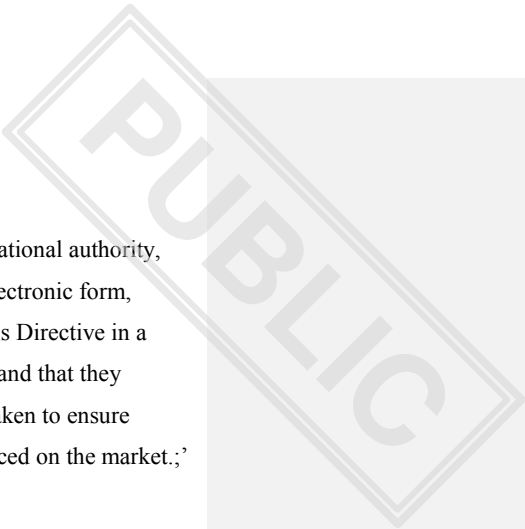
(3) in Article 8, point (b), the second indent is replaced by the following:

‘further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an EEE with this Directive;’

(4) Article 9 is amended as follows:

(a) point (d) is replaced by the following:

‘(d) importers indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the EEE or, where that is not possible, on its packaging or in a document accompanying the EEE. Where other applicable Union legislation contains provisions for the affixing of the importer’s name, postal address and digital contact which are at least as stringent, those provisions shall apply;’



(b) point (h) is replaced by the following:

‘(h) importers, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in electronic form, necessary to demonstrate the conformity of an EEE with this Directive in a language which can be easily understood by that authority, and that they cooperate with that authority, at its request, on any action taken to ensure compliance with this Directive of EEE which they have placed on the market.;

(5) in Article 10, point (d) is replaced by the following:

‘(d) distributors, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of EEE with this Directive, and that they cooperate with that authority, at its request, on any action taken to ensure the compliance with this Directive of the EEE which they have made available on the market.;

(6) in Article 13, the following paragraph 4 is added:

‘4. Where other Union legislation applicable to EEE requires the economic operator to include the information that the product complies with the requirement set out in that legislation in a digital product passport or to upload the declaration of conformity in a digital product passport, the information required in Annex VI to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the instructions and safety information** shall be provided only in that digital product passport.;

(7) The following Article 16a is inserted:

‘Article 16a

Common Specifications

1. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications that enable compliance with the essential covering requirements set out in Article 4 in any of that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following ~~cases~~ conditions are fulfilled:**

(a) **there is no harmonised standard covering those requirements set out in Article 4 are not covered by harmonised standards, or parts thereof, the**

~~reference~~ **the reference** of which ~~have been~~ published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

- (b) ~~requirements set out in the Commission has requested, pursuant to Article 4 are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the~~ **10(1) of Regulation 1025/2012, one or more European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of materials, components and EEE with the essential** ~~for those requirements set out in Article 4; and:~~
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant materials, components and EEE.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article ~~19(3)~~ **19(2)**.

2. Materials, components and EEE that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 4.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group**

as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.

5. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.
6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(8) in Article 19, the following paragraph 3 is added:

‘3. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.’;

(9) Annexes V and VI are amended in accordance with Annex II to this Directive.

Article 3

Amendments to Directive 2013/53/EU

Directive 2013/53/EU is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (19a) is inserted:

‘(19a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’

(b) The following point (20a) is inserted:

(20a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Article 4(1) and Annex I of this Directive** applicable to a product, ~~device, service, process or system;~~”

(2) Article 7 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up a declaration referred to in Article 15, in electronic form, and mark and affix the CE marking, as set out in Articles 17 and 18.’

(b) in paragraph 4, the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards or common specifications by reference to which conformity of a product is declared shall be adequately taken into account.’

(c) paragraphs 6 and 7 are replaced by the following:

‘6. Manufacturers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;

7. Manufacturers shall ensure that the product is accompanied by instructions and safety information in the owner’s manual in a language or languages which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of product intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;
- (c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

- (d) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority.’;

- (3) in Article 8(3), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product.’;

- (4) Article 9 is amended as follows:

- (a) paragraph 3 is replaced by the following:

‘3. Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, in the case of components where that is not possible, on the packaging or in a document accompanying the product.’

(b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority.’

(5) in Article 10(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product.’

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications ~~that enable compliance with the essential~~ **covering** requirements ~~set out in Article 4 in any of~~ **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements ~~set out in Article 4 are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

(b) ~~requirements set out in~~ **the Commission has requested, pursuant to Article 4** ~~are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the~~ **10(1) of Regulation 1025/2012, one or more** European Union, ~~but application of these standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of products with the essential~~ **for those requirements set out in Article 4; and:**

- PUBLIC
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant products.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article ~~50(2)~~**50(3)**.

- 2. Products that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 4.;
- 3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
- 4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
- 5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(7) Article 15 is amended as follows:

(a) in paragraph 4, the introductory sentence is replaced by the following:

‘The following products, when made available on the market or put into service, shall be accompanied by the internet address of machine-readable code through which the EU declaration of conformity, referred to in paragraph 3, can be **directly** accessed.’;

(b) the following paragraph 6 is added:

‘6. Where other Union legislation applicable to the product 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 7(7) shall be provided only in the digital product passport.’;

(8) in Article 19, the following paragraph 5 is added:

‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to the conformity assessment procedures in electronic form.’;

(9) in Article 20(1), point (b)(i), the indents are replaced by the following:

- where the harmonised standards or common specifications relating to points 3.2 and 3.3 of Part A of Annex I are complied with: Module A (internal production control), Module A1 (internal production control plus supervised product testing), Module B (EU type-examination) together with Module C, D, E or F, Module G (conformity based on unit verification) or Module H (conformity based on full quality assurance);
- where the harmonised standards or common specifications relating to points 3.2 and 3.3 of Part A of Annex I are not complied with: Module A1 (internal production

control plus supervised product testing), Module B (EU type-examination) together with Module C, D, E or F, Module G (conformity based on unit verification) or Module H (conformity based on full quality assurance);;

(10) Article 21 is amended as follows:

(a) in point (a), the introductory sentence is replaced by the following:

‘where tests are conducted using the harmonised standard or common specification, any of the following modules:;’

(b) in point (b), the introductory sentence is replaced by the following:

‘where tests are conducted without using the harmonised standard or common specification, any of the following modules:;’

(11) Article 22 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) in point (a), the introductory sentence is replaced by the following:

‘where tests are conducted using the harmonised standard or common specification for noise measurement, any of the following modules:;’

(ii) point (b) is replaced by the following:

‘(b) Where tests are conducted without using the harmonised standard or common specification for noise measurement, Module G (conformity based on unit verification).;’

(b) paragraph 2 is amended as follows:

(i) in point (a), the introductory sentence is replaced by the following:

‘Where tests are conducted using the harmonised standard or common specification for noise measurement, any of the following modules:;’

(ii) point (b) is replaced by the following:

‘(b) Where tests are conducted without using the harmonised standard or common specification for noise measurement, Module G (conformity based on unit verification).;’

(12) in Article 30(7), point (c) is replaced by the following:

- (c) appropriate knowledge and understanding of the essential requirements, the applicable harmonised standards or common specifications, the relevant Union harmonisation legislation and the relevant national legislation;’
- (13) in Article 38, paragraph 3 is replaced by the following:
- ‘3. Where a notified body finds that requirements laid down in Article 4(1) and Annex I or in corresponding harmonised standards or common specifications have not been met by a manufacturer or a private importer, it shall require that manufacturer or private importer to take appropriate corrective measures and shall not issue a conformity certificate.’
- (14) Annexes I, III, IV and V are amended in accordance with Annex III to this Directive.

Article 4

Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

- (1) Article 2 is amended as follows:
- (a) the following point (7a) is inserted:
- ‘(7a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~**use** an application;’
- (b) the following point (9a) is inserted:
- ‘(9a) ‘common specifications’ means a set of technical ~~requirements~~**specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I of this Directive** applicable to a ~~product, device, service, process or system~~**vessel**;’
- (2) Article 6 is amended as follows:
- (a) in paragraph 2, the second subparagraph is replaced by the following:
- ‘Where compliance of a vessel of which the product of $PS \times V$ exceeds 50 bar.L with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the inscriptions provided for in point 1 of Annex III.’
- (b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in vessels design or characteristics and changes in the harmonised standards, in the common specifications or in other technical specifications by reference to which conformity of a vessel is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the vessel their name, registered trade name or registered trademark as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information referred to in point 2 of Annex III may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the vessel when deciding the specific format for the instructions and safety information.

In the case of vessel for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the vessel, the safety information referred to in point 2 of Annex III. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the vessel, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so

that the end-user can access them at all times, in particular during a breakdown of the vessel; this requirement also applies where the instructions are embedded in the software of the vessel;

- (c) make them accessible online during the expected lifetime of the vessel and for at least 10 years after the placing on the market of the vessel.

However, the end-user may, at time of the purchase of the vessel, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 9, the first sentence, is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the vessel with this Directive, in a language which can be easily understood by that authority.;

- (3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel;;’

- (4) Article 8 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the vessel their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, in a document accompanying the vessel.;

- (b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel in a language which can be easily understood by that authority.;

- (5) in Article 9(5), the first sentence is replaced by the following:

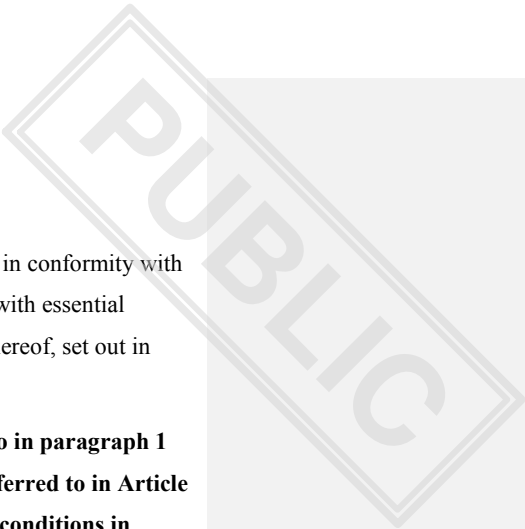
‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a vessel.;

- (6) the following Article 12a is inserted:

Article 12a

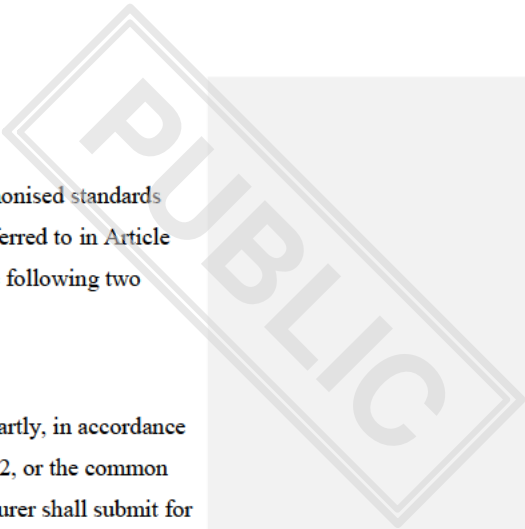
Common Specifications

1. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications that enable compliance with the essential covering requirements set out in Annex I in any of that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
- (a) **there is no harmonised standard covering those requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) **requirements set out in Annex I are covered by harmonised standards the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of vessels of which the product of $PS \times V$ exceeds 50 bar.L with the essential for those requirements set out in Article 4; or and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (c) **where the Commission considers that there is a need to address an urgent concern with regard to non-compliant vessels of which the product of $PS \times V$ exceeds 50 bar.L.**



Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article ~~39(2)~~**39(3)**.

2. Vessels of which the product of $PS \times V$ exceeds 50 bar.L that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I;
 3. **Before preparing the draft of the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
 4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
 5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
 6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**
- (7) Article 13 is amended as follows
- (a) paragraph 1 is amended as follows:
 - (i) in point (a), the introductory sentence is replaced by the following:



‘(a) for vessels manufactured in accordance with the harmonised standards referred to in Article 12 or common specifications referred to in Article 12a, at the choice of the manufacturer, in either of the following two manners;’

(ii) point (b) is replaced by the following:

‘(b) for vessels not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in Article 12, or the common specifications referred to in Article 12a, the manufacturer shall submit for examination a prototype, representative of the production envisaged, of the complete vessel and the technical documentation and supporting evidence for examination and assessment of the adequacy of the technical design of the vessel (Module B – production type).;’

(b) paragraph 3 is replaced by the following:

‘3. The records and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 and 2 shall be drawn up, in electronic form, in an official language of the Member State in which the notified body is established or in a language accepted by that body.;’

(c) the following paragraph 4 is added:

‘4. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.;’

(8) in Article 14, the following paragraph 5 is added:

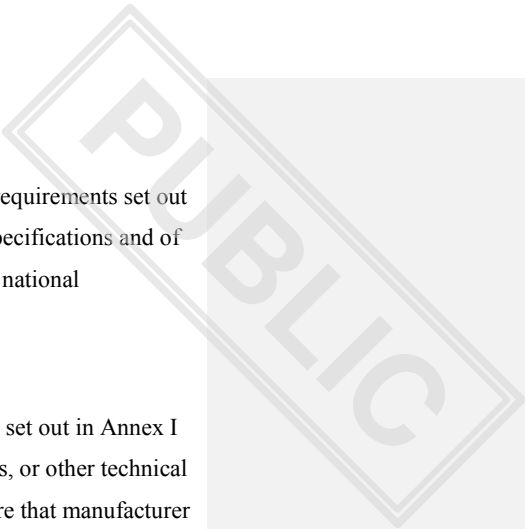
‘5. Where other Union legislation applicable to the vessel requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 6(7) shall be provided only in that digital product passport.;’

(9) in Article 21(7), point (c) is replaced by the following:

Commented [redacted] To ensure the safety of consumers: the safety information in paper format must not be replaced by the digital product passport.

We suggest to add:

“This does not affect the obligation to provide the safety information in paper format according to Article 6 (7).”



- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;;
- (10) in Article 29, paragraph 3 is replaced by the following:
- ‘3. Where a notified body finds that the essential safety requirements set out in Annex I or corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.;;’
- (11) Annexes II, III and IV are amended in accordance with Annex IV to this Directive.

Article 5

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

- (1) Article 3 is amended as follows:
- (a) the following point (15a) is inserted:
- ‘(15a) ‘digital contact’ means any up-to-date and accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~**use an application**.;;’
- (b) the following point (17a) is inserted:
- ‘(17a) ‘common specifications’ means a set of technical ~~requirements~~**specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I of this Directive** applicable to ~~a product, device, service, process or system~~**equipment**.;;’
- (2) Article 7 is amended as follows:
- (a) in paragraph 2, the second subparagraph is replaced by the following:
- ‘Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.;;’
- (b) in paragraph 4, the second sentence is replaced by the following:

‘Changes in apparatus design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.’

- (c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the apparatus. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

- (d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information referred to in Article 18 may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

In the case of apparatus intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the apparatus, the information referred to in Article 18. Such information shall be easily visible and legible for consumers.

When drafting the information referred to in Article 18, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the apparatus, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the apparatus;

- (c) make them accessible online during the expected lifetime of the apparatus and for at least 10 years after the placing on the market of the apparatus.

However, the end-user may, at time of the purchase of the apparatus, or up to six months after that purchase, request the instructions or information referred to in Article 18 in paper format. Where the end-user requests those instructions or information referred to in Article 18, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus with this Directive, in a language which can be easily understood by that authority.;

- (3) in Article 8(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus;;’

- (4) Article 9 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the apparatus their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the apparatus.;

- (b) in paragraph 8, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of apparatus in a language which can be easily understood by that authority.;

- (5) in Article 10(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the apparatus.;

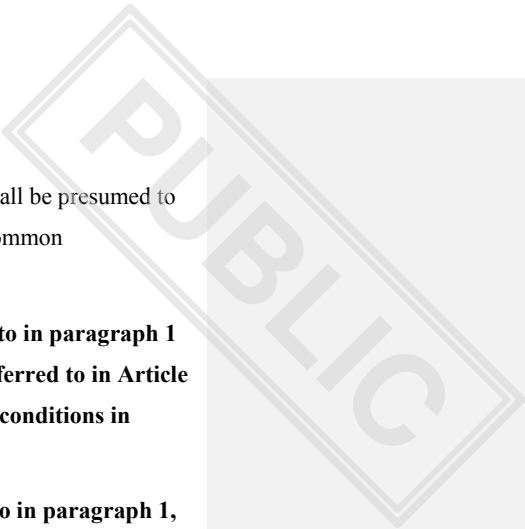
- (6) the following Article 13a is inserted:

‘Article 13a

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications ~~that enable compliance with the essential~~ covering requirements set out in Annex I in any of ~~that~~ **provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
- (a) **there is no harmonised standard covering those requirements set out in Annex I** ~~are not covered by harmonised standards, or parts thereof, the reference of which have been~~ **published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of equipment with the essential for those requirements set out in Annex I; and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (c) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant equipment.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article ~~41(2)~~ **41(2a)**.



2. Apparatus that is in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(7) in Article 14, the following subparagraph is added:

‘The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedure in electronic form.’

(8) in Article 15, the following paragraph 5 is added:

- ‘5. Where other Union legislation applicable to an apparatus 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 7(7) shall be provided only in that digital product passport.;

(9) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation.;

(10) in Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.;

(10a) in Article 41, the following paragraph is inserted:

‘2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.’;

(11) Annexes II, III and IV are amended in accordance with Annex V to this Directive.

Article 6

Amendments to Directive 2014/31/EU

Directive 2014/31/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (9a) is inserted:

‘(9a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~**use** an application.;

(b) the following point (11a) is inserted:

‘(11a) ‘common specifications’ means a set of technical ~~requirements~~**specifications**, other than a standard, that provide means of complying with the essential

requirements applicable to ~~a product, device, service, process or system~~ **an instrument;**”

(2) Article 6 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the supplementary metrology marking.’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in instrument design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

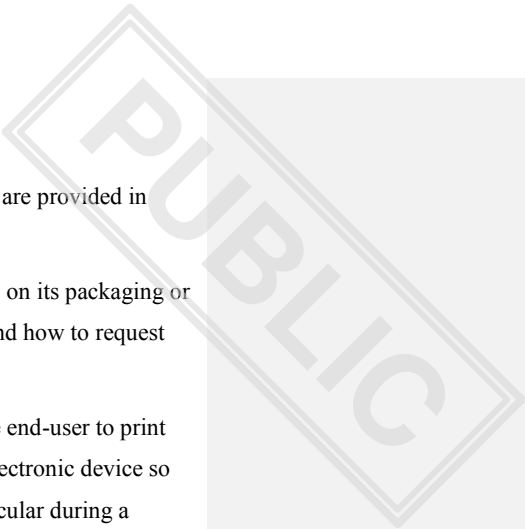
‘Manufacturers shall indicate on the instrument their name, registered trade name or registered trademark as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and information.

In the case of an instrument intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide in paper format, or mark on the product, the information that is essential for using it in a safe way. Such information shall be easily visible and legible for consumers.



When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the instrument, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the instrument; this requirement also applies where the instructions are embedded in the software of the instrument;
- (c) make them accessible online during the expected lifetime of the instrument and for at least 10 years after the placing on the market of the instrument.

However, the end-user may, at time of the purchase of the instrument, or up to six months after that purchase, request the instructions and information in paper format. Where the end-user requests those instructions and information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the instrument with this Directive, in a language which can be easily understood by that authority.;

- (3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument.;

- (4) Article 8 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the instrument their name, registered trade name or registered trademark as well as their postal address and digital contact.;

- (b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument in a language which can be easily understood by that authority.’

(5) in Article 9(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an instrument.’

(6) the following Article 12a is inserted:

‘Article 12a

Common Specifications

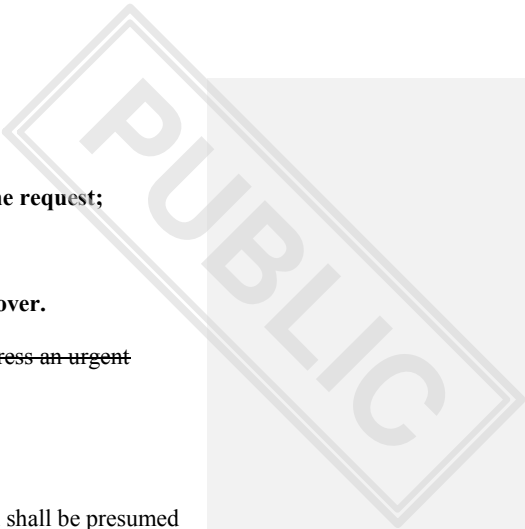
1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **common specifications that enable compliance with the essential** covering requirements ~~set out in Annex I in any of~~ **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements ~~set out in Annex I are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is published** in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

(b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of instruments with the essential for those requirements set out in Annex I; and:**

(1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

(2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**



- (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant instruments.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article 41(2)41(3).

2. Instruments that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

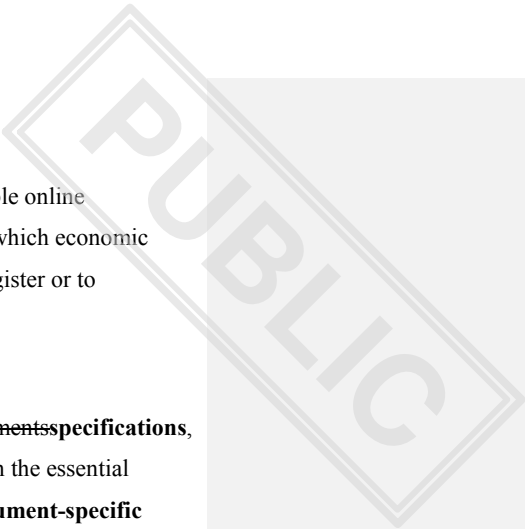
- (7) in Article 13, paragraph (2) is replaced by the following:
- ‘2. The documents and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be drawn up, in electronic form, in one of the official languages of the Member State where those procedures are carried out, or in a language accepted by the body notified in accordance with Article 19.’
- (8) in Article 14, the following paragraph 5 is added:
- ‘5. Where other Union legislation applicable to an instrument 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the** ~~and~~ **instructions and safety information** referred to in Article 6(7) shall be provided only in that digital product passport.’
- (9) in Article 23(7), point (c) is replaced by the following:
- ‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’
- (10) in Article 31, paragraph 3 is replaced by the following:
- ‘3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.’
- (11) Annexes II and IV are amended in accordance with Annex VI to this Directive.

Article 7

Amendments to Directive 2014/32/EU

Directive 2014/32/EU is amended as follows:

- (1) Article 4 is amended as follows:
- (a) the following point (12a) is inserted:



‘(12a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’

(b) the following point (14a) is inserted:

‘(14a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I and in the relevant instrument-specific Annexes of this Directive** applicable to a ~~product, device, service, process or system~~ **measuring instrument**;’

(2) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking and the supplementary metrology marking.’

(b) in paragraph 4, the second sentence is replaced by the following:

‘Changes in measuring instrument design or characteristics and changes in the harmonised standards, common specifications, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.’

(c) paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

(d) in paragraph 7, the first sentence is replaced by the following:

‘7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed, and by instructions and information in accordance with point 9.3 of Annex I in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and information

may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and information in accordance with point 9.3 of Annex I.

In the case of measuring instrument intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the information in accordance with point 9.3 of Annex I. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information in accordance with point 9.3 of Annex I, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions and information play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the measuring instrument, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the measuring instrument; this requirement also applies where the instructions are embedded in the software of the measuring instrument;
- (c) make them accessible online during the expected lifetime of the measuring instrument and for at least 10 years after the placing on the market of the measuring instrument.

However, the end-user may, at time of the purchase of the measuring instrument, or up to six months after that purchase, request the instructions and information in accordance with point 9.3 of Annex I in paper format. Where the end-user requests those instructions information in accordance with point

9.3 of Annex I, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

(e) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority.;

(3) in Article 9(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument.;

(4) Article 10 is amended as follows:

(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears the CE marking and the supplementary metrology marking and is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).;

(b) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the measuring instrument their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I.;

(c) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority.;

(5) Article 11 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed, by the required documents, and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument

is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.;

(b) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a measuring instrument.;

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of adopt~~ **adopt** implementing acts, ~~adopt establishing~~ **adopt** common specifications ~~that enable compliance with the essential covering requirements set out in Annex I and in the relevant instrument-specific Annexes covered by~~ **that provide a means to comply with the applicable essential safety requirements**. Those ~~parts of normative documents, in any~~ **implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled**:

- (a) **there is no harmonised standard covering those** requirements ~~set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents are not covered by harmonised standards, or parts thereof, the references~~ **the reference** of which ~~have been~~ **is published** in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period**;
- (b) ~~requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more** European Union, ~~but application of those~~ **standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of measuring instruments with the essential** **for those** requirements ~~set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents;~~ **and**:

- PUBLIC
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant measuring instruments.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article ~~46(2)~~ **46(3)**.

2. Measuring instruments that are in conformity with the common specification shall be presumed to be in conformity with essential requirements set out in Article 6 covered by those common specifications or parts thereof.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it**

covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(7) Article 17 is amended as follows:

(a) the third subparagraph is replaced by the following:

‘Records and correspondence relating to conformity assessment procedures shall be drawn up in electronic form, in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.’

(b) the following subparagraph is added:

‘The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(8) in Article 18(3), points (f) and (g) are replaced by the following:

(f) a list of the harmonised standards and/or normative documents referred to in Article 14, and/or common specifications referred to in Article 14a applied in full or in part, the references of which have been published in the Official Journal of the European Union;

(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or common specification and/or normative documents referred to in Article 14 have not been applied, including a list of the relevant technical specifications applied;;’

(9) in Article 19, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to measuring instruments 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 Annex XIII to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions **and safety information** referred to in Article 8(7) shall be provided only in that digital product passport.’

(10) in Article 27(7), point (c) is replaced by the following:

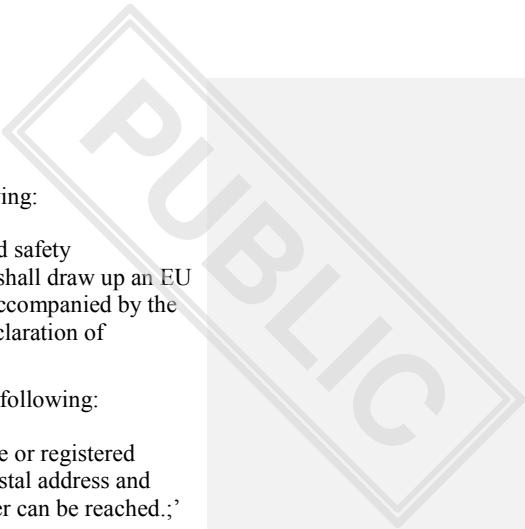
- ‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards or common specifications and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;’
- (11) in Article 36, paragraph 3 is replaced by the following:
- ‘3. Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents, common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.;
- (12) in Article 45(1), point (d) is replaced by the following:
- ‘(d) the measuring instrument is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed;’
- (13) Annexes II and XIII are amended in accordance with Annex VII to this Directive.

Article 8

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

- (1) Article 2 is amended as follows:
- (a) the following point (11a) is inserted:
- ‘(11a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’
- (b) the following point (13a) is inserted:
- ‘(13a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex II of this Directive** applicable to a product; ~~device, service, process or system;;~~’
- (2) Article 7 is amended as follows:



- (a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of the lift with the applicable essential health and safety requirements has been demonstrated by that procedure, the installer shall draw up an EU declaration of conformity, in electronic form, ensure that the lift is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and, affix the CE marking.’

- (b) in paragraph 6, the first and second sentences are replaced by the following:

‘Installers shall indicate, on the lift, their name, registered trade name or registered trademark, as well as their postal address and digital contact. The postal address and digital contact shall indicate a single point through which the installer can be reached.’

- (c) paragraph 7 is replaced by the following:

‘7. Installers shall ensure that the lift is accompanied by the instructions referred to in point 6.2 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State in which the lift is placed on the market. The instructions may be provided in electronic form. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

When the instructions are provided in electronic form, the installer shall:

- (a) mark on the lift, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the lift; this requirement also applies where the instructions are embedded in the software of the lift;
- (c) make them accessible online during the expected lifetime of the lift and for at least 10 years after the placing on the market of the lift.

However, the end-user may, at time of the purchase of the lift, or up to six months after that purchase, request the instructions in paper format. Where the end-user requests those instructions, the installer shall provide them to the end-user, free of charge, within one month of receiving the request.’

- (d) in paragraph 9, the first subparagraph is replaced by the following:

‘Installers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to

demonstrate the conformity of the lift with this Directive, in a language which can be easily understood by that authority.;

(3) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, ensure that the safety component for lifts is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed, and affix the CE marking.;

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of a safety component for lifts is declared shall be adequately taken into account.;

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the safety component for lifts their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on the label referred to in Article 19(1). The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.;

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions may be provided in electronic form. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

When the instructions are provided in electronic form, the manufacturer shall:

- (a) mark on the safety component for lifts, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times; this requirement also

applies where the instructions are embedded in the software of the safety component for lifts;

- (c) make them accessible online during the expected lifetime of the safety component for lifts and for at least 10 years after the placing on the market of safety component for lifts.

However, the end-user may, at time of the purchase of the safety component for lift, or up to six months after that purchase, request the instructions in paper format. Where the end-user requests those instructions, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 9, first subparagraph, the first sentence is replaced the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts with this Directive, in a language which can be easily understood by that authority.;

- (4) in Article 9(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts or the lift.;

- (5) Article 10 is amended as follows:

- (a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

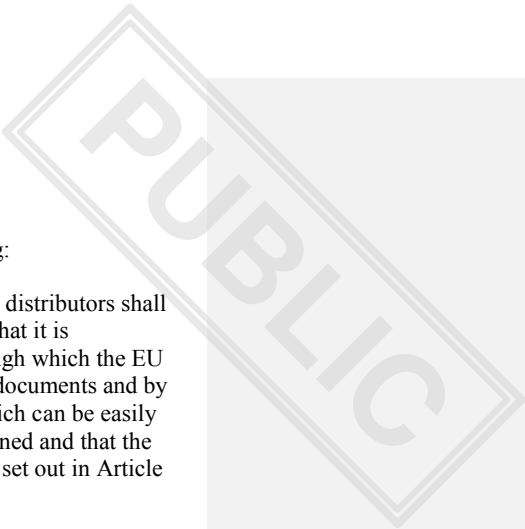
‘They shall ensure that the manufacturer has drawn up the technical documentation, that the safety component for lifts bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).;

- (b) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the safety component for lifts their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the safety component for lifts.;

- (c) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a safety component for lifts in a language which can be easily understood by that authority.;



(6) Article 11 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a safety component for lifts available on the market, distributors shall verify that the safety component for lifts bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed, by the required documents and by the instructions referred to in point 6.1 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3), respectively;’

(b) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a safety component for lifts.’

(7) the following Article 14a is inserted:

‘Article 14a

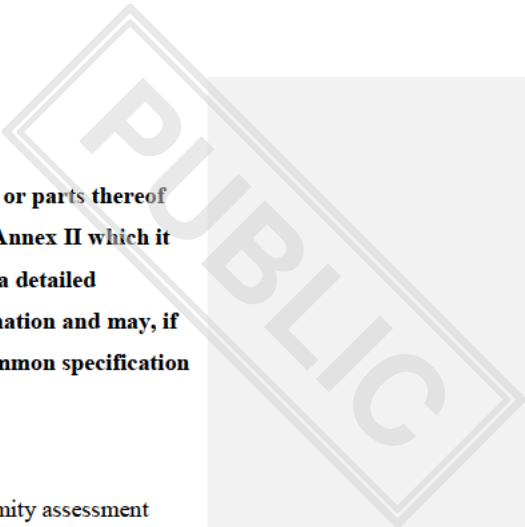
Common Specifications

1. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications that enable compliance with the essential covering requirements set out in Annex I in any of that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
 - (a) **there is no harmonised standard covering those requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) **requirements set out in Annex I are covered by harmonised standards the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of lifts and components for lifts with the essential for those requirements set out in Annex I; or and:**

- PUBLIC**
- (1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) are not delivered within the deadline set in the request;**
 - (b) do not comply with the request; or**
 - (c) do not satisfy the requirements they aim to cover.**
 - ~~(e) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant lifts and components for lifts.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article ~~42(2)~~**42(3)**.

- 2. Lifts and safety components for lifts that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex I;
- 3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
- 4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
- 5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**



6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(8) in Article 15, the following subparagraph is added:

‘The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures for safety components for lifts in electronic form.;

(9) in Article 16, the following paragraph 5 is added:

‘5. The installer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures for lifts in electronic form.;

(10) in Article 17, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to lifts or safety components for lifts 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 Annex II to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity**, and the instructions ~~and safety information~~ referred to in Articles 7(7) and 8(7) shall be provided only in that digital product passport.;

Commented [redacted] We suggest to delete to this as no safety information is introduced in either Art. 7 (7) or Art. 8(7).

(11) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of its relevant national legislation;;’

(12) in Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements of this Directive or corresponding harmonised standards or common specifications or other

technical specifications have not been met by an installer or a manufacturer, it shall require the installer or the manufacturer to take appropriate corrective measures and shall not issue a certificate.;

(13) in Article 41(1), point (g) is replaced by the following:

‘(g) the name, registered trade name or registered trademark, the postal address and digital contact of the installer, manufacturer or importer has not been indicated in compliance with Article 7(6), Article 8(6) or Article 10(3);;’

(14) Annexes II and IV to XII are amended in accordance with Annex VIII to this Directive.

Article 9

Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (16a) is inserted:

‘(16a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~**use** an application;.’

(b) the following point (18a) is inserted:

‘(18a) ‘common specifications’ means a set of technical ~~requirements~~**specifications**, other than a standard, that provide means of complying with the essential requirements applicable to a product, ~~device, service, process or system~~;.’

(2) Article 6 is amended as follows:

(a) in paragraph 2, the second, third and fourth subparagraphs are replaced by the following:

‘Where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking. Where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, manufacturers shall draw up a written attestation of conformity, in electronic form, as referred to in Article 13(3).’

Manufacturers shall ensure that each product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity, as appropriate, can be **directly** accessed. However, where a large number of products are delivered to a single end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.;

- (b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in a product design or characteristics and changes in the harmonised standards, in the common specifications, or in other technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.;

- (c) in paragraph 7, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the product, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.;

- (d) paragraph 8 is replaced by the following:

- ‘8. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of products intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;
- (c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product with this Directive, in a language which can be easily understood by that authority.;

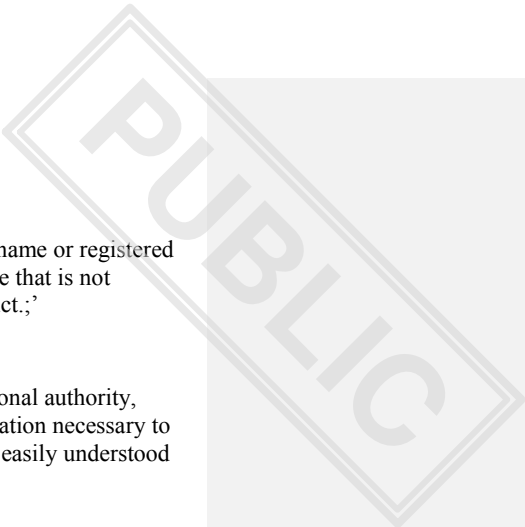
- (3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product.;

- (4) Article 8 is amended as follows:

- (a) in paragraph 2, first subparagraph, the second sentence is replaced by the following

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking, where applicable, and that it is accompanied by the internet address or machine-readable code where the EU declaration of conformity or the attestation of conformity can be **directly** accessed and by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5), (6) and (7).;



(b) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the product their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the product.’

(c) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority.’

(5) Article 9 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a product available on the market distributors shall verify that the product bears the CE marking, where applicable, and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity can be **directly** accessed and by the required documents and by instructions and safety information, in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5), (6) and (7) and Article 8(3) respectively.’

(b) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product.’

(6) the following Article 12a is inserted:

‘Article 12a

Common Specifications

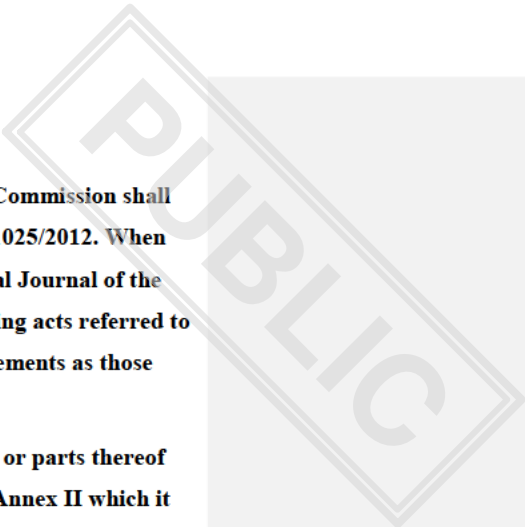
1. **In exceptional cases, the Commission may, by means of adopt implementing acts, adopt establishing common specifications that enable compliance with the essential covering requirements set out in Annex II in any of that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following conditions are fulfilled:**

(a) **there is no harmonised standard covering those requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**

- (b) ~~requirements set out in Annex II are covered by harmonised standards~~**the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of these standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of products with the essential for those requirements set out in Annex II; and:**
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant products.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article ~~39(2)~~**39(3)**.

2. Products that are in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Annex II.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its**



reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;

(7) Article 13 is amended as follows:

(a) paragraph 6 is replaced by the following:

‘6. Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 to 4 shall be drawn up, in electronic form, in a language, determined by the Member State concerned.’

(b) the following paragraph 7 is added:

‘7. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

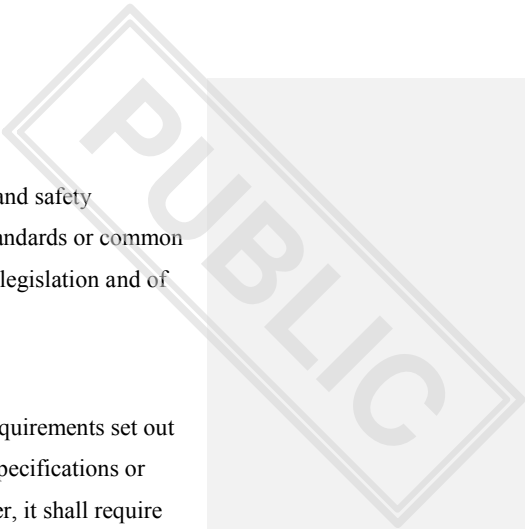
(8) in Article 14, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to a product 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 Annex X to be included in the EU declaration of conformity or, as appropriate, the EU declaration of conformity, and the instructions and safety information referred to in Article 6(7) shall be provided only in that digital product passport.’

(9) in Article 21(7), point (c) is replaced by the following:

Commented To ensure the safety of consumers: the safety information in paper format must not be replaced by the digital product passport.

We suggest to add:
“This does not affect the obligation to provide the safety information in paper format according to Article 6 (8).”



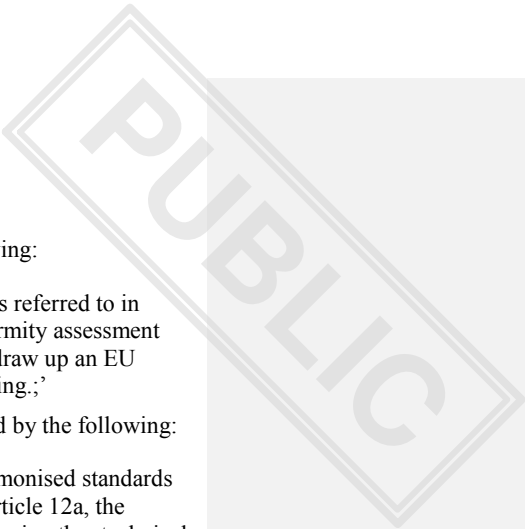
- ‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards or common specifications, of the relevant provisions of Union harmonisation legislation and of national legislation;’;
- (10) in Article 29, paragraph 3 is replaced by the following:
 - ‘3. Where a notified body finds that the essential health and safety requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.’;
- (11) in Article 38(1), point (e) is replaced by the following:
 - ‘(e) the product is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity or the attestation of conformity, as appropriate, can be **directly** accessed;’;
- (12) Annexes II to V and VII to X are amended in accordance with Annex IX to this Directive.

Article 10

Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

- (1) Article 2 is amended as follows:
 - (a) the following point (7a) is inserted:
 - ‘(7a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’;
 - (b) the following point (9a) is inserted:
 - ‘(9a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the safety objectives **referred to in Article 3 and set out in Annex I of this Directive** applicable to a ~~product, device, service, process or system~~; **electrical equipment**;’;



(2) Article 6 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of electrical equipment with the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated by the conformity assessment procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in product design or characteristics and changes in the harmonised standards referred to in Article 12, the common specifications referred to in Article 12a, the international or national standards referred to in Articles 13 and 14, or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the electrical equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

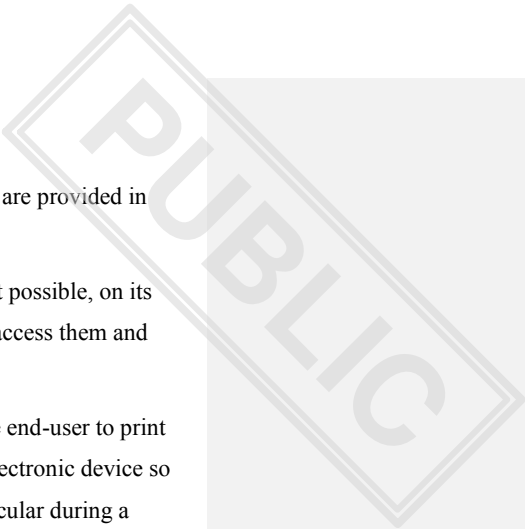
(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the electrical equipment is accompanied by instructions and safety information, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the electrical equipment when deciding the specific format for the instructions and safety information.

In the case of electrical equipment intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.



When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the electrical equipment, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the electrical equipment; this requirement also applies where the instructions are embedded in the software of the electrical equipment;
- (c) make them accessible online during the expected lifetime of the electrical equipment and for at least 10 years after the placing on the market of the electrical equipment.

However, the end-user may, at time of the purchase of the electrical equipment, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (e) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the electrical equipment with this Directive, in a language which can be easily understood by that authority.;

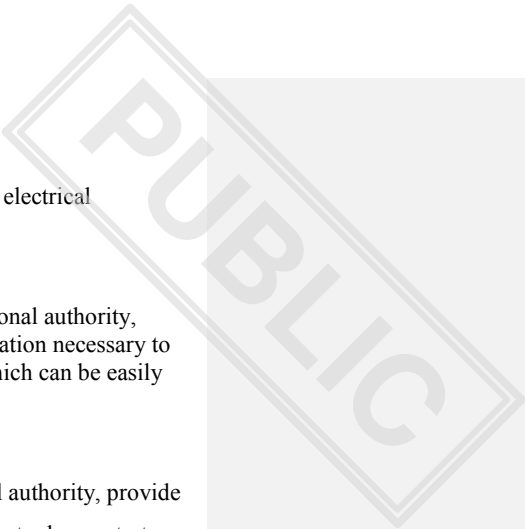
- (3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment.;

- (4) Article 8 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate on the electrical equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that



is not possible, on its packaging or in a document accompanying the electrical equipment.;

(b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment in a language which can be easily understood by that authority.;

(5) in Article 9(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of electrical equipment.;

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

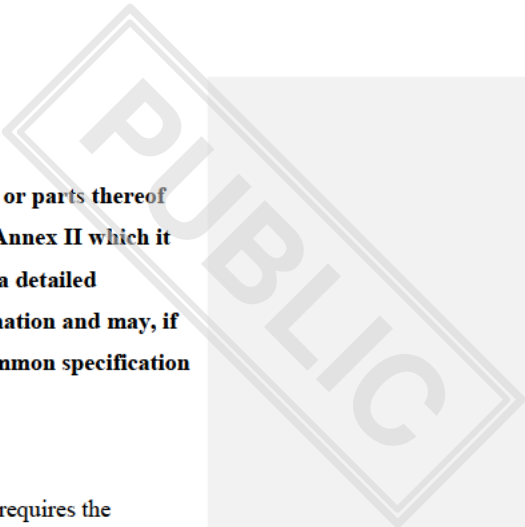
1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt~~ **establishing** common specifications **covering requirements that provide a means to comply that enable compliance** with the **applicable essential** safety objectives referred to in Article 3 and set out in Annex I in any of ~~requirements~~. **Those implementing acts shall only be adopted where the following conditions are fulfilled:**

- (a) ~~objectives referred to in Article 3 and set out in Annex I are not covered by~~ **there is no** harmonised standards, or parts thereof, the reference ~~standard covering those requirements the reference~~ of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**
- (b) ~~objectives referred to in~~ **the Commission has requested, pursuant to Article 3 and set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the** **10(1) of Regulation 1025/2012, one or more** European Union, ~~but application of these standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of electrical equipment with the essential~~ **for those requirements set out in Annex II; and:**

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- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant electrical equipment.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article ~~23(3a)~~**23(2)**.

2. Electrical equipment that are in conformity with the common specification shall be presumed to be in conformity with safety objectives covered by those common specifications or parts thereof, referred to in Article 3 and set out in Annex I;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**



6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(7) in Article 15, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to electrical equipment 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the instructions and safety information** referred to in Article 6(7) shall be provided only in that digital product passport.’;

(8) in Article 23, the following paragraph 3a is inserted:

‘3a. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.’;

(9) Annexes III and IV are amended in accordance with Annex X to this Directive.

Commented [redacted]: To ensure the safety of consumers: the safety information in paper format must not be replaced by the digital product passport.

We suggest to add:
“This does not affect the obligation to provide the safety information in paper format according to Article 6 (7).”

Article 11

Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (16a) is inserted:

‘(16a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’

(b) the following point (18a) is inserted:

(18a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Article 3 of this Directive** applicable to a ~~product, device, service, process or system~~ **radio equipment**;;

(2) Article 10 is amended as follows:

(a) in paragraph 3, the second subparagraph is replaced by the following:

‘Where compliance of radio equipment with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’;

(b) in paragraph 5, the second sentence is replaced by the following:

‘Changes in radio equipment design or characteristics and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account.’;

(c) in paragraph 7, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The postal address and digital contact shall indicate a single point through which ~~through which~~ the manufacturer can be reached.’;

(d) paragraph 8 is replaced by the following:

‘8. Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information. The instructions and safety information may be provided in electronic form in accordance with the sixth subparagraph of this paragraph. The manufacturer shall take into account the intended use and the foreseeable end-user of the radio equipment when deciding the specific format for the instructions and safety information. The instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the instructions in the case of radio equipment intentionally emitting radio waves:

(a) frequency band(s) in which the radio equipment operates;

- (b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

In the case of radio equipment referred to in Article 3(4), the instructions shall contain information on the specifications relating to the radio equipment's charging capabilities and the compatible charging devices, as set out in Part II of Annex Ia. In addition to being included in the instructions, when the manufacturers make such radio equipment available to consumers and other end-users, the information shall be also displayed on a label, as set out in Part IV of Annex Ia. The label shall be included in the instructions and printed on the packaging or affixed to the packaging as a sticker. In the absence of packaging, the sticker with the label shall be affixed to the radio equipment.

When the radio equipment is made available to consumers and other end-users, the label shall be displayed in a visible and legible manner and, in the case of distance selling, close to the price indication. Where the size or nature of the radio equipment does not allow otherwise, the label may be printed as a separate document accompanying the radio equipment.

The instructions and safety information referred to in the first, second and third subparagraphs of this paragraph shall be in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

The Commission is empowered to adopt delegated acts in accordance with Article 44 in order to amend Parts II and IV of Annex Ia, as a consequence of amendments to Part I of that Annex, or as a consequence of future amendments to labelling requirements, or in the light of technological progress, by introducing, modifying, adding or removing any details in relation to the information, graphic or textual elements, as set out in this Article.';

In the case of radio equipment intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, the safety information in paper format. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the radio equipment, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the radio equipment; this requirement also applies where the instructions are embedded in the software of the radio equipment;
- (c) make them accessible online during the expected lifetime of the radio equipment and for at least 10 years after the placing on the market of the radio equipment.

However, the end-user may, at time of the purchase of the radio equipment, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;

(e) paragraph 9 is amended as follows:

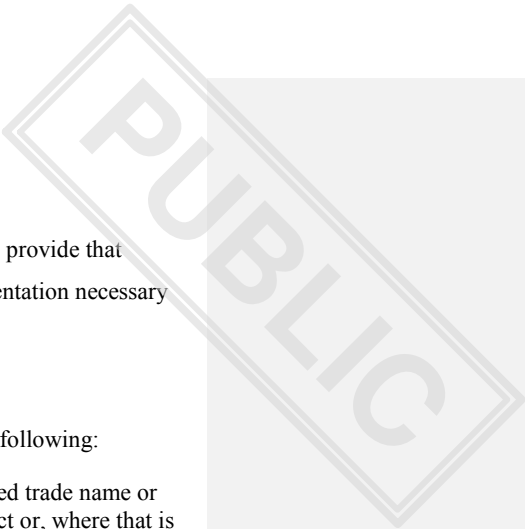
(i) the first sentence is replaced by the following:

‘Manufacturers shall ensure that each item of radio equipment is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.’;

(ii) the second sentence is deleted;

(f) in paragraph 12, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority.’;



(3) in Article 11(2), point (b), is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment;’

(4) Article 12 is amended as follows:

(a) in paragraph 3, the first and second sentences are replaced by the following:

‘Importers shall indicate on the radio equipment their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the radio equipment. This includes cases where the size of radio equipment does not allow it, or where importers would have to open the packaging in order to indicate their name, postal address and digital contact on the radio equipment.’

(b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment in a language which can be easily understood by that authority.’

(5) in Article 13(5), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of radio equipment.’

(6) the following Article 16a is inserted:

‘Article 16a

Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ **establishing** common specifications ~~that enable compliance with the essential covering requirements set out in Article 3 in any of~~ **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements ~~set out in Article 3 are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

- (b) ~~requirements set out in the Commission has requested, pursuant to Article 3~~
~~are covered by harmonised standards, or parts thereof, the references of which~~
~~have been published in the Official Journal of the~~**10(1) of Regulation**
1025/2012, one or more European Union, but application of
~~those standardisation organisations to draft or to revise European standards~~
~~or parts thereof results in non-compliance of radio equipment with the~~
~~essential for those requirements set out in Article 3; or and:~~
- (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant radio equipment.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article 45(2)**45(3)**.

2. Radio equipment that is in conformity with the common specification shall be presumed to be in conformity with essential requirements, covered by those common specifications or parts thereof, set out in Article 3.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its**

reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.

6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(7) Article 17 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘3. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has applied harmonised standards the references of which have been published in the Official Journal of the European Union, ~~or~~ and common specifications, the manufacturer shall use any of the following procedures:’

- (b) In paragraph 4, the first sentence is replaced by the following:

‘4. Where, in assessing the compliance of radio equipment with the essential requirements set out in Article 3(2) and (3), the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, or where such harmonised standards or common specifications do not exist, radio equipment shall be submitted with regard to those essential requirements to either of the following procedures:’

- (c) the following paragraph 5 is added:

‘5. Where applicable, manufacturers shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

- (8) Article 18 is amended as follows:
- (a) in paragraph 2, the second subparagraph is deleted;
 - (b) the following paragraph 5 is added:
 - ‘5. Where other Union legislation applicable to radio equipment 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the instructions and safety information** referred to in Article 10(8)– **and Article 10 (10)** shall be provided only in that digital product passport.’
- (9) in Article 26(7), point (c) is replaced by the following:
- ‘(c) appropriate knowledge and understanding of the essential requirements set out in Article 3, of the applicable harmonised standards, of the applicable common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’
- (10) Annexes Ia, and III to ~~IV, V, VI and VII~~ are amended in accordance with Annex XI to this Directive.

Article 12

Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

- (1) Article 2 is amended as follows:
- (a) the following point (22a) is inserted:
 - ‘(22a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ **use** an application;’
 - (b) the following point (24a) is inserted:

(24a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I of this Directive** applicable to ~~a product, device, service, process or system~~ **pressure equipment or assemblies;**”

(2) Article 6 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of the pressure equipment or assemblies referred to in Article 4(1) and (2) with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph of this paragraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in design or characteristics of pressure equipment or assemblies and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which conformity of pressure equipment or assemblies is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the pressure equipment or assembly their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the equipment or assembly. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(1) and (2) is accompanied by instructions and safety information in accordance with points 3.3 and 3.4 of Annex I in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

Manufacturers shall ensure that the pressure equipment or assemblies referred to in Article 4(3) are accompanied by instructions and safety information in accordance with Article 4(3), in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the pressure equipment or assemblies when deciding the specific format for the instructions and safety information.

In the case of pressure equipment or assemblies intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information in accordance with points 3.3 and 3.4 of Annex I. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

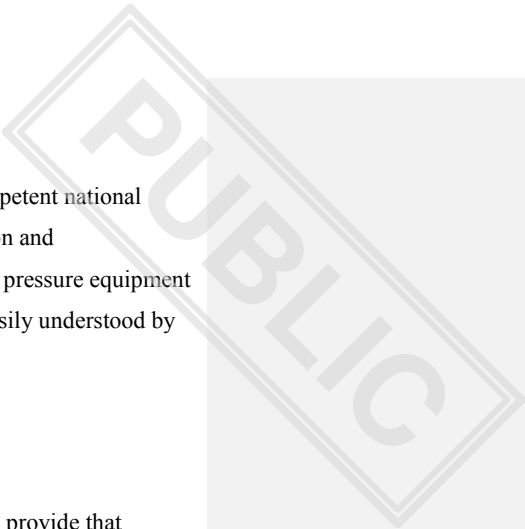
When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the pressure equipment or assemblies or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the pressure equipment or assemblies; this requirement also applies where the instructions are embedded in the software of the pressure equipment or assemblies;
- (c) make them accessible online during the expected lifetime of the pressure equipment or assemblies and for at least 10 years after the placing on the market of the pressure equipment or assemblies.

However, the end-user may, at time of the purchase of the pressure equipment or assemblies, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

(e) paragraph 9 is amended as follows:

- (a) the first sentence is replaced by the following:



‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly with this Directive, in a language which can be easily understood by that authority.;;’

(b) the second sentence is deleted;

(3) in Article 7(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the pressure equipment or assembly.;;’

(4) Article 8 is amended as follows:

(a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the pressure equipment or assembly, or, where that is not possible, on its packaging or in a document accompanying the equipment or assembly.;;’

(b) paragraph 9 is amended as follows:

(i) the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of pressure equipment or ~~an assembly~~ **assemblies** in a language which can be easily understood by that authority.;;’

(ii) the second sentence is deleted;

(5) Article 9 is amended as follows:

(a) the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of pressure equipment or assemblies.;;’

(b) the second sentence is deleted;

(6) the following Article 12a is inserted:

‘Article 12a

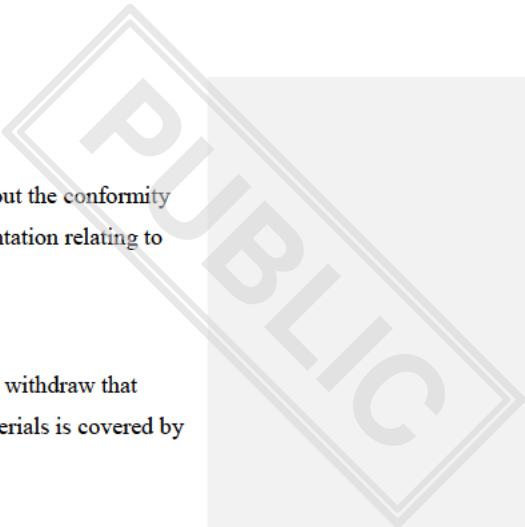
Common Specifications

1. **In exceptional cases**, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications ~~that enable compliance with the essential~~ covering requirements set out in Annex I in any of ~~that~~ **provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where the following conditions are fulfilled:**
- (a) **there is no harmonised standard covering those requirements set out in Annex I** ~~are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of pressure equipment or assemblies referred to in Article 4(1) and (2) with the essential** ~~for those requirements set out in Annex I; or~~ **and:**
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**
 - (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant pressure equipment or assemblies.~~

Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 44(2) ~~44(3)~~.

2. Pressure equipment or assemblies that are in conformity with the common specification shall be presumed to be in conformity with essential requirements covered by those common specifications or parts thereof, set out in Annex I.;
 3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
 4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
 5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
 6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**
- (7) Article 14 is amended as follows:
- (a) paragraph 8 is replaced by the following:

‘8. The records and correspondence relating to conformity assessment procedures shall be drafted, in electronic form, in an official language of the Member State where the body responsible for carrying out these conformity assessment procedures is established, or in a language accepted by that body.’
 - (b) the following paragraph 9 is added:



‘9. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(8) in Article 15(5), the first sentence is replaced by the following:

‘The notified body which issued the European approval for materials shall withdraw that approval if it finds that it should not have been issued or if the type of materials is covered by a harmonised standard or common specifications.’

(9) in Article 17, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to the pressure equipment or assembly 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 Annex IV to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the instructions and safety information** referred to in Article 6(7) shall be provided only in that digital product passport.’

(10) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’

(11) in Article 25(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’

(12) in Article 34, paragraph 3 is replaced by the following:

‘3. Where a conformity assessment body finds that essential safety requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that

Commented [redacted]: To ensure the safety of consumers: the safety information in paper format must not be replaced by the digital product passport.

We suggest to add:
This does not affect the obligation to provide the safety information in paper format according to Article 6 (7).

manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.;

- (13) Annexes I, III and IV are amended in accordance with Annex XII to this Directive.

Article 13

Amendments to Directive 2014/90/EU

Directive 2014/90/EU is amended as follows:

- (1) in Article 2, the following point (14a) is inserted:

‘(14a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be reached or engaged without the need to register or to ~~download~~ use an application;’

- (2) Article 12 is amended as follows:

- (a) paragraph 3 is replaced by the following:

‘3. Where the compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity, in electronic form, in accordance with Article 16, and affix the wheel mark in accordance with Articles 9 and 10.’

- (b) paragraphs 7 and 8 are replaced by the following:

‘7. Manufacturers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate. The postal address and digital contact must indicate a single point through which the manufacturer can be reached.

8. Manufacturers shall ensure that the product is accompanied by instructions and all necessary information for safe installation on board and safe use of the product, including limitations of use, if any, that can be easily understood by the end-users, together with any other documentation required by the international instruments or testing standards. The instructions and all the necessary information may be provided in electronic form.

In the case of products intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the product, information for safe installation on board and safe use of the product, including limitations of use. Such safety information shall be easily visible and legible for consumers.

When the instructions, referred to in the first subparagraph, are provided in electronic form, manufacturers shall:

- (a) mark on the product, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the product; this requirement also applies where the instructions are embedded in the software of the product;
- (c) make them accessible online during the expected lifetime of the product and for at least 10 years after the placing on the market of the product.

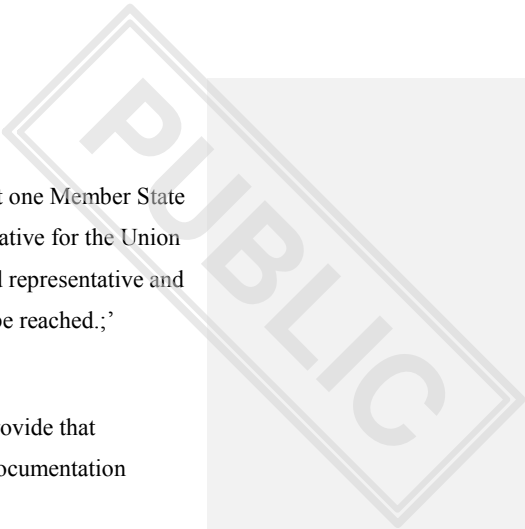
However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or information for safe installation on board and safe use of the product, including limitations of use in paper format. Where the end-user requests those instructions or information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

- (c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent authority, promptly provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by or is acceptable to that authority, grant that authority access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008 and provide samples or access to samples in accordance with Article 25(4) of this Directive.;

- (3) Article 13 is amended as follows:

- (a) paragraph 1 is replaced by the following:



- ‘1. A manufacturer who is not located in the territory of at least one Member State shall, by a written mandate, appoint an authorised representative for the Union and shall indicate in the mandate the name of the authorised representative and the postal address and digital contact through which it can be reached.’
- (b) in paragraph 3, point (b) is replaced by the following:
- ‘(b) further to a reasoned request from a competent authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product;’
- (4) Article 14 is amended as follows:
- (a) paragraph 1 is replaced by the following:
- ‘1. Importers shall indicate their name, registered trade name or registered trademark as well as their postal address and digital contact on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate.’
- (b) in paragraph 2, the first sentence is replaced by the following:
- ‘Importers and distributors shall, further to a reasoned request from a competent authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by, or is acceptable to, that authority.’
- (5) in Article 15, the following paragraph 4 is added:
- ‘4. The manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and documentation relating to conformity assessment procedures in electronic form.’
- (6) Article 16 is amended as follows:
- (a) in paragraph 4, the first sentence is replaced by the following:
- ‘When marine equipment is placed on board an EU ship the manufacturer shall upload the EU declaration of conformity covering the equipment concerned onto the database set up by the Commission in accordance with Article 35(4).’
- (b) paragraph 5 is replaced by the following:
- ‘5. The EU declaration of conformity shall be provided to the notified body or to the bodies which carried out the relevant conformity assessment procedures via the database set up by the Commission in accordance with Article 35(4).’

- (7) the following paragraph 6 is added:
- ‘6. Where other Union legislation applicable to the marine equipment 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 Annex III to Decision No 768/2008/EC to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and ~~and~~ the instructions and safety information** referred to in Article 12(8) shall be provided only in that digital product passport.’
- (8) in Article 29(1), point (f) is replaced by the following:
- ‘(f) the EU declaration of conformity has not been made accessible electronically to the ship;’
- (9) Annex II is amended in accordance with Annex XIII to this Directive.

Article 14

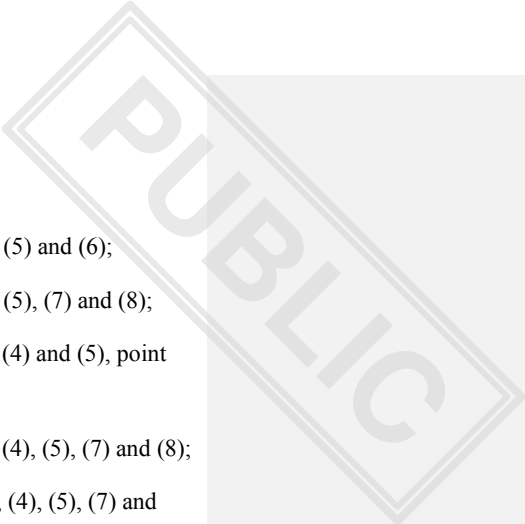
Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU before [PO: Please insert the date set out in Article 15(1), second subparagraph].

Article 15

Transposition

1. Member States shall adopt and publish, by [OP:Please insert 12 months after entry into force of this amending Directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.
- They shall apply those provisions from [OP: Please insert 12 months after entry into force of this amending Directive].
- However, Member States shall apply the following provisions from [OP: Please insert 24 months after entry into force of this amending Directive]:

- 
- (a) Article 1;
 - (b) Article 2, point (1)(a), point (2)(a), (c) and(d), and points (3), (4), (5) and (6);
 - (c) Article 3, point (1)(a), point (2)(a), (c) and(d), and points (3), (4), (5), (7) and (8);
 - (d) Article 4, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4) and (5), point (7)(b) and(c), and point (8);
 - (e) Article 5, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);
 - (f) Article 6, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7) and (8);
 - (g) Article 7, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7), (9) and (12);
 - (h) Article 8, point (1)(a), point (2), point (3)(a), (c), (d) and (e), and points (4) (5), (6), (8), (9), (10) and (13);
 - (i) Article 9, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);
 - (j) Article 10, point (1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5) and (7);
 - (k) Article 11, point (1)(a), point (2)(a), (c), (d), (e) and (f), and points (3), (4) and (5), point (7)(c) and point (8);
 - (l) Article 12, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (9);
 - (m) Article 13;
 - (n) Annexe I;
 - (o) Annex II, point (1) and point (2)(a);
 - (p) Annex III, point (1)(a)(ii) and (b)(i), point (2)(a), point (3)(a) and point (4);
 - (q) Annex IV, point (1)(a)(i) and(c), point (2) and point (3)(a);
 - (r) Annex V, point (2)(a)(i) and (b) and point 3(a);
 - (s) Annex VI, point (1)(a)(i),(c), (d) and(g) and point (2)(a);
 - (t) Annex VII, point (1)(b)(i), first indent, (b)(iii), (d)(i), (e)(i), (f)(i), (g)(i), (k)(i), (l)(i), (l)(iv), first indent, and (l)(v), and point (2)(a);

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- (u) Annex VIII, point (1)(a)(i), (a)(iii), (b)(i) and (b)(iii), point (2)(a)(i), (a)(v), (b)(i) and (b)(v), point (4)(a), point (5)(a), point (6)(a), point (7)(a), point (8)(a), point (9)(a) and point 10(a);
 - (v) Annex IX, point (1), point (2)(a), (d) and (a), point 5(a) and point 8(a);
 - (w) Annex X, point (2)(a);
 - (x) Annex XI, point (1), point (2)(a)(i) and (b), point (3)(a), point (5)(a) and point (6);
 - (y) Annex XII, point (2)(c)(i), first indent, (c)(iv), (c)(v), first indent, (c)(viii), (e)(i), (f)(ii), (g)(i), (h)(ii), (k)(i), (l)(i), (l)(v) and (l)(viii), and point (3)(a) and (c);
 - (z) Annex XIII.
2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 16

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President



ANNEX I

Annexes II and V to VIII to Directive 2000/14/EC are amended as follows:

- (1) Annex II is amended as follows:
 - (a) the first and second indents are replaced by the following:
 - ‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community
 - name, postal address and digital contact of the person who keeps the technical documentation;’
 - (b) the fourth indent is replaced by the following:
 - ‘— conformity assessment procedure followed, and, where appropriate, name, postal address and digital contact of the notified body involved;’
- (2) Annex V is amended as follows:
 - (a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the ~~ECEU~~ declaration of conformity.’
 - (b) in point 3, the first indent is replaced by the following:
 - ‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community;’
- (3) Annex VI is amended as follows:
 - (a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the ~~ECEU~~ declaration of conformity.’
 - (b) in point 3, the first indent is replaced by the following:
 - ‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community;’
- (4) in Annex VII, point 2, the first indent is replaced by the following:
 - ‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact in addition;’

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(5) in Annex VIII, point 3.1, first indent, the first subindent is replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community.’

ANNEX II

Annexes V and VI to Directive 2011/65/EU are amended as follows:

- (1) in Annex V, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the applicant;’
- (2) Annex VI is amended as follows:
 - (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer or his authorised representative;’
 - (b) point 6 is replaced by the following:
 - ‘6. Where applicable, references to the relevant harmonised standards or common specifications used or references to the technical specifications in relation to which conformity is declared.’

ANNEX III

Annexes I, III, IV and V to Directive 2013/53/EU are amended as follows:

- (1) Annex I is amended as follows:
- (a) Part A is amended as follows:
 - (i) in point 2.1., the second subparagraph is replaced by the following:

‘Detailed requirements for the identification number referred to in the first paragraph are set out in the relevant harmonised standard or common specification.’
 - (ii) in point 2.2, point (a) is replaced by the following:

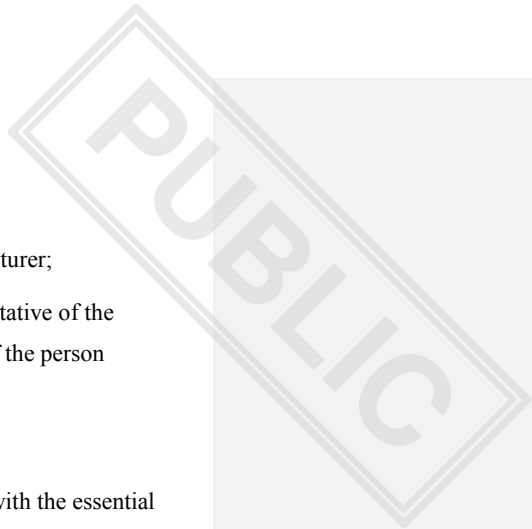
‘(a) manufacturer’s name, registered trade name or registered trade mark and as well as the postal address and digital contact;’
 - (b) Part B is amended as follows:
 - (i) in point 1.1, point (a) is replaced by the following:

‘(a) engine manufacturer’s name, registered trade name or registered trade mark as well as the postal address and digital contact; and, if applicable, the name, postal address and digital contact of the person adapting the engine;’
 - (ii) in point 2.3, the fourth subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests cycles as specified in a harmonised standard or common specification and as applicable for the engine duty cycle.’
 - (iii) in point 2.5, the second subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests fuel as specified in a harmonised standard or common specification.’
 - (iv) in point 4, point (b) is replaced by the following:

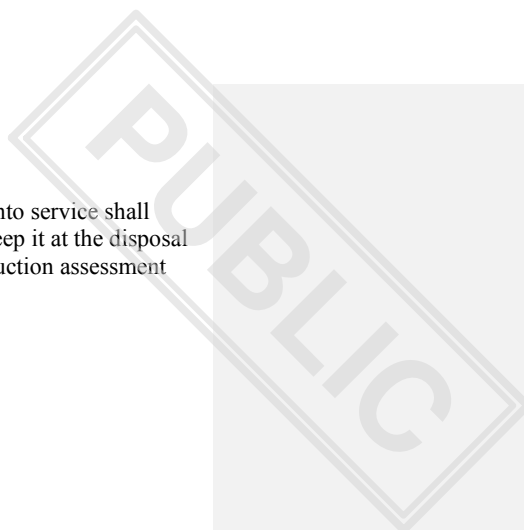
‘(b) specify the power of the engine when measured in accordance with the harmonised standard or common specification.’
- (2) Annex III is amended as follows:



- (a) points (a), and (b) are replaced by the following:
- ‘(a) the name, postal address and digital contact of the manufacturer;
 - (b) the name, postal address and digital contact of the representative of the manufacturer established in the Union or, if appropriate, of the person responsible for the placing on the market;’
- (b) point (d) is replaced by the following:
- ‘(d) a statement that the partly completed watercraft complies with the essential requirements that apply at this stage of construction; this shall include references to the relevant harmonised standards or common specifications used, or references to ~~the~~**other technical** specifications in relation to which compliance is declared at this stage of construction; furthermore, it is intended to be completed by other legal or natural persons in full compliance with this Directive.’
- (3) Annex IV is amended as follows:
- (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer or his authorised representative [The authorised representative must also give the business name, postal address and digital contact of the manufacturer] or the private importer.’
 - (b) point 6 is replaced by the following:
 - ‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’
- (4) Annex V is amended as follows:
- (a) in point 2, the first subparagraph is replaced by the following:

‘The person who is placing the product on the market or putting it into service shall lodge an application for a post-construction assessment of the product with a notified body and must provide the notified body, in electronic form, with the documents and technical file enabling the notified body to assess the conformity of the product with the requirements of this Directive and any available information on the use of the product after its first putting into service.’
 - (b) in point 4.2, first subparagraph, the first sentence is replaced by the following:

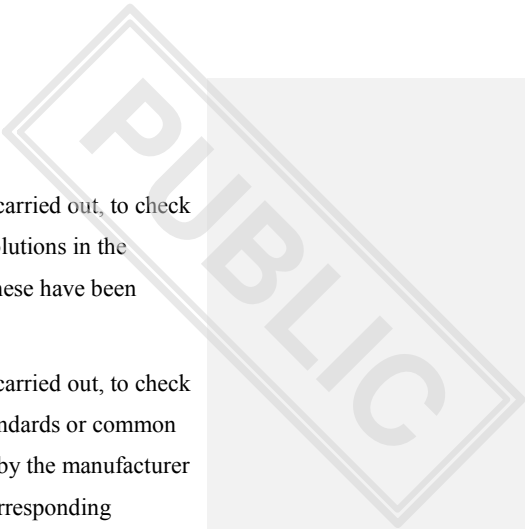
‘The person who is placing the product on the market or putting it into service shall draw up, in electronic form, an EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the date the post-construction assessment certificate has been issued..’



ANNEX IV

Annexes II, III and IV to Directive 2014/29/EU are amended as follows:

- (1) Annex II is amended as follows:
- (a) point 1.3 is amended as follows: :
- (i) point (a) is replaced by the following
- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
- (ii) in point (c), point (iv) is replaced by the following:
- ‘(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the Official Journal of the European Union, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’
- (iii) in point (e), the second sentence is replaced by the following:
- ‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full;’
- (b) points 1.4.2., 1.4.3 and 1.4.4. are replaced by the following:
- ‘1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;



1.4.3 carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;;'

(c) in point 1.6, first paragraph, the second sentence is replaced by the following:

'That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.;

(d) in point 3.3., first subparagraph, the second sentence is replaced by the following:

'An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.;

(2) in Annex III, point 1.2, point (e) is replaced by the following:

'(e) the name, registered trade name or registered trade mark as well as the postal address and digital contact of the manufacturer;;'

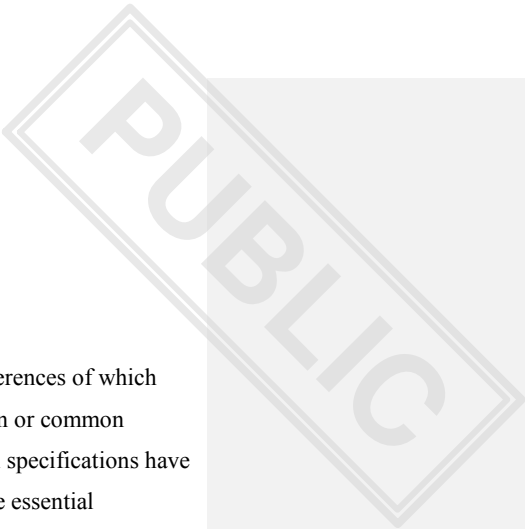
(3) Annex IV is amended as follows

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;;'

(b) point 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.;



ANNEX V

Annexes II, III and IV to Directive 2014/30/EU are amended as follows:

- (1) in Annex II, point 3, point (d) is replaced by the following:
 - ‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’
- (2) Annex III, Part A is amended as follows:
 - (a) point 3 is amended as follows:
 - (i) point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (ii) in point (c), point (iv) is replaced by the following:
 - ‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’
 - (b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential

requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.;

(3) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative.;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard or common specification, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared.’

ANNEX VI

Annexes II and IV to Directive 2014/31/EU are amended as follows:

(1) Annex II is amended as follows:

(a) point 1.3 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’

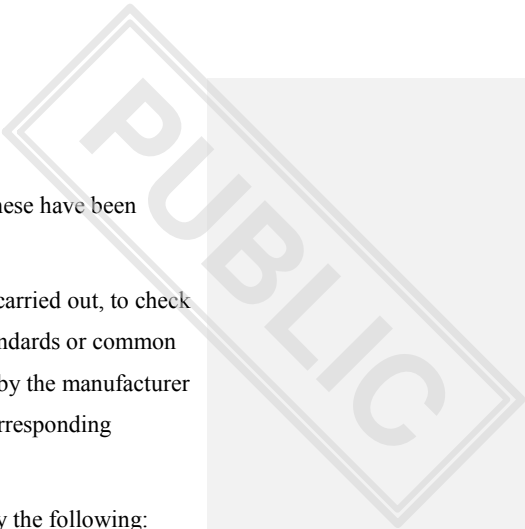
(iii) in point (e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full;’

(b) point 1.4.2, 1.4.3 and 1.4.4. are replaced by the following:

‘1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the



relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;;'

(c) in point 1.6, first subparagraph, the second sentence is replaced by the following:

'That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.;

(d) in point 2.3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;;'

(e) in point 2.3.3., the second subparagraph is replaced by the following:

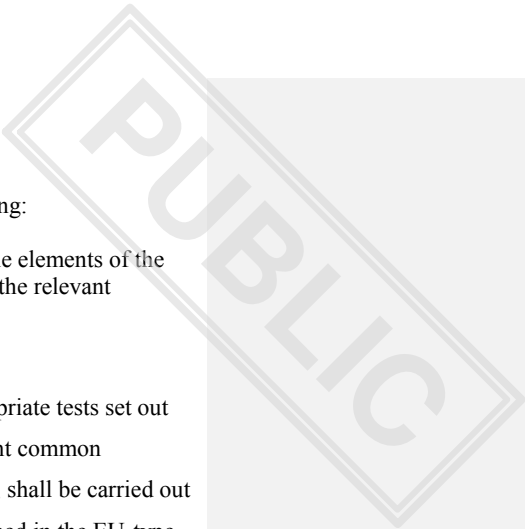
'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;

(f) in point 3.2., point (d) is replaced by the following:

'(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;;'

(g) in point 3.5.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;;'



(h) in point 3.5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;

(i) point 4.4.1. is replaced by the following:

‘4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or in the relevant common specifications and/or other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(j) in point 5.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;;’

(k) point 5.5.1. is replaced by the following:

‘5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in the relevant common specifications or other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.;

(l) in point 6.2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or

common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;;

(m) in point 6.4., the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or in the relevant common specifications and/or other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’

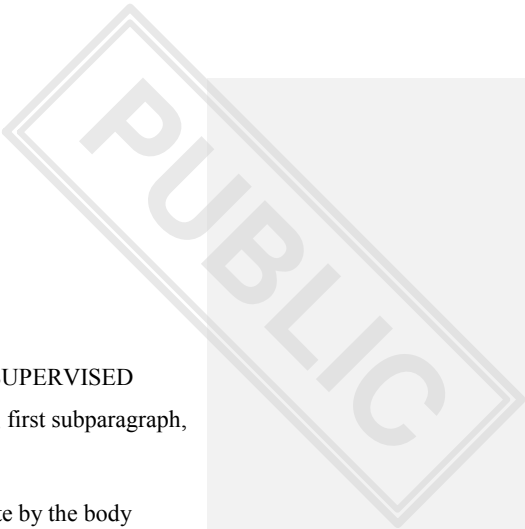
(2) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;’

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’



ANNEX VII

Annexes II and XIII to Directive 2014/32/EU are amended as follows:

(1) Annex II is amended as follows:

- (a) in Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 4, first subparagraph, the second and third sentences are replaced by the following:

‘An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard, and/or normative document, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Directive. In the absence of a relevant harmonised standard or normative document or common specification, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.’

(b) Module B: EU-TYPE EXAMINATION is amended as follows:

- (i) point 3 is amended as follows

- point (a) is replaced by the following:

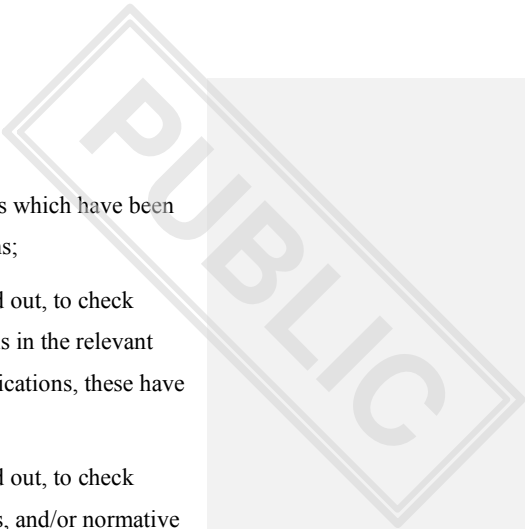
‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

- point (e) is replaced by the following

‘(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or common specifications, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.’

(ii) in point 4, points 4.2, 4.3 and 4.4 are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative



documents, and/or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, normative documents, and common specifications, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents, and/or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;;

- (iii) in point 6, first subparagraph, the second sentence is replaced by the following:

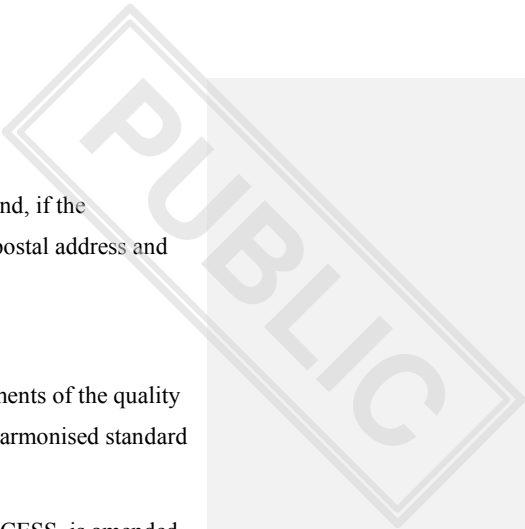
‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’

- (c) in Module C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the harmonised standards, and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instrument with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.’

- (d) Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

- (i) in point 3.1, point (a) is replaced by the following:



- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
- (ii) in point 3.3, the second subparagraph is replaced by the following:

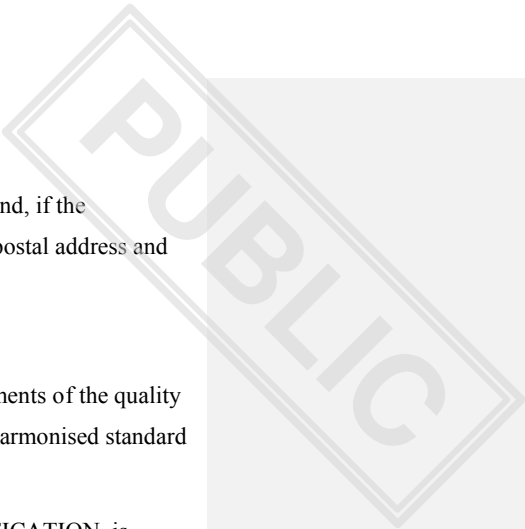
‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’
- (e) Module D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS, is amended as follows:
 - (i) in point 5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (ii) in point 5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’
- (f) Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE is amended as follows:
 - (i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (ii) in point 3.3, the second subparagraph is replaced by the following:

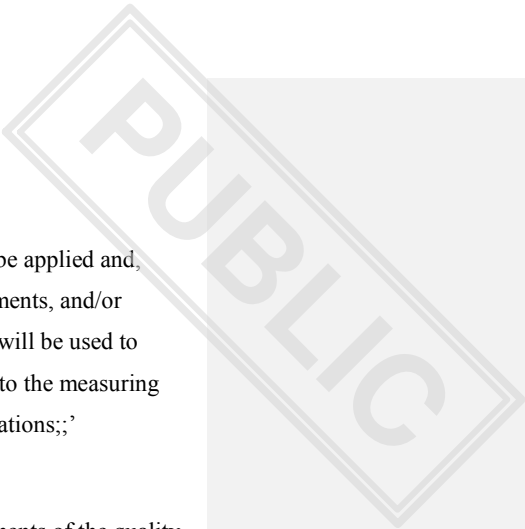
‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’
- (g) Module E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING is amended as follows:
 - (i) in point 5.1, point (a) is replaced by the following:



- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
- (ii) in point 5.3, the second subparagraph is replaced by the following:
‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’
- (h) Module F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION, is amended as follows:
- (i) in point 4, point 4.1 is replaced by the following:
‘4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’
- (ii) in point 5, point 5.2 is replaced by the following:
‘5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’
- (i) Module F1: CONFORMITY BASED ON PRODUCT VERIFICATION, is amended as follows:

- (i) In point 5, point 5.1 is replaced by the following:
- ‘5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or normative documents, and/or common specifications and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’
- (ii) in point 6, point 6.3 is replaced by the following:
- ‘6.3. All measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’
- (j) in Module G: CONFORMITY BASED ON UNIT VERIFICATION, point 4, the first subparagraph is replaced by the following:
- ‘A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or normative documents, and/or common specifications or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’
- (k) Module H: CONFORMITY BASED ON FULL QUALITY ASSURANCE, is amended as follows:
- (i) in point 3.1, point (a) is replaced by the following:
- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’



(ii) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;’

(iii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(l) Module H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(ii) in point 3.2., point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications;’

(iii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

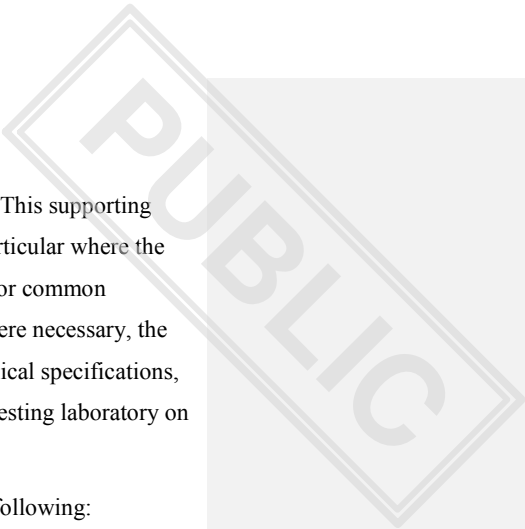
‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(iv) point 4.2 is amended as follows:

- point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’

- point (d) is replaced by the following:

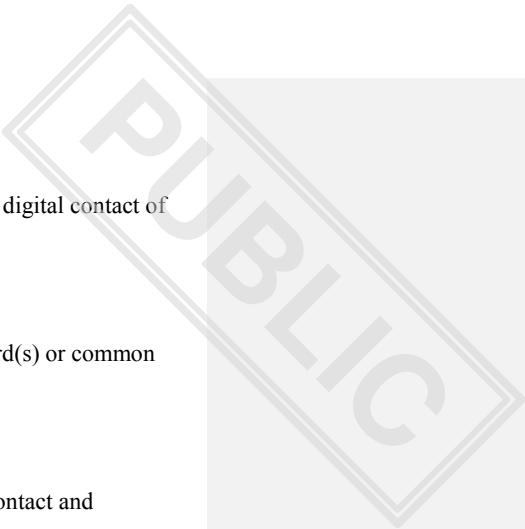


- ‘(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents, and/or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.’
- (v) in point 4.3, first subparagraph, the second sentence is replaced by the following:
‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’
- (2) Annex XIII is amended as follows:
 - (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;’
 - (b) point 6 is replaced by the following:
 - ‘6. References to the relevant harmonised standards or normative documents or common specifications used or references to the other technical specifications in relation to which conformity is declared.’

ANNEX VIII

Annexes II and VI to XII to Directive 2014/33/EU are amended as follows:

- (1) Annex II is amended as follows:
- (a) Part A is amended as follows:
- (i) points (a) and (b) are replaced by the following:
- ‘(a) business name, postal address and digital contact of the manufacturer;
- (b) where appropriate, business name, postal address and digital contact of the authorised representative;’
- (ii) point (h) are replaced by the following:
- ‘(h) where appropriate, reference(s) to harmonised standard(s) or common specification(s) used;’
- (iii) points (i) to (k) are replaced by the following:
- ‘(i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of safety components for lifts set out in Annex IV, Part A and Annex VI, and the reference of the EU-type examination certificate issued by that notified body;
- (j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the conformity to type with random checking for safety components for lifts set out in Annex IX;
- (k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality system operated by the manufacturer in accordance with the conformity assessment procedure set out in Annex VI or VII;’
- (b) Part B is amended as follows:
- (i) points (a) and (b) are replaced by the following:
- ‘(a) business name, postal address and digital contact of the installer;



- (b) where appropriate, business name, postal address and digital contact of the authorised representative;’
 - (ii) points (g) is replaced by the following:
 - ‘(g) where appropriate, reference(s) to harmonised standard(s) or common specifications used;’
 - (iii) points (h) to (k) are replaced by the following:
 - ‘(h) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of lifts set out in Annex IV, Part B and the reference of the EU-type examination certificate issued by that notified body;
 - (i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the unit verification for lifts set out in Annex VIII;
 - (j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the final inspection for lifts set out in Annex V;
 - (k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality assurance system operated by the installer in accordance with the conformity assessment procedure set out in Annex X, XI or XII;’
- (2) Annex IV is amended as follows:
- (a) Part A is amended as follows:
 - (i) in point 2, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well and the place of manufacture of the safety components for lifts;’
 - (ii) in point 2(e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents, including other relevant technical specifications, that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’

(iii) in point 3, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to enable the safety component for lifts to meet the conditions referred to in point 1, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

- ‘(c) verify that the representative specimen(s) has(have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;
- (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications enable the safety component for lifts to meet the conditions referred to in point 1.’

(v) in point 5, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’

(b) Part B is amended as follows:

(i) in point 2, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer; and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(ii) in point 2(e), the second sentence is replaced by the following:

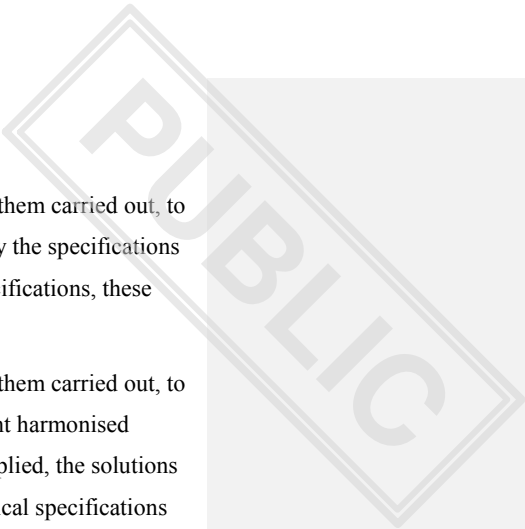
‘This supporting evidence shall mention any documents, including other relevant technical specifications that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’

(iii) in point 3, point (e) is replaced by the following:

‘(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

‘(c) examine the specimen lift to check that it has been manufactured in accordance with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;



- (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the installer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the installer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive.;

(v) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the installer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’

(3) Annex V is amended as follows:

(a) in point 2, point (b) is replaced by the following:

‘(b) a lift designed and manufactured in accordance with a quality system pursuant to Annex XI and the EU design examination certificate if the design is not wholly in accordance with the harmonised standards or common specifications.’

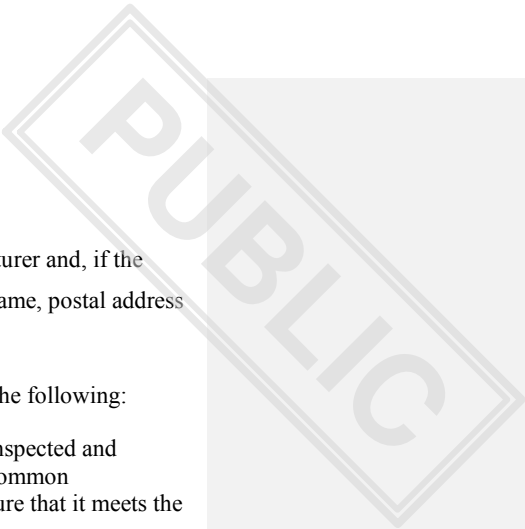
(b) in point 3.1, the third subparagraph is replaced by the following:

‘The appropriate examinations and tests set out in the relevant harmonised standard(s) or common specifications, or equivalent tests shall be carried out in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.’

(c) in point 3.2, point (b) is replaced by the following:

‘(b) examination of the documents referred to in point 3.1 to check that the lift conforms with the lift designed and manufactured in accordance with an approved quality system pursuant to Annex XI and if the design is not wholly in accordance with the harmonised standards or common specifications, with the EU design examination certificate.’

(4) Annex VI, is amended as follows:

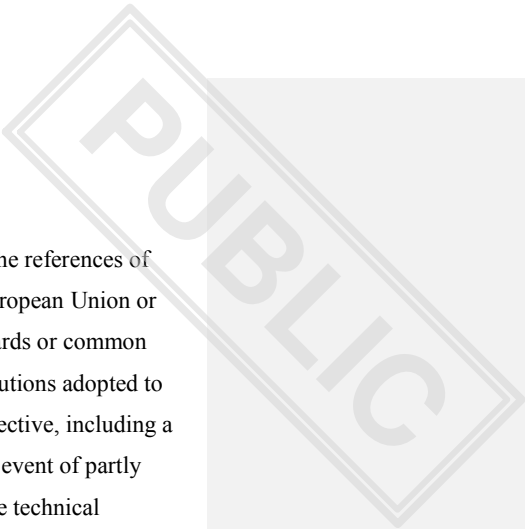


- (a) point 3.1, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (b) in point 3.2., first subparagraph, the first sentence is replaced by the following:

‘Under the quality system, each safety component for lifts shall be inspected and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be carried out in order to ensure that it meets the conditions referred to in point 1.’
 - (c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.’
- (5) Annex VII is amended as follows:
- (a) in point 3.1, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (b) in point 3.2, point (b) is replaced by the following:
 - ‘(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;’
 - (c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.’
- (6) Annex VIII is amended as follows:
- (a) in point 2.2, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’



(b) in point 3, point (e) is replaced by the following:

‘(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’

(c) in point 4, first subparagraph, the first sentence is replaced by the following:

‘The notified body chosen by the installer shall examine the technical documentation and the lift and carry out the appropriate tests as set out in the relevant harmonised standard(s) or common specification(s), or equivalent tests, to check its conformity with the applicable essential health and safety requirements set out in Annex I.’

(7) Annex IX is amended as follows:

(a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 4, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final safety components for lifts, taken on site by the notified body, shall be examined and appropriate tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check whether the safety components for lifts meets the conditions referred to in point 1.’

(8) Annex X is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.2, the first subparagraph is replaced by the following:

‘Under the quality system, each lift shall be examined and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be

carried out in order to ensure its conformity with the applicable essential health and safety requirements set out in Annex I.;

- (c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.;

- (9) Annex XI is amended as follows:

- (a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

- (b) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications that will be used to ensure that the applicable essential health and safety requirements set out in Annex I will be met;;’

- (c) in point 3.3, point 3.3.1 is replaced by the following:

‘3.3.1. When the design is not entirely in accordance with harmonised standards or common specifications, the notified body shall ascertain whether the design conforms to the essential health and safety requirements set out in Annex I and, if it does, issue an EU design examination certificate to the installer, stating the limits of the certificate’s validity and giving the details required for identification of the approved design.;

- (d) in point 3.4, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.;

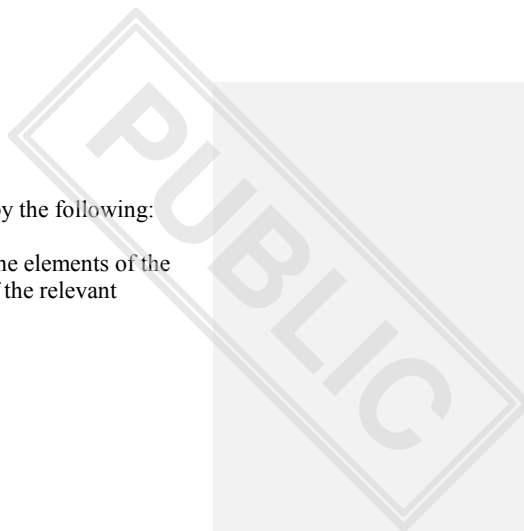
- (10) Annex XII is amended as follows:

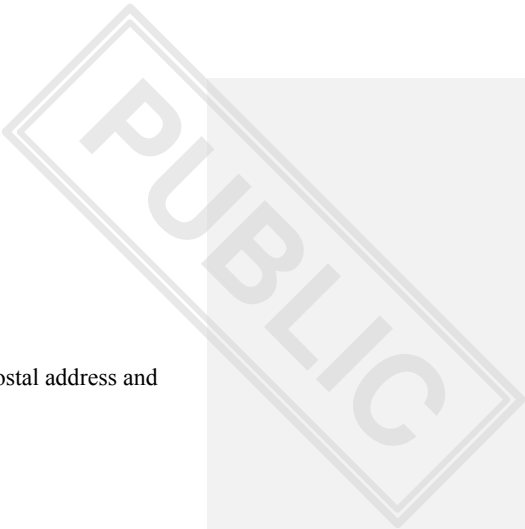
- (a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification..’





ANNEX IX

Annexes II to V and VII to X to Directive 2014/34/EU are amended as follows:

- (1) in Annex II, point 1.0.5, the first indent is replaced by the following:

‘— name, registered trade name or registered trade mark as well as postal address and digital contact of the manufacturer;’
- (2) Annex III is amended as follows:
 - (a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (b) in point 3, point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’
 - (c) in point 4, points 4.1, 4.2, and 4.3 are replaced by the following:
 - ‘4.1. examine the technical documentation, verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;
 - 4.2. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive;;

(d) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’

(3) Annex IV is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well.’

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(4) in Annex V, point 4, point 4.1 is replaced by the following:

‘4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’

(5) Annex VII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well.’

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(6) in Annex VIII, point 2, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.’

(7) Annex IX is amended as follows:

(a) in point 2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.’

(b) in point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’

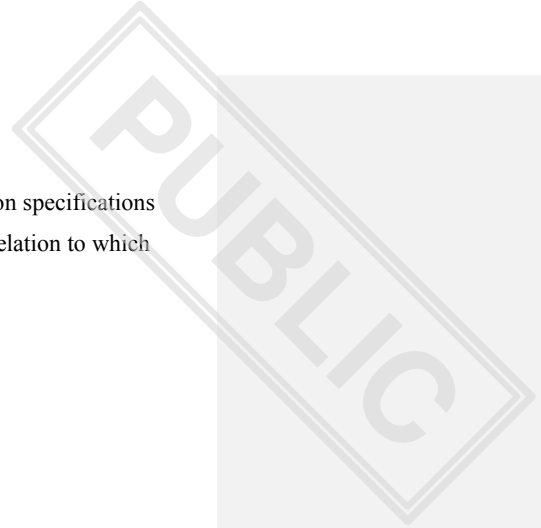
(8) Annex X is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative.’

(b) point 6 is replaced by the following:

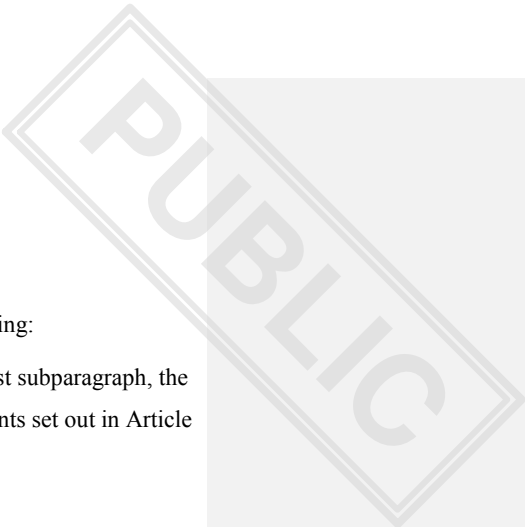
- ‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:.’



ANNEX X

Annexes III and IV to Directive 2014/35/EU are amended as follows:

- (1) in Annex III, point 2, point (d) is replaced by the following:
 - ‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or international or national standards referred to in Articles 13 and 14 or common specifications referred to in Article 12a and, where those harmonised standards or international or national standards or common specifications have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14 or common specifications, the technical documentation shall specify the parts which have been applied;’
- (2) Annex IV is amended as follows:
 - (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer or his authorised representative;’
 - (b) point 6 is replaced by the following:
 - ‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’



ANNEX XI

Annexes Ia, and III to VII to Directive 2014/53/EU are amended as follows:

- (1) in Annex Ia, Part II, the introductory sentence is replaced by the following:

‘In the case of radio equipment falling within the scope of Article 3(4), first subparagraph, the following information shall be indicated in accordance with the requirements set out in Article 10(8);:’
- (2) Annex III, Module B: EU-type examination, is amended as follows:
 - (a) point 3 is amended as follows:
 - (i) point (a) and (d) are replaced by the following:

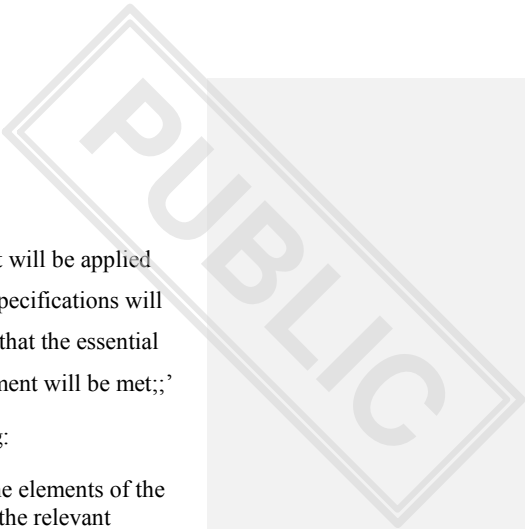
‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (ii) in point (d), the second sentence is replaced by the following:

‘That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied or have not been fully applied. ;’
 - (b) in point 6, first subparagraph, the second sentence is replaced by the following:

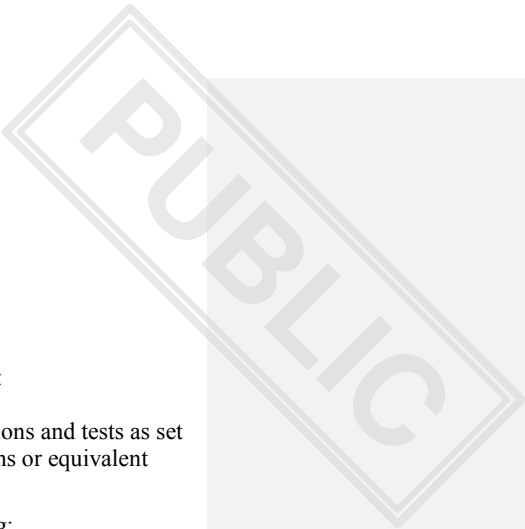
‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type.;’
 - (c) in point 8, third subparagraph, the first sentence is replaced by the following:

‘Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union or common specifications have not been applied or not been fully applied.;’
- (3) Annex IV is amended as follows:
 - (a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;.’



- (b) in point 3.2, point (b) is replaced by the following:
 - ‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;;’
- (c) in point 3.3, the second subparagraph is replaced by the following:
 - ‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;’
- (4) in Annex V, point (d) is replaced by the following:
 - ‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;;’
- (5) Annex VI is amended as follows:
 - (a) point 2 is replaced by the following:
 - ‘2. Name, postal address and digital contact of the manufacturer or his authorised representative;;’
 - (b) in point 6, the first sentence is replaced by the following:
 - ‘References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.;’
- (6) Annex VII is deleted.



ANNEX XII

Annexes I, III and IV to Directive 2014/68/EU are amended as follows:

- (1) Annex I is amended as follows:
- (a) in point 3.1.2, the fifth subparagraph is replaced by the following:

‘To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or common specifications or equivalent examinations and tests or shall have them performed.’
 - (b) in point 4.2., point (b), the first indent is replaced by the following:

‘— by using materials which comply with harmonised standards or common specifications.’
 - (c) in point 7, first subparagraph, the second sentence is replaced by the following:

‘However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards or common specifications are applied, the manufacturer shall demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.’
- (2) Annex III is amended as follows:
- (a) in Part 1: Module A: (INTERNAL PRODUCTION CONTROL), point 2, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.’
 - (b) in Part 2: Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 2, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised

standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,;

(c) Part 3: Module B: EU-TYPE EXAMINATION is amended as follows:

(i) in point 3.1 EU-Type examination – production type, point 3 is amended as follows:

- in the second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,;’

- in the second subparagraph, third indent, fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,;’

- in the fourth subparagraph, only indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.;;’

(ii) in point 4.1, second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,;’

(iii) points 4.2., 4.3. and 4.4. are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance

with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.

- 4.3. carry out appropriate examinations and necessary tests to check whether when the manufacturer has chosen to apply the solutions the relevant harmonised standards or common specifications, these have been applied correctly.
- 4.4. carry out appropriate examinations and necessary tests to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.;

(iv) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.;

(v) in point 3.2. EU-Type examination – design type, point 3 is amended as follows:

- in the second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well.;

- in the second subparagraph, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.;

- in the second subparagraph, fourth indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.;

(vi) in point 4.1., second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials.;

(vii) points 4.2. and 4.3. are replaced by the following:

‘4.2. carry out appropriate examinations to check whether where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications these have been applied correctly.

4.3. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive.;

(viii) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.;

(d) in Part 4: MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 3, the third subparagraph is replaced by the following:

‘An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.;

(e) Part 5: MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

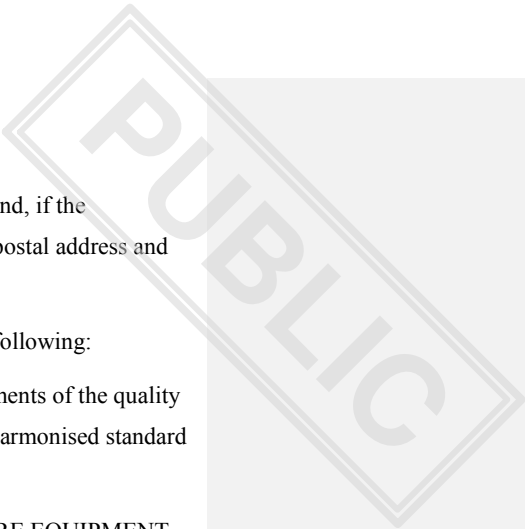
- ‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,;’
- (ii) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;;’
- (f) Part 6: MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:
 - (i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.;;’
 - (ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,;’
 - (iii) in point 5.3, first subparagraph, the second sentence is replaced by the following:

‘The elements of the quality system which conform to the relevant harmonised standard or common specification are presumed to comply with the corresponding requirements referred to in point 5.2.;;’
- (g) Part 7: MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE is amended as follows:
 - (i) in point 3.1, second subparagraph, the first indent is replaced by the following:



‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,;’

(ii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;;’

(h) Part 8: MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING is amended as follows:

(i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards, the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,;’

(ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,;’

(iii) in point 5.3, the second subparagraph is replaced by the following:

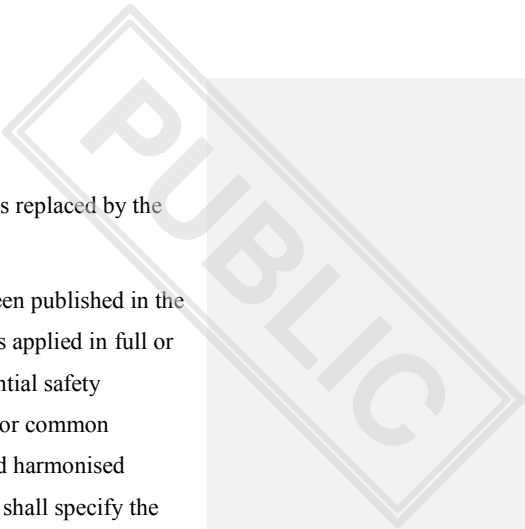
‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;;’

(i) in Part 9: MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION, point 4.1., the first subparagraph is replaced by the following:

‘All pressure equipment shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) or common specifications or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the EU-type

examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

- (j) Part 10: MODULE G: CONFORMITY BASED ON UNIT VERIFICATION is amended as follows:
- (i) in point 2, third subparagraph, the fourth indent is replaced by the following:
- ‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications, have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.;
- (ii) in point 4, the first subparagraph is replaced by the following:
- ‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests, to check the conformity of the pressure equipment with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.;
- (iii) in point 4, second subparagraph, the second indent is replaced by the following:
- ‘— assess the materials used where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I.;
- (k) Part 11: MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE is amended as follows:
- (i) point 3.1, second subparagraph, the first indent is replaced by the following:
- ‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well.;



- (ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:
- ‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’
- (iii) in point 3.2, third subparagraph, the second indent is replaced by the following:
- ‘— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the pressure equipment will be met;’
- (iv) in point 3.3, first subparagraph, the second sentence is replaced by the following:
- ‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification;’
- (l) Part 12: MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:
- (i) in point 3.1, second subparagraph, the first indent is replaced by the following:
- ‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
- (ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:
- ‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised

standards or common specifications, the technical documentation shall specify the parts which have been applied,;

(iii) in point 3.2, third subparagraph, the second indent is replaced by the following:

‘— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,;’

(iv) in point 3.3, second subparagraph, the first sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.;;’

(v) in point 4.2, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer,;’

(vi) in point 4.2, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the Official Journal of the European Union, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,;’

(vii) in point 4.2, the fourth indent is replaced by the following:

‘— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.;;’

(viii) in point 4.3, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’

(3) Annex IV is amended as follows:

(a) point 1 is replaced by the following:

‘1. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative.’

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’

(c) point 7 is replaced by the following:

‘7. Where appropriate, the name, postal address, digital contact and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, EU design examination certificate or certificate of conformity.’

ANNEX XIII

Annex II to Directive 2014/90/EU is amended as follows:

- (1) Part I: Module B: EC-TYPE EXAMINATION is amended as follows:
- (a) in point 3, second subparagraph, the first indent is replaced by the following:
- ‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well;’
- (b) in point 6, first subparagraph, the second sentence is replaced by the following:
- ‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’
- (2) in Part II: Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS, point 3.1, second subparagraph, the first indent is replaced by the following:
- ‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well;’
- (3) in Part III: Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE, point 3.1, second subparagraph, the first indent is replaced by the following:
- ‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well.’

Brussels, 27 August 2025
(OR. en)

12227/25

Interinstitutional File:
2025/0134 (COD)

LIMITE

SIMPL 90	TELECOM 266
ANTICI 100	POLCOM 192
EF 268	COMPET 817
ECOFIN 1107	ENV 771
MI 597	CLIMA 310
ECO 23	TRANS 338
ENT 143	ENER 407
IA 106	CODEC 1157
IND 313	

NOTE

From: General Secretariat of the Council

To: Delegations

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 76512008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 202311542 and (EU) 2024/1781 as regards digitalisation and common specifications
- Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal, for examination at the meeting of the Antici Group (Simplification) on 1 September 2025.

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~.

ANNEX

2025/0134 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil their intended purpose and to limit the administrative burden, it is important to streamline those requirements.
- (2) In its Communication on ‘Long-term competitiveness of the EU: looking beyond 2030’⁶, the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.
- (3) In its Better regulation Guidelines ², the Commission promotes the ‘digital by default’ principle to support digital transformations, by facilitating digital-ready policies which consider the fast-evolving world of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.

¹ OJ C , , p .

² https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en.

- (4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators' obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators' obligations when they do not affect protection and safety of consumers **or require an excessive burden for the economic operators**. Embracing digitalisation will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike. **A smooth transition should be pursued.**
- (5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it into service. Such legal acts include Regulations (EU) 2016/424³, (EU) 2016/425⁴, (EU) 2016/426⁵, (EU) 2023/1230⁶, (EU) 2023/1542⁷ and (EU) 2024/1781⁸ of the European Parliament and of the Council (the 'Regulations concerned'). The Regulations concerned are based on the principles of the 'new approach' to technical harmonisation and are aligned with the reference provisions laid down in Decision No 768/2008/EC of the European Parliament and of the Council⁹.
- (6) In accordance with the Regulations concerned, manufacturers are to draw up an EU declaration of conformity stating that the fulfilment of essential requirements set out in the applicable Regulations has been demonstrated. In order to enable seamless electronic processes, the EU declaration of conformity should be drawn up only in electronic form.

³ Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/424/oj>).

⁴ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51, ELI: <http://data.europa.eu/eli/reg/2016/425/oj>).

⁵ Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99, ELI: <http://data.europa.eu/eli/reg/2016/426/oj>).

⁶ Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and amending Directive (EU) 2021/647 (OJ L 165, 29.6.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1230/oj>).

⁷ Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).

⁸ Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L 281, 28.6.2024, p. 1, ELI: <http://data.europa.eu/eli/reg/2024/1781/oj>).

⁹ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82, ELI: [http://data.europa.eu/eli/dec/2008/768\(1\)/oj](http://data.europa.eu/eli/dec/2008/768(1)/oj)).

- (7) Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, and (EU) 2023/1230 require that a copy of the EU declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity electronically accompany the product. The manufacturer will ~~make sure~~ ensure that the EU declaration of conformity is **directly** accessible through an internet address or a machine-readable code, **free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the EU declaration of conformity.**
- (8) Taking into account that in 2024 no less than 94% of EU households had access to internet¹⁰, the paper format of the instructions accompanying the products under the scope of the Regulations concerned is ~~outdated~~ **becoming less important** and not aligned with ~~the~~ current technologies, the ~~practice~~ **practices** of consumers ~~not with~~ the green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Regulations concerned. This will allow manufacturers to provide instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to ~~still~~ protect the safety of consumers, the safety information, including instructions having **an** impact on product safety, should be provided in paper format or marked on the product. **Instructions and safety information provided in digital format should be directly accessible through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading an application, or the obligation to register solely to access the instructions and safety information.** Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of ~~the~~ purchase and for a certain period of time after their purchase.
- (-9) **Regulation (EU) 2016/425 contains certain sectoral specificities, including the fact that the entirety of the instructions and information set out in point 1.4 of Annex II are related to the safe use of the product. Thus, in order to protect the safety of consumers, where the product is intended for, or can be reasonably foreseen to be used by, consumers, all the instructions and information set out in point 1.4 of Annex II should be provided in a paper format or made visible on the packaging**

¹⁰ [1] Source: Digital economy and society statistics - households and individuals - Statistics Explained.

- (9) In order to facilitate communication between economic operators and national competent authorities and end-users, the indication of a digital contact of the manufacturer on the product and in the EU declaration of conformity is necessary to enhance the effectiveness of market surveillance and to expedite the process of tracing non-compliant products. Currently, economic operators are required to indicate their postal address on the product, but this is not always sufficient to ensure that competent authorities can establish rapid contact. It is therefore necessary to require economic operators to provide both a postal address and a digital contact on the product and in the EU declaration of conformity. Such a digital contact should be defined in the Regulations concerned. **The digital contact should allow consumers and competent authorities to communicate with economic operators directly, and should be accessible free of charge, without the obligation to provide personal data, download additional specific applications or the obligation to register solely to contact the economic operator. Such digital contact may include, for example, an email address or a contact form on a website. However, it should not be understood as encompassing automatic replies to queries, chatbots, fax numbers, or telephone lines. The term ‘digital contact’, similarly to the term ‘electronic address’ in Regulation (EU) 2023/988 on general product safety, should be interpreted in a technologically neutral manner, capable of evolving with future technological developments, and should cover all forms of direct digital communication.**
- (10) The Regulations concerned require that economic operators provide, ~~on~~**upon** a reasoned request from a competent national authority, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Regulations, in paper or electronic form. The paper-based form is ~~an outdated requirement~~**becoming less important**, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the necessary information and documentation in electronic form only. Documentation provided in electronic form could be made available, for example, in a digital printable format, which allows the possibility to print, download and save the documentation on an electronic device.

- (11) The current Union standardisation framework, which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹¹, represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation**. However, ~~where no~~ **in the absence of relevant references to harmonised standards exist or where they are insufficient**, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation, provided that in doing so it duly respects the role and functions of the European standardisation organisations**, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety ~~or other requirements~~ **of the Regulations amended by this Regulation**.
- (12) As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542¹², it is essential to require economic operators to store the information contained in the EU declaration of conformity and instructions in the digital product passport where a product is covered by multiple pieces of legislation. This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents - **such as declarations of conformity - required under the various pieces of product legislation that may apply to the same product, thereby upholding the principle of a single declaration of conformity. In addition, instructions provided in electronic form would be stored together with the declaration of conformity**. By storing the documentation in one place, all necessary documents demonstrating product compliance would be easily accessible, ensuring transparency and facilitating compliance. This streamlined approach would enhance the overall efficiency of the regulatory framework, and it aligns with the principle that where several pieces of Union harmonisation legislation apply to a product, the manufacturer or other economic operator, where appropriate, should provide a single EU declaration of conformity.

¹¹ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12, ELI: <http://data.europa.eu/eli/reg/2012/1025/oj>).

¹² **Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/1542/oj>).**

- (13) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States as this Regulation amends Regulations which are harmonising products legislations but can rather by reason of better harmonisation of EU applicable rules to products, be achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (14) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to adjust to the new requirements amendments to Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.
- (15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations (EU) ~~765/2008~~, ~~(EU) 2016/424~~, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with those Regulations in their version applicable before that date.
- (16) Regulations ~~(EU) 765/2008~~, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009~~, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 765/2008

~~Regulation (EU) 765/2008 is amended as follows:~~

- (1) ~~Article 2 is amended as follows:~~
- (a) ~~the following point (9a) is inserted:~~

~~‘(9a) ‘a common specification’ means a set of technical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a product, device, service, process or system;’~~

(b) paragraph 10 is replaced by the following:

~~‘10. ‘accreditation’ shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards or common specifications and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;’~~

(2) in Article 10, paragraph 5 is replaced by the following:

~~‘5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account the relevant harmonised standards or common specifications referred to in Article 11.’~~

(3) in Article 11, paragraph 1 is replaced by the following:

~~‘1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, or with the criteria laid down in common specifications, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.’~~

Article 2

Amendments to Regulation (EU) 2016/424

Regulation (EU) 2016/424 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (17a) is inserted:

~~‘(17a) ‘digital contact’ means any up-to-date and freely accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted** or engaged without the need to register or to ~~download~~**use** an application;’~~

(b) the following point (19a) is inserted:

(19a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provide means of complying with the essential requirements **set out in Annex II of this Regulation** applicable to a ~~product, device, service, process or system;~~ **subsystem or safety component;**’

(2) Article 11 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity **referred to in Article 19**, in electronic form, and affix the CE marking- **referred to in Article 20;**’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the subsystem or safety component. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~ **contacted or engaged.**’

(d) paragraph 7 is replaced by the following:

‘7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information, in a language which can be easily understood by ~~end-users~~ **users**, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible.

The manufacturer shall take into account the intended use and the foreseeable ~~end-user~~ **user** of the product when deciding the specific format for the instructions and safety information. When drafting **instructions and** the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the ~~end-user~~ **user**, as well as the role which the instructions play for ensuring safety.

However, where a large number of subsystems or safety components are delivered to a single economic operator or ~~end-user~~, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be accessed.

When the instructions **and safety information**, referred to in the first subparagraph, are provided in electronic form the manufacturer shall:

- (a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to access them **directly** and how to request them in paper format;
- (b) present them in a format that makes it possible for the ~~end-user~~ to print and download the instructions **and safety information** and save them on an electronic device so that the ~~end-user~~ can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions **and safety information** are embedded in the software of the subsystem or the safety component;
- (c) make them accessible online during the expected lifetime of the subsystem or the safety component and for at least 30 years after the placing on the market of the subsystem or the safety component.

However, the ~~end-user~~ may, at time of the purchase of the ~~product~~**subsystem or the safety component**, or up to six months after that purchase, request the instructions or safety information in paper format. Where the ~~end-user~~ requests those instructions or safety information, the manufacturer shall provide them to the ~~end-user~~, free of charge, within one month of receiving the request.;

- (e) paragraph 9 is replaced by the following:

‘9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its

request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.;

(3) in Article 12(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component.;

(4) Article 13 is amended as follows:

(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).;

(b) in paragraph 3, first subparagraph, the first sentence is replaced by the following:

‘Importers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the subsystem or safety component.;

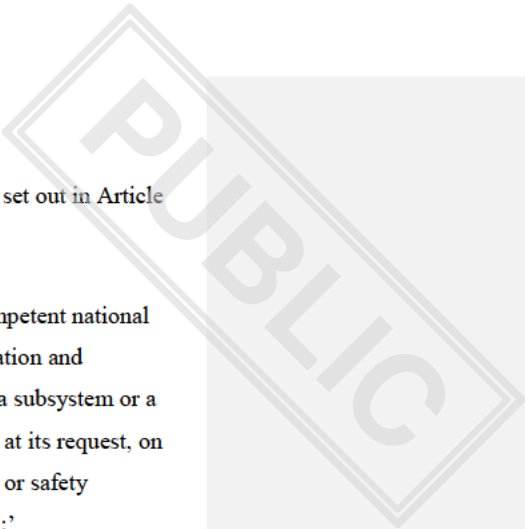
(c) paragraph 9 is replaced by the following:

‘9. Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.;

(5) Article 14 is amended as follows:

(a) in paragraph 2, the first subparagraph is replaced by the following:

‘Before making a subsystem or a safety component available on the market, distributors shall verify that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information and, where appropriate, by other required documents, in a language which can be easily understood by end-users as determined by the Member State concerned, and that the



manufacturer and the importer have complied with the requirements set out in Article 11(5) and (6) and Article 13(3) respectively.;

(b) paragraph 5 is replaced by the following:

‘5. Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have made available on the market.;

(6) the following Article 17a is inserted:

‘Article 17a

Common Specifications

1. **In exceptional cases, the Commission may ~~by means of adopt~~ implementing acts ~~adopt~~ establishing common specifications ~~that enable compliance with the essential~~ covering requirements ~~set out in Annex II in any of~~ that provide a means to comply with the applicable essential **safety requirements. Those implementing acts shall only be adopted where** the following ~~cases~~ conditions are fulfilled:**

(a) **there is no harmonised standard covering those requirements ~~set out in Annex II are not covered by harmonised standards, or parts thereof, the reference~~ the reference of which ~~have been~~ is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**

(b) **~~requirements set out in Annex II are covered by harmonised standards~~ the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more ~~or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of a product with the essential~~ for those requirements set out in Annex II; **or and:****

(1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

Commented [A9]: It should be ensured that the terms “health and/or safety” are only inserted where this restriction is necessary. If not, we prefer the use of the generic term “essential requirements”.

- (2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:
- (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Commented [A10]: Germany deems these two conditions to be redundant. We favour the deletion of lit. c if it can't be demonstrated that there is an additional scope compared to lit. b.

Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure referred to in Article 44(2)44(3).

2. Subsystems and safety components that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with essential requirements covered by those specifications or parts thereof, set out in Annex II.;
3. Before preparing the draft of the implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.
4. When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.
5. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.
6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed

Commented [A11]: Unclear what this restriction exactly means. Does the pronoun "it" refer to essential requirements or to the Annex II? What is the ratio of this restriction?

explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend or withdraw the implementing act establishing the common specification in question.’;

Commented [A12]: The option to withdraw the implementing act establishing the common specification should be inserted, if the essential requirements are not (entirely) met.

(7) in Article 18, paragraph 3 is replaced by the following:

‘3. Records and correspondence relating to the conformity assessment procedures shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’

(8) in Article 19, the following paragraph 5 is added:

‘5. Where other Union legislation applicable to ~~the~~ subsystem or ~~a~~ safety ~~component~~**components** 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 ~~in~~ Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 19, and the instructions and safety information** ~~and~~ referred to in Article 11(7) shall be provided only in that digital product passport.’

(9) in Article 26, paragraph 7, point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards ~~or~~ **and** common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation.’

(10) in Article 34, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(11) in Article 43(1), point (d) is replaced by the following:

‘(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’

(12) Annexes III to IX are amended in accordance with Annex I to this Regulation.

Article 3

Amendments to Regulation (EU) 2016/425

Regulation (EU) No 2016/425 is amended as follows:

(1) Article 3 is amended as follows:

(a) the following point (8a) is inserted:

‘(8a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted** or engaged without the need to register or to download an application;’

(b) the following point (10a) is inserted:

‘(10a) ‘common specifications’ means a set of technical ~~requirements~~**specifications**, other than a standard, that provides a means of complying with the essential requirements **set out in Annex II of this Regulation** applicable to ~~a product, device, service, process or system~~**PPE**;’

(2) Article 8 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15, in electronic form, and affix the CE marking referred to in Article 16.’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in the design or characteristics of the PPE and changes in the harmonised standards, or in the common specifications, or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.’

(c) in paragraph 6, the first and second sentences are replaced by the following:

‘Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the PPE. The postal

address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~**contacted or engaged**;

(d) paragraphs 7 and 8 are replaced by the following:

‘7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

The manufacturer shall take into account the intended use and the foreseeable end-user of the PPE when deciding the specific format for the instructions and information set out in point 1.4 of Annex II.

In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make ~~them~~ visible on the packaging, the instructions and information set out in point 1.4 of Annex II-, **which are related to the safe use of the PPE**. Such information shall be easily visible and legible for consumers.

When drafting the instructions and information set out in point 1.4 of Annex II, **which are related to the safe use of the PPE**, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.

When the instructions **and information**, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the PPE, or, where that is not possible, on its packaging or in an accompanying document, how to access them **directly** and how to request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions **and information** and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the PPE; this requirement also applies where the instructions **and information** are embedded in the software of the PPE;

- (c) make them accessible online during the expected lifetime of the PPE and for at least 10 years after the placing on the market of the PPE.

However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.

8. The manufacturer shall provide the internet address or machine-readable code through which the EU declaration of conformity can be accessed with the PPE.;

- (e) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority.;

- (3) in Article 9(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE;;’

- (4) Article 10 is amended as follows:

- (a) in paragraph 3, the first sentence is replaced by the following:

‘Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be ~~reached~~ **contacted or engaged** or, where that is not possible, on its packaging or in a document accompanying the PPE.;

- (b) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of PPE **with this Regulation** in a language which can be easily understood by that authority.;

- (5) in Article 11(5) the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the PPE.’

(6) the following Article 14a is inserted:

‘Article 14a

Common Specifications

1. **In exceptional cases**, the Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications ~~that enable compliance with essential~~ **covering** requirements ~~set out in Annex II in any of~~ **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled**:
 - (a) **there is no harmonised standard covering those** requirements ~~set out in Annex II~~ **are not covered by harmonised standards, or parts thereof, the reference of which have been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;**
 - (b) ~~requirements set out in Annex II are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of PPE with the for those requirements set out in Annex II, or and**:
 - (1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**
 - (2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested**:
 - (a) **are not delivered within the deadline set in the request;**
 - (b) **do not comply with the request; or**
 - (c) **do not satisfy the requirements they aim to cover.**

- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant PPE.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure referred to in Article 44(2)~~(4)~~(3).

2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.”**

(7) in Article 15, the following paragraph 5 is added:

- ‘5. Where other Union legislation applicable to the PPE 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 Annex IX to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity required in Article 15**, and the instructions referred to in Article 8(7) shall be provided only in that digital product passport.;

(8) in Article 19, the following paragraph is added:

‘Where applicable, the manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and documentation relating to conformity assessment procedures in electronic form.;

(9) in Article 24(7), point (c) is replaced by the following:

‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards or common specifications, and of the relevant provisions of Union harmonisation legislation and of national legislation.;

(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~~ *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.;

(11) In Article 32, paragraph 3 is replaced by the following:

‘3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’

(12) Annexes II, III, V, VII, VIII, and IX are amended in accordance with Annex II to this Regulation.

Commented [A13]: To ensure the safety of consumers: the information set out in point 1.4 of Annex II, which are related to the safe use of the PPE, in paper format must not be replaced by the digital product passport.

We suggest to add:

“This does not affect the obligation to provide the information set out in point 1.4 of Annex II, which are related to the safe use of the PPE, in paper format according to Article 8 (7).”



Article 4

Amendments to Regulation (EU) 2016/426

Regulation (EU) No 2016/426 is amended as follows:

(1) Article 2 is amended as follows:

(a) the following point (21a) is inserted:

‘(21a) digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be **reached** or engaged without the need to register or to ~~download~~ use an application;’

(b) the following point (23a) is inserted:

‘(23a) ‘common specifications’ means a set of technical ~~requirements~~ **specifications**, other than a standard, that provides a means of complying with the essential requirements **set out in Annex I of this Regulation** applicable to a ~~product, device, service, process or system~~; **an appliance or a fitting**;’

(2) Article 7 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of an appliance or a fitting with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking;’

(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:

‘Changes in appliance or fitting design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account;’

(c) paragraphs 6 and 7 are replaced by the following:

‘6. Manufacturers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be **reached** or engaged. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Manufacturers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~ **contacted or engaged**. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.

7. Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and safety information may be provided in an electronic form. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

Manufacturers shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.

In the case of appliance or fitting intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the equipment, the safety information. Such safety information shall be easily visible and legible for consumers.

When drafting the safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.

Manufacturers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly** and the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned. The instructions may be provided in electronic form.

However, where a large number of fittings are delivered to a single end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be **directly** accessed.

When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:

- (a) mark on the appliance or fitting, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to **directly** request them in paper format;
- (b) present them in a format that makes it possible for the end-user to print and download the instructions **and safety information** and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the appliance or fitting;
- (c) make them accessible online during the expected lifetime of the appliance or fitting and for at least 10 years after the placing on the market of the appliance or fitting.

However, the end-user may, at time of the purchase of the appliance or fitting, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;’

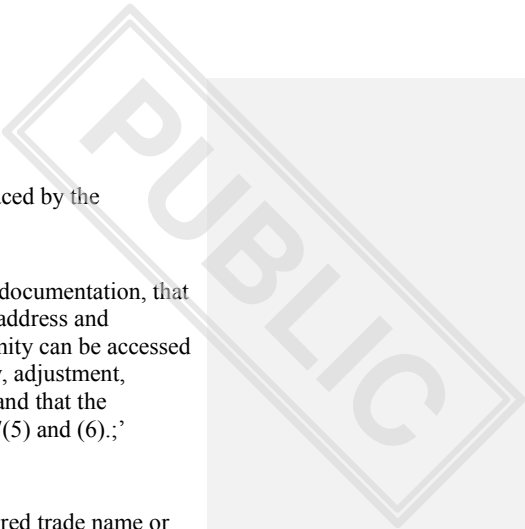
- (d) in paragraph 9, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting with this Regulation, in a language which can be easily understood by that authority.’;

- (3) in Article 8(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the appliance or the fitting;’;

- (4) Article 9 is amended as follows:



- (a) in paragraph 2, second subparagraph, the second sentence is replaced by the following:

‘They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking and is accompanied by the internet address and machine-readable code through which the EU declaration of conformity can be accessed **directly** and by, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).;’

- (b) paragraph 3 is replaced by the following:

‘3. Importers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the appliance. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Importers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the fitting. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.;’

- (c) in paragraph 4, the second subparagraph is replaced by the following:

‘Importers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly** and by, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.;’

- (d) in paragraph 9, the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting in a language which can be easily understood by that authority.;’

- (5) Article 10 is amended as follows:

- (a) in paragraph 2, the second subparagraph is replaced by the following:

‘Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly**, and by, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which

can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.;

(6) in paragraph 5, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of an appliance or a fitting.;

(7) the following Article 13a is inserted:

‘Article 13a

Common Specifications

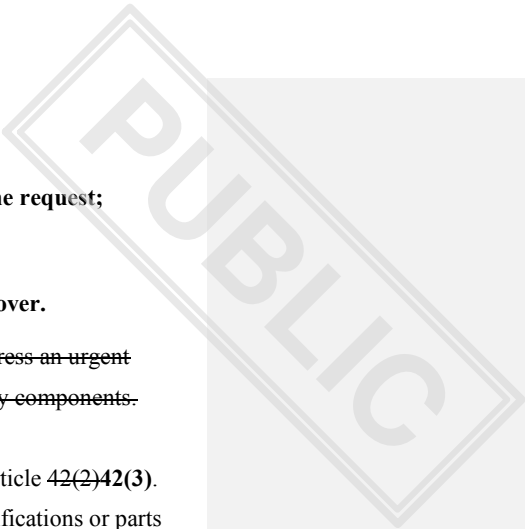
1. **In exceptional cases**, the Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications ~~that enable compliance with essential~~ **covering** requirements set out in Annex I in any of ~~that~~ **that provide a means to comply with the applicable essential safety requirements. Those implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

(a) **there is no harmonised standard covering those** requirements set out in Annex I ~~are not covered by harmonised standards, or parts thereof, the reference~~ **the reference** of which ~~have been~~ **is** published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

(b) ~~requirements set out in Annex I are covered by harmonised standards~~ **the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standardisation organisations to draft or to revise European standards or parts thereof result in non-compliance of appliances and fittings with the for those requirements set out in Annex I, or** **and:**

(1) **the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or**

(2) **the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:**

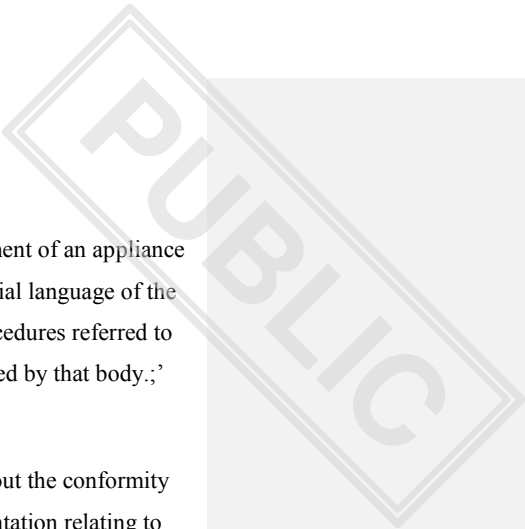


- (a) are not delivered within the deadline set in the request;
 - (b) do not comply with the request; or
 - (c) do not satisfy the requirements they aim to cover.
- (e) ~~where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~

Those implementing acts shall be adopted in accordance with the ~~advisory examination~~ procedure as ~~provided for~~ referred to in Article ~~42(2)~~42(3).

2. Appliances and fittings that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those **common** specifications or parts thereof, set out in Annex I.;
3. **Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.**
4. **When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.**
5. **Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1, or parts thereof which cover the same requirements as those covered by that harmonised standard.**
6. **When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.’;**

(8) Article 14 is amended as follows:



- (a) paragraph 4 is replaced by the following:
- ‘4. Records and correspondence relating to conformity assessment of an appliance or a fitting shall be drawn up, in electronic form, in an official language of the Member State where the notified body carrying out the procedures referred to in paragraphs 2 and 3 is established or in a language accepted by that body.’
- (b) the following paragraph 5 is added:
- ‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.’
- (9) Article 15 is amended as follows:
- (a) paragraph 6 is replaced by the following:
- ‘6. The fitting shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed **directly**.’
- (b) the following paragraph 7 is added:
- ‘7. Where other Union legislation applicable to an appliance or a fitting 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 Annex HV to be included in the EU declaration of conformity, **or as appropriate, the EU declaration of conformity required in Article 15, and the instructions and safety information** referred to in Article 7(7) shall be provided only in that digital product passport. **This does not affect the obligation to provide the safety information in paper format according to Article 7(7)**.’
- (10) in Article 23(7), point (c) is replaced by the following:
- ‘(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards ~~or~~ **and** common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;’
- (11) in Article 31, paragraph 3 is replaced by the following:

- ‘3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.’
- (12) in Article 40(1), point (f) is replaced by the following:
- ‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’
- (13) Annexes III and V are amended in accordance with Annex III to this Regulation.

Article 5

Amendments to Regulation (EU) 2023/1230

Regulation (EU) 2023/1230 is amended as follows:

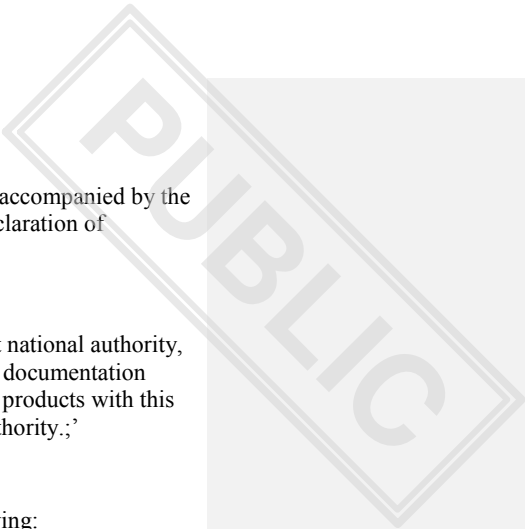
- (1) in Article 3, the following point (22a) is inserted:
- ‘(22a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be **reached** contacted or engaged without the need to register or to ~~download~~ use an application.’
- (2) Article 10 is amended as follows:
- (a) in paragraph 2, the second subparagraph is replaced by the following:
- ‘Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.’

(b) paragraph 6, the first sentence is replaced by the following:

Manufacturers shall indicate their name, registered trade name or registered trade mark, and the postal address and website, e-mail address or other digital contact at which they can be contacted, on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product.

- (b) in paragraph 8, the first subparagraph is replaced by the following:

Commented [A14]: To ensure coherence with other legislation only the “digital contact” should be mentioned. Thus the “website, e-mail address” should be deleted.



‘Manufacturers shall ensure that the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity set out in Part A of Annex V can be accessed **directly**.;’

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority.’

(3) Article 11 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

‘Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Part B, of Annex IV, manufacturers shall draw up the EU declaration of incorporation, in digital format, in accordance with Article 22.’

(b) in paragraph 8, the first subparagraph is replaced by the following:

‘Manufacturers shall ensure that the partly completed machinery is accompanied by the internet address or machine-readable code through which the EU declaration of incorporation set out in Part B of Annex V can be accessed **directly**.;’

(c) in paragraph 10, the first sentence is replaced by the following:

‘Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority.’

(4) in Article 12(2), point (b) is replaced by the following:

‘(b) further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation;;’

(5) in Article 13(9), the first sentence is replaced by the following:

‘9. Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority.’

(6) in Article 14(8), the first sentence is replaced by the following:

‘Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to



demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority.;

(7) Article 15 is amended as follows:

(a) in paragraph 2, point (b) is replaced by the following:

‘(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be accessed;’

(b) in paragraph 6, the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority.;

(8) in Article 16(6), the first sentence is replaced by the following:

‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation.;

(9) in Article 21, the following paragraph 5 is added:

‘5. 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 or, as appropriate, the EU declaration of conformity required in Article 21, and the instructions ~~and safety information?~~ referred to in Article 10(7) shall be provided only in that digital product passport. **This does not affect the obligation to provide the safety information in paper format according to Article 10(7);**’

Commented [A15]: For Machinery the safety information must not be mentioned there, because they must only be provided by the manufacturer, if the machinery can be used by consumers. If the Machinery is a B2B product, then safety information must not be provided but only instructions.

(10) in Article 22, the following paragraph 5 is added:

‘5. 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 incorporation or instructions in a digital product passport, the

Thus, we suggest to delete this part to ensure that the safety information are provided for consumers in paper format. This point represents a red line.

information required in Parts B of Annex V to be included in the EU declaration of incorporation **or, as appropriate, the EU declaration of incorporation required in Article 22**, and the instructions referred to in Article 11(7) shall be provided only in that digital product passport.;

- (11) in Article 25, the following paragraph 6 is added:
- ‘6. Where applicable, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in digital format.;
- (12) Annexes III, V, VII, IX, and X are amended in accordance with Annex IV to this Regulation.

Article 6

Amendments to Regulation (EU) 2023/1542

Regulation (EU) 2023/1542 is amended as follows:

- (1) in Article 3 the following point (23a) is inserted:
- ‘(23a) ‘digital contact’ means any up-to-date and **such as email addresses** accessible online communication channel **such as email addresses** through which economic operators can be ~~reached~~**contacted** or engaged without the need to register or to ~~download~~**use** an application.;
- (2) Article 17 is amended as follows:
- (a) paragraph 4 is replaced by the following:
- ‘4. Records and correspondence relating to the conformity assessment procedures of batteries shall be drawn up, in electronic form, in the official language or languages of the Member State where the notified body carrying out the conformity assessment procedures is established, or in one or more languages accepted by that body.;
- (b) the following paragraph 5 is added:
- ‘5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.;
- (3) in Article 18(2), the third sentence is replaced by the following:

‘It shall be drawn up in electronic form.;

(4) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. When placing a battery on the market or putting it into service, including for the manufacturers’ own purposes, manufacturers shall ensure that the battery:

(a) has been designed and manufactured in accordance with Articles 6 to 10 and Articles 12 and 14, and is, for stationary battery energy storage systems, accompanied by clear, understandable and readable instructions and safety information in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be placed on the market or put into service; and

(b) is marked and labelled in accordance with Article 13.

The instructions and safety information for stationary battery energy storage systems may be provided in electronic form. In the case of stationary battery energy storage systems intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information.

When the instructions are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

The end-user may, at time of the purchase of the stationary battery energy storage systems, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.;

(b) in paragraph 7, the first sentence is replaced by the following:

‘Manufacturers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.;

(c) in paragraph 10, the second sentence is replaced by the following:

‘That information and documentation shall be provided in electronic form.;

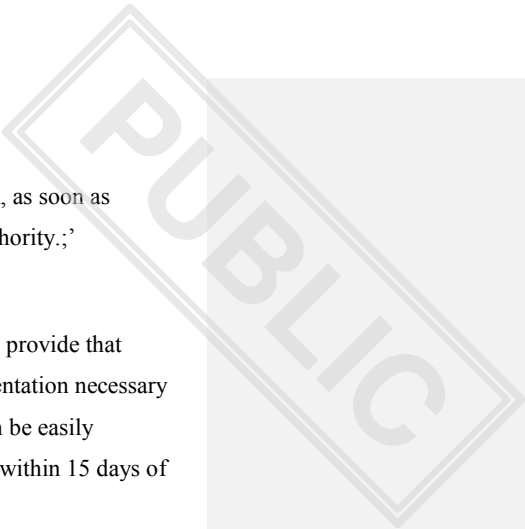
- (5) in Article 39, the second sentence is replaced by the following:
‘That information and documentation shall be provided, in electronic form, free of charge.’;
- (6) in Article 40(3), point (b) is replaced by the following:
‘(b) further to a reasoned request from a national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the battery.’;
- (7) Article 41 is amended as follows:
(a) in paragraph 3, the first sentence is replaced by the following:
‘Importers shall indicate on the battery their name, registered trade name or registered trademark as well as their postal address and digital contact, indicating a single contact point.’;
(b) in paragraph 8, the second sentence is replaced by the following:
‘That information and the documentation shall be provided in electronic form.’;
- (8) in Article 42(6), the second sentence is replaced by the following:
‘That information and the documentation shall be provided in electronic form.’;
- (9) Annexes VIII, IX and XIII are amended in accordance with Annex V to this Regulation.

Article 7

Amendments to Regulation (EU) 2024/1781

Regulation (EU) 2024/1781 is amended as follows:

- (1) in Article 2, the following point (46a) is inserted:
‘(46a) ‘digital contact’ means any up-to-date and **freely** accessible online communication channel **such as email addresses** through which economic operators can be **reached** or engaged without the need to register or to **download** an application.’;
- (2) in Article 24(2), the second sentence is replaced by the following:
‘Such information and documentation shall be provided, in electronic form, within 30 days of receipt of the request.’;
- (3) in Article 27(10), the second sentence is replaced by the following:



‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’

(4) in Article 28(2), point (c) is replaced by the following:

‘(c) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a product, in a language that can be easily understood by that authority as soon as possible and in any event within 15 days of receipt of such a request; and;’

(5) in Article 29(8), the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.’

(6) in Article 30(5), first subparagraph, the second sentence is replaced by the following:

‘That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority.’

(-7) in Article 36(2), second subparagraph, the second sentence is replaced by the following: ‘That information shall be provided in electronic form within 15 days of receipt of a request by the market surveillance authority’.

(7) in Annex V, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, the manufacturer’s authorised representative..’

Article 8

Transitional provision

Member States shall not impede the making available on the market of products which were placed on the market in accordance with Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1542 and (EU) 2024/1781 before [OP: please insert 24 months after entry into force of this amending Regulation)].

Article 9

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 5 and Annex IV shall apply from 20 January 2027.

The following provisions shall apply from [OP: please insert 24 months after entry into force of this amending Regulation]:

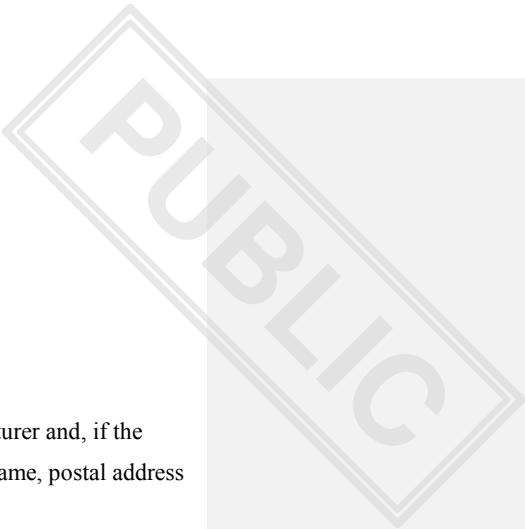
- (a) Article 2, point(1)(a), point (2)(a), (c), (d) and (e), and points (3), (4), (5), (7), (8) and (11);
- (b) Article 3, point (1)(a), point (2)(a), (c), (d) and(e), and points (3), (4), (5), (7) and (8);
- (c) Article 4, point (1)(a), points (2)(a), (c) and (d), and points (3), (4), (5), (6), (8), (9) and (12);
- (d) Articles 6 and 7;
- (e) Annex I, point (1)(a) and (c), point (2)(a), point (3)(a), point (4)(a), point (5)(a), (d) and (e), and point (7)(a);
- (f) Annex II, point (1)(a), point (3)(a), (c)(i) and (d)(i), point (4)(a), point (5)(a) and point (6)(a);
- (g) Annex III, point (1)(a)(i), (c), (e) and(g) and point (2)(a);
- (h) Annex V.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President



ANNEX I

Annexes III to IX to Regulation (EU) 2016/424 are amended as follows:

- (1) Annex III is amended as follows:
 - (a) in point 3, point (a) is replaced by the following:

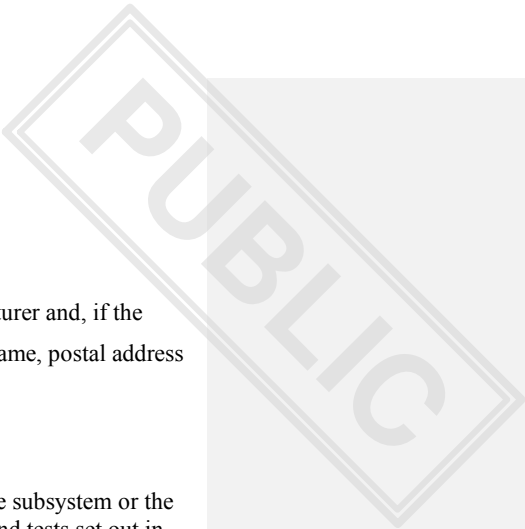
‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
 - (b) in point 4, points 4.2 and 4.3 are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;;

4.3a. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation’
 - (c) in point 6, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning.;;’
- (2) Annex IV is amended as follows:
 - (a) in point 3.1., point (a) is replaced by the following:



(4) Annex VI is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.2., paragraph 1 is replaced by the following:

‘The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the subsystem or the safety component with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’

(5) Annex VII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 3.2., point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;’

(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(d) in point 3.6.2., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’

(e) in point 3.6.3, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’

(6) in Annex VIII, point 2, point (c) is replaced by the following:

‘(c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the Official Journal of the European Union, ~~and~~ a list of common specifications **referred to in Article 17a**, applied in full or in part, and where those harmonised standards or common specifications, have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;.’

(7) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;.’

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’



ANNEX II

Annexes II, III, V, VII, VIII, and IX to Regulation (EU) 2016/425 are amended as follows:

- (1) in Annex II, point 1.4 is amended as follows:
 - (a) in the first subparagraph, the first sentence is replaced by the following:

‘In addition to the name, postal address and digital contact of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:;’
 - (b) points (k) and (l) are replaced by the following:
 - ‘(k) references to the relevant harmonised standard(s) or common specification (s) used, including the date of the standard(s) or specification(s), or references to the other technical specifications used;
 - (l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed.;’
- (2) in Annex III, points (f) and (g) are replaced by the following:
 - ‘(f) the references of the harmonised standards referred to in Article 14 ~~or~~and the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;
 - (g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;;’
- (3) Annex V is amended as follows:
 - (a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;;’
 - (b) in point 4, points (d) to (f) are replaced by the following:

- PUBLIC**
- ‘(d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed in accordance with other technical specifications;
 - (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;
 - (f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.’
- (c) point 6.2., is amended as follows:
- (i) point (b) is replaced by the following:
 - ‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, the latter’s name, postal address and digital contact;’
 - (ii) point (e) is replaced by the following:
 - ‘(e) where harmonised standards or common specifications have been fully or partially applied, the references of those standards or specifications or parts thereof;’
- (d) point 7.6. is amended as follows:
- (i) point (a) is replaced by the following:
 - ‘(a) his name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’
 - (ii) point (b) is replaced by the following:

‘(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications or other technical specifications applied;’

(4) Annex VII is amended as follows:

(a) in point 3., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact;’

(b) point 4.3. is replaced by the following:

‘4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.’

(5) Annex VIII is amended as follows:

(a) in point 3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

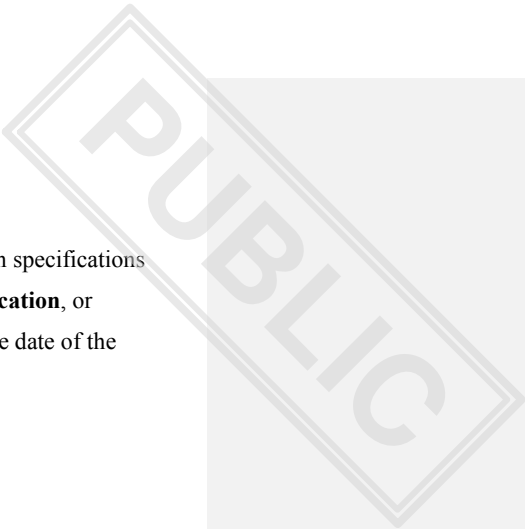
(b) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

(6) Annex IX is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;’



(b) point 6 is replaced by the following:

- '6. References to the relevant harmonised standards or common specifications used, including the date of the standard **or common specification**, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:.'

ANNEX III

Annexes III and V to Regulation (EU) 2016/426 are amended as follows:

- (1) Annex III is amended as follows:
- (a) point 1.3.1. is amended as follows:
- (i) point (a) is replaced by the following:
- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’
- (ii) in point (c), point (4) is replaced by the following:
- ‘(4) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union ~~and~~ a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’
- (iii) in point (e), the second sentence is replaced by the following:
- ‘(e) This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full;’
- (b) in point 1.4., points 1.4.3. and 1.4.4. are replaced by the following:
- ‘1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer

applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;;

- (c) in point 1.6., first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, and, if relevant, descriptions of its functioning.’

- (d) In point 2.3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation.’

- (e) in point 3.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

- (f) in point 3.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

- (g) in point 4.3.1., point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

- (h) in point 4.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’

- (i) point 5.4.1. is replaced by the following:

‘5.4.1. All appliances or fittings shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the

approved type described in the EU type-examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(j) point 5.5.2. is replaced by the following:

‘5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.;

(k) in point 6.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, ~~and~~ a list of common specifications, applied in full or in part, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Regulation, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied.;

(l) in point 6.4., the first subparagraph is replaced by the following:

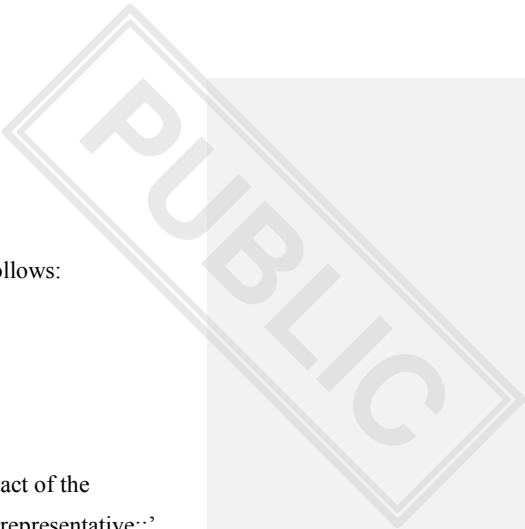
‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.;

(2) Annex V is amended as follows:

(a) point 2 is replaced by the following:

- ‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative;’
- (b) paragraph 6 is replaced by the following:
- ‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.’

PUBLIC



ANNEX IV

Annexes III, V, VII, IX, and X to Regulation (EU) 2023/1230 are amended as follows:

- (1) Annex III is amended as follows:
 - (a) in point 1.7.4.2., point 1 is amended as follows:
 - (i) point (a) is replaced by the following:

‘(a) the business name, full postal address and digital contact of the manufacturer and, where applicable, of its authorised representative;’
 - (ii) point (c) is replaced by the following:

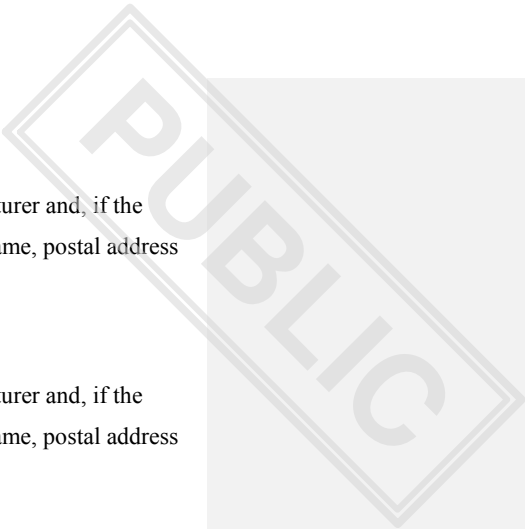
‘(c) the EU declaration of conformity, or the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);’
 - (b) point 4.3.1. is amended as follows:
 - (i) the first subparagraph is replaced by the following:

‘Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name, postal address and digital contact of the manufacturer and the identifying reference of the relevant certificate.’
 - (ii) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;’
- (2) Annex V is amended as follows:
 - (a) in Part A, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’
 - (b) in Part B, point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative.’
- (3) Annex VII is amended as follows:
 - (a) in point 3., point (a) is replaced by the following:



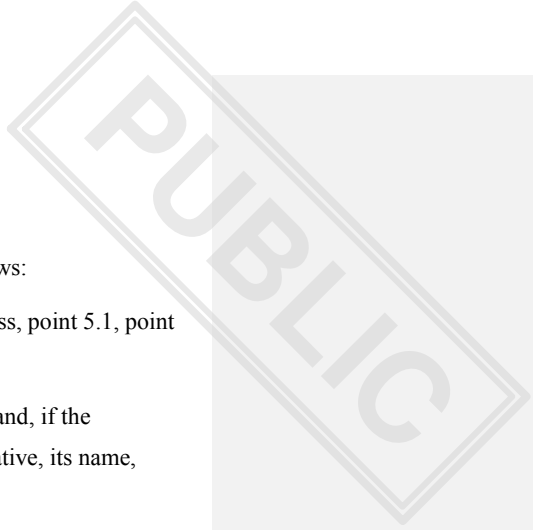
- ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’
 - (b) in point 6.2., point (b) is replaced by the following:
 - ‘(b) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’
 - (c) in point 7.6., point (a) is replaced by the following:
 - ‘(a) its name, postal address and digital contact and data identifying the EU type-examination certificate concerned;’
- (4) in Annex IX, point 3.1., point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’
- (5) Annex X is amended as follows:
 - (a) in point 2., point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by an authorised representative, the name, postal address and digital contact of that authorised representative;’

ANNEX V

Annexes VIII, IX and XIII to Regulation (EU) 2023/1542 are amended as follows:

- (1) in Annex VIII, Module D1: Quality assurance of the production process, point 5.1, point (a) is replaced by the following:
 - ‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the manufacturer’s authorised representative, its name, postal address and digital contact as well;’
- (2) in Annex IX, point 2 is replaced by the following:

‘Name, postal address and digital contact of the manufacturer and, where applicable, its authorised representative;’
- (3) in Annex XIII, point 1, the following point (t) is added:
 - ‘(t) ‘clear, understandable and readable instructions for use in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).’



DE Amendments to Omnibus IV (Digit. and Common Specifications), first compromise text by the Presidency:

In addition to the amendments proposed (see Pcy text documents), we would like to propose the following amendments to the text:

DIRECTIVE:

1. On Directive 2000/14/EC (Art. 1), Annex I:
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 or on the customer’s request be made available electronically in a standardized data format. National legislation may require a printed ticket for fiscal reasons.”**

REGULATION:

On Art. 74 para. 5 of the Regulation on Batteries (Regulation (EU) 2023/1542) we propose the following amendment:

Germany welcomes the amendments proposed by the Presidency to the Commission’s proposal for amending Regulation (EU) 2023/1542. In particular, Germany supports the deletion of Art. 74 para 5 as well. Practice has shown that this requirement creates considerable effort for the affected businesses, without providing a correspondingly high added value.

In the spirit of reaching a compromise, Germany could also support the Commission’s proposal to convert Article 74(5) of Regulation (EU) 2023/1542 into a voluntary provision, analogous to Article 14(1) of Directive 2012/19/EU.

GDPR:

1. We support the Commission’s concerns regarding the amendments to Recitals 5 and 10.

Recital 5: The phrase “adjusting the level of protection in the relevant Union act” is misleading, since, at least in relation to the GDPR, the level of protection is not adjusted. The actual objective is to take account of the needs of SMEs, which is already reflected in the preceding sentence. The sentence containing the contested wording should therefore be deleted.

Recital 10: The phrase “would not always likely result in a high risk to data subjects” should be deleted. It is confusing and would, in an unclear manner, duplicate the wording added at the end.

2. We welcome the orientation of the Danish Presidency with regard to Article 1(2) of the Omnibus IV draft Regulation (Article 30(5) GDPR). However, the proposed addition does not seem entirely appropriate or sufficiently clear in linguistic terms. The formulation “The obligations (...) shall not apply (...) to the extent that the processing it carries out is likely to result in a high risk (...)” could be read as meaning that the obligations would not apply precisely in cases of high-risk processing.

A clearer, positive wording could be:

“The obligations referred to in paragraphs 1 and 2 shall only apply to an enterprise or organisation employing fewer than 750 persons to the extent that the processing it carries out is likely to result in a high risk to the rights and freedoms of data subjects, within the meaning of Article 35.

Germany also supports the compromise text proposed by the Presidency based on the wording of the Toy Safety Regulation. With a few adjustments, this text provides a good basis for horizontal harmonization of the requirements for the adoption of common specifications (CS). It emphasizes that common specifications are a strictly limited solution and preserves the primacy of harmonized European standards. The compromise proposal thus creates and safeguards coherence within the standardization system.

In this context, we would like to **emphasize the following points**, which the Presidency already included in the compromise text, as indispensable for us:

- a) Clear stipulation of the “exceptional situation” for the adoption of CS (only “in exceptional cases”), also in recitals where appropriate
- b) Mandatory request to European standardization organizations before issuing common specifications
- c) Appropriate involvement of Member States through the application of the examination procedure when issuing the implementing act.
- d) No discretion regarding the withdrawal of CS by the COM after a harmonized standard has been published.
- e) Besides, we refer to our written comments on the compromise text sent to the Presidency (which apply accordingly to all legislative acts in the Omnibus IV package) and reserve the right to make further comments.

With regard to the Commission proposal on “urgency”:

PUBLIC

a) Germany does not support the proposal for an urgency clause presented by the Commission in the run-up to the meeting on September 1 and does not want it to be included in the Presidency's compromise text.

b) The accelerated procedure chosen for the Omnibus IV package does not allow for adequate scrutiny of this far-reaching competence which would be conferred to the Commission. The "urgency clause" would thus create a parallel "fast track" to harmonized standards that is not bound by the established procedures of the Standardization Regulation. We are in favor of accelerating the standardization process, but within the proven standardization system. We believe that the revision of the Standardization Regulation (EU) 1025/2012 is the right forum for this.

c) Furthermore, the proposed text on urgency has not been subject to an impact assessment, nor have stakeholders been consulted. In its current form, it would give the Commission excessive powers compared to the Member States, as the Commission would decide alone on the existence of the factual requirements and, moreover, would not have to involve the European standardization organizations.

d) In our understanding, the dismissal of the "urgency clause" proposed by the Commission will not impact the process for the adoption of Omnibus IV.

DE One-Pager - Article 79(1)(a)(i) of Regulation (EU) 2024/1781

Adjusting the timeline – proposal to extend the deadline specified in Article 79(1)(a)(i) of Regulation (EU) 2024/1781

Germany calls for a one-off extension of the deadline specified in **Article 79(1)(a)(i)** of Regulation (EU) 2024/1781 by two years – to **31 December 2028**. This requires a corresponding amendment to **Article 7** of the **Omnibus IV** (s. below).

Why the deadline should be extended?

In line with **Recital 120** of Regulation (EU) 2024/1781, the **Article 79(1)(a)(i)** lists a number of product groups that are expected to be negotiated under transitional rules allowing implementing measures on those products to be adopted pursuant to **Directive 2009/125/EC**.

Germany acknowledges and supports, that the preparatory work assessing the feasibility of ecodesign requirements pursuant to **Directive 2009/125/EC** for the product groups in question is at a substantially advanced stage. Thanks to that preparatory work, numerous areas where energy and material can be saved have been identified, and extensive consultations of citizens and stakeholders have taken place.

However, Germany – as other member states - anticipates that the transitional period currently specified in **Article 79(1)(a)(i)** will not be sufficient to adopt all the legal acts referred to therein.

According to the Commission's statements to date, this means that the regulatory process for the product groups in question would have to be restarted, resulting in a considerably delay of the adoption of requirements concerning energy and material savings for those products.

A one-off extension of the deadline, as requested by Germany and supported by several member states, would enable the Commission to successfully complete the work already begun.



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 7

Amendments to Regulation (EU) 2024/1781

Regulation (EU) 2024/1781 is amended as follows:

[...]

(6) in Article 30(5), first subparagraph, the second sentence is replaced by the following: 'That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority;'

(-7) in Article 36(2), second subparagraph, the second sentence is replaced by the following: 'That information shall be provided in electronic form within 15 days of receipt of a request by the market surveillance authority'.

***(-8) in Article 79 (1), point (a) (i) is replaced by the following:
(i) until 31 December 2028, as regards photovoltaic panels, space and combination heaters, water heaters, solid fuel local space heaters, air conditioners including air-to-air heat pumps and comfort fans, solid fuel boilers, air heating and cooling products, ventilation units, vacuum cleaners, cooking appliances, water pumps, industrial fans, circulators, external power supplies, computers, servers and data storage products, power transformers, professional refrigeration equipment and imaging equipment;***

[...]

PUBLIC

IRELAND

Ireland's national accreditation authority, INAB, do not agree that there are effective existing mechanisms, in particular the EA's determination that the biobanking standard can be considered harmonised, to address the issue around harmonising standards.

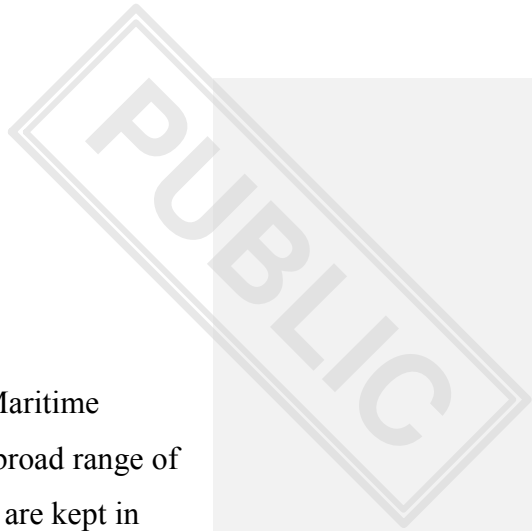
INAB have further noted that, if the intention of adopting common specifications is as a fallback option to the Accreditation Regulation, whatever alternative approach is chosen the text needs to make it explicitly clear that the requirements of Regulation 765/2008 are legally fulfilled by the approach so that National Accreditation Bodies (NABs) can accredit Conformity Assessment Bodies in compliance with Regulation 765/2008. Ireland has no opposition to the deletion of 765/2008 from Omnibus IV and supports the removal of same from scope as per the compromised text.'

Ireland Comments – Omnibus IV

SME rights, supports and access to funding

Ireland welcomes clarifications in recital 5 (proposal for Regulation and proposal for Directive) and recital 13 (proposal for a Regulation) that existing rights at European level for SMEs will not be affected by extending certain mitigating measures for SMEs to SMCs. At the same time, these clarifications refer to administrative burdens and access to trade defence instruments.

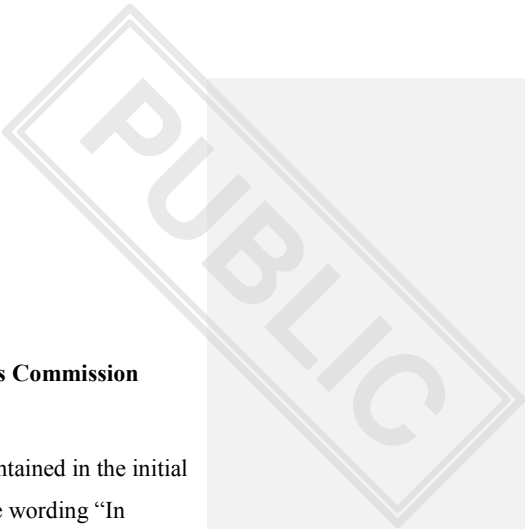
We consider it important to ensure that existing and future funding opportunities for SMEs are not adversely affected by the introduction of a new definition of SMCs as set out in the Commission Recommendation on the definition of small mid-cap enterprises. It would therefore be helpful to explore how this could be reflected or clarified as part of the overall package to ensure that SMEs are not adversely affected when it comes to present or future funding decisions.



Amendments to Marine Equipment Directive

The Marine Equipment Directive transposes International Maritime Organisation requirements into EU law. It relates to a very broad range of certificates relating to many of the elements of ships. These are kept in paper format at present as part of a vessel construction file. Should a vessel be inspected by a third country port state, under IMO protocols these certificates would be required in paper format. While the IMO is working towards electronic certification, with 176 member states, this process is slow.

It would be useful to clarify the impact of the proposed amendments to the Marine Equipment Directive in respect of the interaction between EU and international regimes. In particular the practical application of the proposal as it would relate to an IMO-aligned inspection by a third country of an EU-flagged vessel, or where an EU entity purchases a third country vessel and seeks to have it registered in the EU needs to be considered.



SPAIN

ES comments to the last presidency proposal on Omnibus IV:

a) Common specifications and digitalisation

- **On the Commission proposal (Omnibus IV – Common Specifications Commission proposal)**

ES does not agree with this proposal, as it reintroduces a number of concepts contained in the initial draft. Consequently, ES cannot support either the deletion, in paragraph 1, of the wording “In exceptional cases”, nor the inclusion of the new paragraph 1b.

- **On the Presidency proposal (documents st12226.en25; st12227.en25)**

By contrast, ES agrees with the Presidency these proposals. Nevertheless, we would like to make a minor drafting comment in order to align the wording with the Toy Regulation and other relevant legislation.

In this context, we consider that paragraph 2 should be drafted as follows (taking as reference the amendment of the Pressure Equipment Directive 2014/68/EU):

“Pressure equipment or assemblies that are in conformity with the common specification or parts thereof shall be presumed to be in conformity with essential requirements covered by those common specifications or parts thereof, set out in Annex I.”

b) Mid Caps

ES does NOT support raising the threshold to 1,000 employees:

- **Consistency with EU law:** As noted by the Danish Presidency in the explanatory note, the Commission’s Recommendation already establishes specific thresholds. Introducing different ones in this context may lead to taxonomic fragmentation and undermine the coherence of the EU regulatory framework.
- **Excessive coverage:** The main criterion used by the Commission to define the thresholds for MCIs was to include companies up to three times larger than the biggest SMEs. Raising the threshold beyond this point would create an overly broad category, extending special treatment to a very wide and heterogeneous range of companies.

We would accommodate the transposition period decided by the majority.

Regarding Omnibus IV, our environment counsellors raise also a point on the fact that document ST 12525/25 uses as a basis for the Reglamentation (UE) 2024/573 on F-Gases a former version of the text, whereas the current version of art. 22 does not include the obligation of registry for importers of equipment “ *whose functioning relies upon those gases*” (but only importers of equipment with fluorinated gases incorporated).

FRANCE

Objet : Commentaires écrits des autorités françaises à la suite de la réunion du groupe Antici sur la simplification du 1^{er} septembre 2025

1. Commentaires portant sur l'omnibus IV numérisation et spécification communes (ref.st12226.en25 et st12227.en25)

A l'invitation de la présidence, les autorités françaises souhaitent faire part des commentaires écrits suivants relatifs aux propositions d'Omnibus de la Commission européenne cités en objet. Le 27 août 2025 la Présidence a transmis ses premiers compromis intégrant pour partie les retours des différents Etats Membres, notamment ceux de la France. La France soutient pour partie ce nouveau texte et souhaite faire part à la présidence des observations suivantes :

Appréciation générale sur ces textes de compromis

Les autorités françaises soutiennent le principe de ce paquet de mesures visant à simplifier les règles et à réduire les charges administratives au sein du marché unique, afin de favoriser l'activité, l'innovation et la croissance des entreprises.

Elles rappellent en outre leur souhait que ces modalités soient rendues applicables à l'ensemble des textes sectoriels relevant du Nouveau Cadre Législatif (NCL). Elles ont en effet constaté que certains secteurs, tels que celui des jouets ou des équipements sous pression transportables, ne sont pas mentionnés dans la proposition. Elles estiment également que le règlement (UE) 2019/1020 devrait être inclus dans le champ du règlement Omnibus pour certains aspects liés à la numérisation, et que les éléments suivants devraient en particulier être intégrés dans le règlement 2019/1020 :

- la définition du point de contact numérique ;
- la modification de l'article 4, paragraphe 5, du règlement 2019/1020, par l'alinéa suivant :

4. Without prejudice to the respective obligations of economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trade mark, and contact details, including the postal address **and the digital contact** of the economic operator referred to in paragraph 1 shall be indicated on the product or on its packaging, the parcel or an accompanying document.

- Le paragraphe (d) de l'article 26 du règlement 2019/1020 remplacé par l'alinéa suivant :

the name, registered trade name or registered trade mark and the contact details, including the postal address and the digital contact, of an economic operator with tasks regarding the product subject to certain Union harmonisation legislation is not indicated or identifiable in accordance with Article 4(4); or

Enfin, compte tenu des contraintes législatives internes propres à chaque État membre, il apparaît nécessaire de prévoir un délai de transposition plus long que les 12 mois actuellement proposés. Un délai d'au moins 18 mois, à l'instar du dispositif Omnibus adopté en 2024 dans le cadre de l'instrument d'urgence pour la résilience du marché intérieur en situation de crise, serait plus approprié. En conséquence, à l'article 15 de la directive *Omnibus*, l'amendement suivant est proposé :

Member States shall adopt and publish, by [OP:Please insert 12 **18** months after entry into force of this amending Directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from [OP: Please insert 12 **18** months after entry into force of this amending Directive)

I. Volet ayant pour objectif de soutenir la numérisation

Sur le volet de la numérisation, les autorités françaises saluent les nombreuses modifications introduites par la Présidence dans ce premier compromis, dans la perspective d'un alignement avec la rédaction initiale de chaque règlement. Elles relèvent toutefois que pour la directive 2014/29/UE et 2014/31 la notion de « consumer » n'existe pas dans le texte initial et est introduite par la directive *Omnibus*. Dans un souci d'alignement avec la directive d'origine, il est proposé de supprimer le paragraphe suivant du point 2(d) de l'article 4 et le du point (3) (d) de l'article 6

~~point 2(d) de article 4 « In the case of vessel for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the vessel, the safety information referred to in point 2 of Annex III. Such safety information shall be easily visible and legible for consumers”~~

~~point (3) (d) de article 6 In the case of an instrument intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide in paper format, or mark on the product, the information that is essential for using it in a safe way. Such information shall be easily visible and legible for consumers~~

Pour certains secteurs, l'*Omnibus* prévoit la transmission aux consommateurs des informations relatives à la sécurité sous format papier. Il importe d'assurer la cohérence avec les autres législations relevant du Nouveau Cadre Législatif (NCL) et d'éviter toute insécurité juridique, ainsi les autorités françaises souhaitent que cette notion d'« informations relatives à la sécurité » soit précisée, en indiquant qu'elle concerne les informations essentielles à la mise en service du produit ainsi qu'à son utilisation en toute sécurité (pouvant inclure, dans certains secteurs, le montage, la maintenance et les contrôles en service). Elles proposent en conséquence l'amendement suivant pour le règlement *Omnibus* au paragraphe 4 de l'article 3(2)(c), paragraphe 3 de l'article 3(2)(d), paragraphe 4 de l'article 4(2)(c) et paragraphe 2 de l'article 6(4) et pour la *directive Omnibus* au paragraphe 3 de l'article 4(2)(d), paragraphe 2 de l'article 5(2)(d), paragraphe 3 de l'article 6(2)(d), paragraphe 3 de l'article 7(2)(d), paragraphe 3 de l'article 9(2)(d), paragraphe 3 de l'article 10(2)(d), paragraphe 7 de l'article 11(2)(d), paragraphe 4 de l'article 12(2)(d) et paragraphe 3 de l' article 13(2)(b)

In the case of product intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, manufacturer shall provide, in paper format, or mark on the product, the safety information **that is essential for putting the product into service and for using it safe way**. Such safety information shall be easily visible and legible for consumers.

Les autorités françaises saluent également la clarification de la définition du « contact numérique » et notamment de l'ajout de la mention de l'adresse électronique. Toutefois, afin d'éviter le renvoi à des éléments ne permettant pas une communication directe, efficace et traçable (comme un agent conversationnel par exemple), les autorités françaises proposent de compléter la définition avec les éléments ci-après :

'digital contact' means any up-to-date and freely accessible online communication channel such as email addresses **that is up-to-date, accessible, direct, and traceable, and** through which economic operators can be contacted or engaged without the need to register or to use an application

Concernant les instructions, dans un commentaire général, elles suggèrent d'exiger l'indication de la date de création et le numéro de la version des instructions sous format numérique afin de garantir la traçabilité des informations et ainsi faciliter les activités de surveillance du marché.

Enfin, concernant le secteur des équipements de protection individuelle et le règlement (UE) 2016/425, les autorités françaises soulignent la nécessité de laisser à disposition les instructions et les informations uniquement en format papier, dans toutes circonstances et sans opération nécessitant l'emploi d'équipements numériques, pour les équipements de protection individuelle protégeant les utilisateurs contre les risques pouvant avoir des conséquences très graves comme la mort ou des dommages irréversibles pour la santé et définis en catégorie III dans l'annexe I du règlement (UE) 2016/425. Ainsi, elles proposent d'insérer au (2)(d) de l'article 3 relatif aux amendements du règlement (UE) 2016/425 :

“ 7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. The instructions and information may be provided in electronic form. **However, electronic form instructions and information set out in point 1.4 of Annex II are not permitted for PPE category 3 as set out in Annex I.** Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.”

II. Volet relatif à l'harmonisation des alternatives pour démontrer la conformité des produits par le recours à des spécifications communes

Les autorités françaises sont favorables à la nouvelle rédaction proposée sur la base des textes sectoriels existants. Ce compromis formule explicitement les conditions de recours aux spécifications communes en tant que solution de repli et introduit des dispositions visant à assurer la cohérence avec les normes harmonisées.

Elles sont favorables à la nouvelle définition proposée des « spécifications communes », en cohérence avec la définition de « norme » au (1) de l'article 2 du règlement (UE) 1025/2012.

Les autorités françaises soutiennent aussi :

- le recours à la procédure d'examen pour l'adoption des actes d'exécution ;
- la prise en compte du point de vue de tout autre organisme compétent pour l'élaboration du projet d'acte d'exécution ;
- l'exclusion du règlement (CE) n°765/2008 relatif à l'accréditation et à la surveillance du marché du champ d'application de l'Omnibus IV.

Elles soulignent l'utilisation non appropriée du terme « *safety* » aux 1. des articles relatifs aux spécifications communes et proposent de le supprimer des articles 2(6), 3(6) et 4(6) du règlement *Omnibus IV* et 2(7), 3(7), 5(7), 6(7), 7(7), 8(7), 9(7), 10(7) et 11(7) de la directive *Omnibus IV* :

« Common Specifications

1. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the applicable essential **safety** requirements. Those implementing acts shall only be adopted where the following cases conditions are fulfilled: »

Les autorités françaises souhaitent connaître les raisons de l'ajout de « *which it covers* » aux 6. des articles relatifs aux spécifications communes, elles suggèrent la suppression de ce terme ou à minima son remplacement par par « *which aims to cover* ».

6. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex II ~~which it covers~~ **(or which aims to cover)**, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed

explanation and may, if appropriate, amend the implementing act establishing the common specification in question.';

Enfin, les autorités françaises ne soutiennent pas la proposition de clause d'urgence présentée par la Commission. En l'état, elle conférerait à la Commission des pouvoirs excessifs par rapport aux États membres. Cette proposition nécessiterait a minima que la nature urgente et exceptionnelle de la situation soit partagée par les États membres.

2. Battery regulation (2023/1542)

- Nous soutenons la proposition de compromis de la présidence concernant les obligations de diligence raisonnable, qui promeut le respect des obligations du règlement pour les acteurs économiques.
- En ce qui concerne la proposition de suppression de l'article 74, paragraphe 5, relatif à l'information relative à la prévention et à la gestion des déchets de batteries, **les autorités françaises s'y opposent fondamentalement pour deux raisons principales** : premièrement, la disposition du règlement permet de diffuser des informations sur le montant de l'éco-contribution à toutes les parties prenantes, y compris les consommateurs ; deuxièmement, nous craignons que si cette disposition est supprimée pour les batteries, elle pourrait remettre en question la redevance visible d'autres secteurs en France, y compris les équipements électriques et électroniques, ce qui est essentiel.
- Nous proposons donc le projet d'amendement au compromis ci-dessous en rouge:

Recital 19A should be deleted :

~~(19a) Article 74(5) of Regulation 2023/1542 of the European Parliament and of the Council requires producers of batteries to separately show the costs covered by the producer under Article 56(4), points (a) to (d), to the end user at the point of sale of a new battery. However, the burden resulting from that requirement may be disproportionate in terms of administrative red tape and costs for the producers compared to its benefits in terms of consumer protection. Therefore, Article 74(5) of Regulation 2023/1542 should be deleted.~~

Article 5 - Amendments to Regulation (EU) 2023/1542

[...]

~~(2a) in Article 74, paragraph 5 is deleted.~~

PUBLIC

CROATIA

Croatian position on the Extension of the Transitional Period under Article 79(1) of Regulation (EU) 2024/1781 and Related Issues:

Extension of the Transitional Period

Croatia expresses its support for the German non-paper regarding the adaptation of the transitional period under Article 79(1) of Regulation (EU) 2024/1781 and the proposal for a two-year extension of the deadline, until 31 December 2028.

Terminology – “End User” vs. “Consumer”

Croatia finds the use of the term “end user” instead of “consumer” to be fully appropriate. The products addressed by the relevant Directives and Regulations are technical in nature and intended for use by end users, while consumers are typically the purchasers or recipients of such goods. Recognising the potential for variations in the use of these terms across legislative contexts, we underline that, in this instance, the designation “end user” better reflects the technical character of the subject matter.

Printed Instructions

Croatia reaffirms its support for the requirement to provide printed instructions for use, with a continued focus on the safety of consumers and end users. Such printed instructions should be available on request, both at the time of purchase and for a designated period thereafter, in line with current regulatory requirements. This approach is vital for ensuring clarity and safety, especially for those who may not have access to digital documentation.

Deadline Extensions

Croatia generally supports all proposals relating to the extension of deadlines for compliance, including the proposal submitted by Italy. Such extensions are crucial for the protection of SMEs and industrial actors, taking into account the different situations in the Member States as well as the diverse resources and expertise of economic operators in the EU. In view of varying levels of digital network infrastructure and experience among the Member States, we emphasise the necessity of a gradual phase-in of digitalisation requirements, as well as extended transposition timelines for relevant obligations.

Urgency Clause

Croatia support the urgency clause proposed by the European Commission only in strictly defined (described) cases.



ITALY

Digitalisation

Italy welcomes the improvements to the definition of “digital contact”, however we consider that the obligation to fully digitalise declaration of conformity and safety information especially cannot apply from 24 months after the entry into force of this legislative proposal. In fact, the respect of this deadline may be too onerous for SMEs and a longer deadline is required by Italy.

Over this transitional period, the information should be provided preferably in electronic form, but also in written format if decided so by the manufacturer.

Regarding the safety information, we seek the Presidency to give the maximum attention to this aspect. Italy believes that it is essential that safety information continues to be provided on paper to ensure adequate protection for the most fragile consumers in particular. Therefore, it seems too long the requirement that such information should be produced by the manufacturer in paper form at the request of the consumer within one month. Italy seeks that this information is made available on paper at the moment of purchase so that fragile consumers may have them immediately to ensure a safe use of the product.

We recall the amendment that we proposed to Regulation 2024/17981 (ESPR) aimed at extending the transitional period for the products listed in Article 79 by two years (and so until 31.12.2028), in consideration of the reasons illustrated in recital (120) and the delay of the related works.

Common Technical Specifications

Italy welcomes the compromise text and considers the modifications to the procedure to adopt common specifications very appropriate. Italy has also analysed carefully the proposal of the Commission to add a clause on “urgent market concerns”, and we would like to remind that Italy is not against the principle to develop common specifications in case of urgent needs. However, this possibility shall be undertaken when there is no time to run the full normal standardisation route, and provided that this solution is temporary and that the common specifications are repealed as soon as there is an harmonized standard cited in the OJEU that would fix the original “urgent market concerns”. With this regard, Italy observes that the compromise text has already provided for several “safeguard clauses” in line with our points, like the inclusion of point 5 of in the new article

on common specifications, where the European Commission is expected to withdraw the text of the implementing act once that the harmonised standard has been published in the Official Journal.

We also have a series of comments on the operative text and on the recitals:

- Directive 2014/33/EU: the term “product” is too generic considering the absence of a definition in the text of the Directive. Therefore, it is suggested to replace it with the term “lift”.
- Recital 4: Italy has already highlighted that reporting obligations are often fragmented, with different deadlines, formats and transmission procedures depending on the applicable regulations. This lack of consistency creates unnecessary complexities for economic operators, increasing the risk of non-compliance and administrative inefficiency. For that reason, the addition of the term “harmonisation” among the essential elements – together with “reduction” and “modernisation” – of reporting requirements and burdens on economic operators was already proposed in order to simplify the requirements and ensure legal clarity.
- Recital 8: Italy's request to introduce a graduality in the manufacturers' obligations to provide the information in electronic form was not taken into account. We would like to seek the introduction of this principle, in line with the Italian comments on digitalization.
- Recital 10: Italy has already proposed the addition of a specific reference to SMEs which was intended to stress the fact that reporting requirements often impose an excessive administrative burden on this category of enterprises. Bear in mind that these enterprises frequently lack the human resources, technical expertise or infrastructure that would be necessary to manage complex and fragmented procedures.
- Recital 11: the formula “and other requirements” remained after “essential health and safety”. Since this formula “and other..” is used only in one place, we believe it may be a typo and we seek the Presidency to double check. We profit to remark that for Italy it is essential that the common technical specifications are, from the point of view of substance, activated only for health and safety reasons.

PUBLIC

LATVIA

LV's comments on the Presidency compromise text for Omnibus IV.

Regarding Omnibus IV on digitalisation and common specifications, Latvia overall supports the Presidency's approach and the compromise text. In our written comments, we propose the following amendment:

Proposal for a Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU as regards digitalisation and common specifications

Article 15 (1):

Latvia considers it necessary for the transposition period to be extended from 12 to 24 months to allow sufficient time for national implementation.

LITHUANIA

2025-09-03. Lithuanian comments on Omnibus IV (Digitalisation and Common specification) Directives and Regulations.

Suggested changes in the text are marked as **color** and ~~crossed out~~.

1. We support the **deletion of Regulation (EU) 765/2008** from the package.
2. We support common specifications as a fallback systemic solution, as proposed under the **Toy Regulation model**.
3. We support the presidency text, which provided a much clearer explanation regarding the relationship between common specifications and harmonized standards.
4. We have concerns about the proposed **transposition period**. Lithuania acknowledges the importance of ensuring a timely entry into force of the Directives to achieve the objectives of simplification, digitalisation, and common specifications. Transposing these amendments into national law would require substantial changes, including amendments to the Laws, adopted by the Parliament. This process is complex and time-consuming (in average it takes min 1 year), requiring close coordination among various national authorities. Therefore, Lithuania supports the proposals made by other Member States to extend the transposition period from 12 to 24 months, allowing sufficient time for thorough legal alignment and effective implementation at national level. In the event that the transposition period is not changed, we would like to hear the reasons why.

Article 15, Transposition:

Member States shall adopt and publish, by *[OP: Please insert ~~12~~ 24 months after entry into force of this amending Directive]* at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from *[OP: Please insert ~~12~~ 24 months after entry into force of this amending Directive]*

5. **Regarding the Commission's proposal** to article 17 a, including conditions that would allow prepare CSs drafts without obligatory application of paragraph 1 (a) and 1 (b) in duly justified, exceptional; and urgent cases . The direction chosen by the Commission understandable but we suggest adding more legal clarity to the text and recitals regarding justification of *exceptionality and urgency*, include a bit more clarification and conditions, for example in the preamble. Also to note, we believe the proposal should not grant the power to develop technical specifications based on unofficial sources.

~~“(11) [...] This includes situations when european standardisation organisations cannot accept or deliver on standardisation requests as well as, in exceptional cases, situations where urgent market concerns relating to compliance with essential health and safety requirements~~

cannot be addressed in a timely manner by european standardisation **organisations and Commission has justifying information.**

Article 17a

Common Specifications

[...]

[...]

1b. In exceptional cases, where it has received information on urgent market concerns about the application of essential health and safety requirements due to the absence of harmonised standards or parts thereof published in the Official Journal, ~~or~~, the Commission may adopt an implementing act referred to under paragraph 1 even if conditions 1a and 1b are not fulfilled.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article [Insert correct reference] and justified by Commission as per paragraph 3 .

2. Subsystems and safety components that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with essential requirements covered by those specifications or parts thereof, set out in Annex II.;

3. Before preparing the draft of the implementing acts referred to in paragraph 1 and 1b of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 and 1b of this Article are fulfilled. In the case of implementing acts referred to in paragraph 1b of this Article, the Commission must duly justify the exceptional and urgent nature of the situation

6. **On instructions in paper format:** we believe the text should clearly specify how paper instructions will be transmitted between manufacturers and distributors/retailers, and between distributors/retailers and consumers (end-users). In our view, the omnibus should establish a common approach and similar rules for how economic operators will fulfill the obligation to provide written instructions. Many questions arise on how instructions will be transferred between distributors and retailers. **We strongly believe the Commission should provide recommendations to ensure a common EU-level approach and consistent interpretation across Member States.**

Suggested addition in recitals:

(9b) In order to ensure that instructions for use provided in paper format reach economic operators and end-users in a consistent and effective manner, it is necessary to clarify the obligations of manufacturers, distributors and retailers regarding the transmission of such instructions. A common approach should be established at Union level, accompanied by recommendations from the Commission, to ensure a uniform interpretation across Member States and to facilitate compliance with the obligation to provide written instructions.

7. We believe that the **Accessibility Act** should be mentioned in text. Especially in the context of digital instructions and safety information, accessibility requirements must be ensured. E.g. it is not enough to be able to download the doc. The document must be accessible to people with different disabilities. Hence, we believe that a general reference to an Accessibility Act should be made either in the recitals or in each NLF, which is being amended by this Omnibus.

Suggested addition in recitals:

(9a) In order to ensure that the digital provision of instructions for use, safety information and other product documentation does not create barriers for persons with disabilities, such information should comply with the accessibility requirements laid down in Directive (EU) 2019/882 of the European Parliament and of the Council. This will guarantee that end-users with different types of disabilities can effectively access, perceive and use the information provided in digital form.

8. 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. 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, 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.

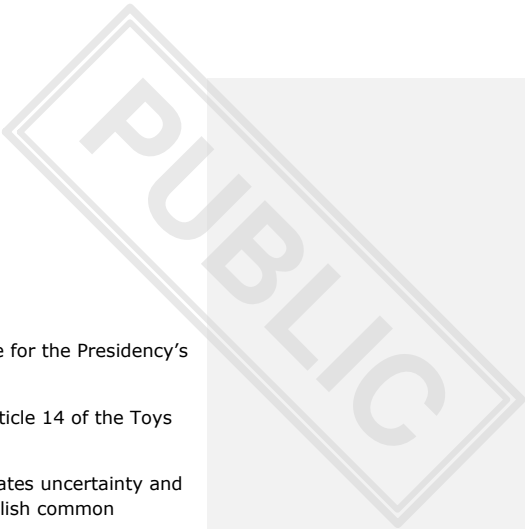
Article 7 Amendments to Directive 2014/32/EU

‘(14a) ‘common specifications’ means a set of technical requirements **specifications or a normative document**, other than a standard, that provide means of complying with the essential requirements **set out in Annex I and in the relevant instrument-specific Annexes of this Directive** applicable to a **product, device, service, process or system measuring instrument;**”

HUNGARY

HU has the following comments to make:

- We suggest adding the last sentence in point (b) of Article 4(9) of the Regulation (*‘This does not affect the obligation to provide the safety information in paper format according to Article 7(7);’*) to every relevant paragraph in other articles where the amendments keep an obligation to provide paper-based safety information. As a useful clarification, adding it to every relevant provision – in both the proposed regulation and directive – would increase the consistency of the legal texts.
- Regarding the urgency clause proposed by the Commission, we are skeptical as it is not justified, therefore, we do not find it acceptable.



NETHERLANDS

NL final written comments on Omnibus IV

Digitalisation & common specifications

- NL supports the Presidency's compromise text.
- Regarding common specifications, the Netherlands expresses a strong preference for the Presidency's proposal:
 - As it provides a sufficient basis for common specifications (in line with Article 14 of the Toys Safety Directive);
 - The additional proposal by the Commission is unnecessarily broad. It creates uncertainty and too much discretionary power for the Commission to intervene and establish common specifications whenever they deem it necessary;
 - The NL believes that the Presidency's proposal already provides a sufficient legal basis for common specifications as a fallback option. The Commission should only make use of common specifications where the standardisation system is unable to deliver harmonised standards in a timely manner, and where no suitable international or national standards are available as a temporary alternative.

Small mid-caps

- NL supports the proposed definition for small mid-caps, including the current thresholds included in the Presidency's compromise text (250-750 employees).
 - At this stage, it is difficult to foresee the consequences of a possible extension of these thresholds without an impact assessment, also in relation to the application of this definition to other (future) legislation.

AUSTRIA

Austrian comments regarding Omnibus IV (all) – Deadline 03-09-2025 cob

general remarks on common specifications (CS)

- The current text proposal regarding Common Specifications seems to be going to the right direction.
- However, AT deems more time for a thorough and sound discussion on Common Specifications necessary; Member States still need sufficient to discuss the current draft text, in particular on Common Specifications, with national stakeholders.
- For AT, it is key, that the implementation of the relevant principles regarding Common Specifications, derives from the Regulation on machinery (EU) 2023/1230.
- A text based on the wording of Article 14 of the Toys Safety Regulation would also be suitable for this purpose.
- The present draft text complies with the principle of consistent wording across all legal acts. Therefore AT asks for further details concerning paragraph 1b of for Regulation (EU) 2016/424.
- For AT, the following principles are of great importance when implementing Common Specifications and need to be reflected in the current text:
 - The adoption of Common Specifications is only acceptable in exceptional cases.
 - Common Specifications may only temporarily substitute harmonized European standards (function as placeholders)
 - Common Specifications must be completely withdrawn as soon as suitable harmonized European standards are available – priority for harmonized European standards. (Avoidance of the creation of a “Common Specifications loophole”).

regarding (EU) 2016/424

- AT welcomes the presidency compromise text (ST 12227/25).
- AT rejects the EC text proposal (Commission proposal 2608)
- Without the conditions set out in Article 17a paragraph 1a and 1b, AT sees no necessity for the introduction of common specifications (CS).

regarding 2013/53/EU, 2014/30/EU, 2014/34/EU, 2014/35/EU

- In particular regarding 2014/30/EU, 2014/34/EU, 2014/35/EU negative effects may arise if common specifications remain in place despite the availability of suitable harmonized European standards, i.e., they are not completely withdrawn.
- Around 80% of harmonized European standards relating to electrical engineering originate from international standards.
- This demonstrates the strong link between European standards and international standards and thus the international market.
- Common specifications issued in exceptional cases that remain in force after suitable harmonized European standards become available, i.e., are not completely withdrawn, could have a disruptive effect on the European market.
- For this reason, common specifications should be completely withdrawn as soon as suitable harmonized European standards become available.

regarding 2014/31/EU and 2014/32/EU

General: We thank the Presidency for their efforts and the compromise text. The inclusion of provisions for common specifications and digitalisation is in principal acceptable for directives 2014/31/EU (Non-automatic weighing instruments, NAWID) and 2014/32/EU (Measuring instruments, MID). We appreciate provisions on digital contacts and electronic documentation. We understand that provisions should be as consistent as possible. But as there are differences between products, this will not always be possible.

With regard to the proposed text st12226 for MID and NAWID we see a need for the following changes:

Article 7 - Dir. 2014/32/EU Measuring instruments

- **The relation between the existing normative documents and the new common specifications is not clear enough.**
- Therefore a correction of the definition of “common specifications” is necessary, for example by the following amendment “... means a set of technical specifications, other than a standard **or a normative document**...” These corrections are also in articles necessary, especially in Art 14a. (Detailed wording proposals in the previously submitted template regarding text ST 9327 (deadline 23-06-2025)).
- To cover normative documents and to take into account, that there are **almost no safety requirements in MID** the entire new Article 14a would be useless with the recent amendments, we propose to formulate Article 14a (1) as follows:

“Article 14a

Common specifications

1. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements set out in Annex I and in the relevant instrument-specific Annexes. Those implementing acts shall only be adopted where the following conditions are fulfilled:

a) requirements set out in Annex I and in the relevant instrument-specific Annexes are not covered by harmonised standards or normative documents, or parts thereof, the references of which have been published in the Official Journal of the European Union;

b) the Commission has requested, pursuant to Article 10 (1) of Regulation 1025/2012, one or more European Union standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of measuring instruments with the essential for those requirements set out in Annex I and in the relevant instrument-specific and:

(1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed or

(2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:

(i) are not delivered within the deadline set in the request;

(ii) do not comply with the request; or

(iii) do not satisfy the requirements they aim to cover.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 46(3).”

Article 6 - Dir. 2014/31/EU Non-automatic weighing instruments

- We propose to include normative documents as in MID. (Detailed wording proposals in the previously submitted template regarding text ST 9327 (deadline 23-06-2025)).
- Amend in 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 or on the customer’s request be made available electronically in a standardized data format. National legislation may require a printed ticket for fiscal reasons.*”

- Amend in Annex III, 1.4: *“The inscriptions Max, Min, e, and d, shall also be shown near the display of the result if they are not already located there. **Data may be presented either on a data plate (i.e., by hardware) or permanently indicated on the display (i.e., by software).**”*
- To cover normative documents and to take into account, that there are **almost no safety requirements in NAWID** the entire new Article 12a would be useless with the recent amendments, we propose to formulate Article 12a (1) as follows:

“Article 12a

Common specifications

1. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements set out in Annex I. Those implementing acts shall only be adopted where the following conditions are fulfilled:

a) requirements set out in Annex I are not covered by harmonised standards or normative documents, or parts thereof, the references of which have been published in the Official Journal of the European Union;

b) the Commission has requested, pursuant to Article 10 (1) of Regulation 1025/2012, one or more European Union standardisation organisations to draft or to revise European standards or parts thereof results in non-compliance of measuring instruments with the essential for those requirements set out in Annex I and in the relevant instrument-specific and:

(1) the request has not been accepted by any of the European standardisation organisations to which the request was addressed or

(2) the request has been accepted by at least one of the European standardisation organisations to which the request was addressed, but the European standards requested:

(i) are not delivered within the deadline set in the request;

(ii) do not comply with the request; or

(iii) do not satisfy the requirements they aim to cover.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 46(3).”

If common specifications are restricted to safety provisions, their inclusion in the MID and NAWID can be omitted without replacement.

SMC

regarding (EU) 2016/679 (GDPR)

- AT supports the compromise and the approach to clarify amendments in the recitals.
- In this sense, AT shares the position of the Joint Opinion of the EDPB/EDSB of July 8, 2025.

regarding (EU) 2022/2557

- AT generally welcomes the amendments proposed by the Presidency to adapt Directive (EU) 2022/2557.
- However, due to the tight timeframe for the member states at national level, AT suggests extending the implementation period to at least 24 months.

AT Additional comments:

We share the concerns and support the comments submitted by German delegation regarding the Commission’s proposal for an “urgency clause”. Therefore, we do not support the addition of the proposed para 1b in Regulation (EU) 2016/424 in the next Presidency compromise text, nor the proposed changes to recital 11.

POLAND

Polish comments on the first Presidency compromise texts on Omnibus IV

Comments concerning proposal on small mid-cap companies (SMCs)

General remarks

Poland understands and supports the idea of introducing legislation for small mid-cap companies (SMCs), which aim is to provide a consistent definition across a number of legal acts in order to facilitate scaling of SMEs. In Poland's view the definition of small mid-caps should be harmonised.

It should also be noted that the possibility to define small mid-cap companies differently in different legal acts will make it more difficult to collect data on this group of companies and to continue monitoring their development and needs.

However, prior to the publication of the EC Communication [1] containing the new SMC definition, it was understood that the definition of small mid-caps would be based on the previously applicable and seemingly most commonly adopted GBER definition: Regulation 651/2014 – Article 2(103e): “‘small mid-cap’ means an undertaking that is not an SME and whose number of employees does not exceed 499, calculated in accordance with Articles 3 to 6 of Annex I, the annual turnover of which does not exceed EUR 100 million or the annual balance sheet of which does not exceed EUR 86 million; several entities shall be considered as one undertaking if any of the conditions listed in Article 3(3) of Annex I is fulfilled (...)”.

The EC recommendation does not sufficiently explain or analyse why the thresholds for the new definition of small mid-caps are three times higher than for SMEs. Thus, the proposals for an additional increase in the threshold for the number of employees for SMC seem to lack sufficient justification.

In support of the objections to the increase of the thresholds in the definition of small mid caps, it should be noted that both proposals provide justification based on a study whose methodology assumes that small mid caps are companies with between 250 and 499 employees [2].

Additionally, the introduction of provisions amending the definition of a small mid-cap company as well as the possibilities in individual legal acts to modify it will lead to a lack of continuity in statistical data.

It is therefore difficult to understand why the thresholds for the new definition of small mid-caps set out in the Commission's recommendation are three times higher than those for SMEs.

[1] https://single-market-economy.ec.europa.eu/document/download/1642f461-1ed1-41c3-ae82-ee9266a57ed9_en?filename=Recommendation%20-%20Small%20mid-caps.pdf

[2] <https://www.esri.ie/system/files/publications/BKMNEXT429.pdf>, p. 7

GDPR

1. Register of processing activities - Art. 5 GDPR

The proposed derogation from the obligation to keep a record of processing activities, provided for in the new wording of Art. 5 GDPR, limits this obligation to entities employing more than 750 persons, unless and to the extent that the processing is likely to result in a high risk to the rights and freedoms of data subjects in accordance with Article 35 GDPR. The DPO maintains its previous position, also expressed by the European Data Protection Board, which accepted the increase to 500 employees.

In addition, we propose to amend recital 9

- Recital 9 of the amending Regulation introduces the words ‘upon assessment’ (under 750 workers may benefit from a derogation unless the processing, after an assessment, results in a high risk...). We agree with the Presidency that organisations should assess whether the processing poses a high risk so that, in the event of a denial, they can benefit from the exception. Currently, the wording suggests that until the company carries out an assessment, it can use it.

Rewording proposal in recital-> *In order to reflect the above, it is necessary to amend Article 30(5) of Regulation (EU) 2016/679, by extending the scope of the derogation from the record-keeping obligation to **enterprises and organisations with fewer than 750 500 employees to allow them to also benefit from that derogation and by providing that the derogation applies if the processing, upon assessment, is unlikely to** unless the processing, upon assessment, is likely to result in a ‘high risk’ to data subjects’ rights and freedoms, within the meaning of Article 35 of Regulation (EU) 2016/679.*

It should be stressed that maintaining the high-risk exception is key to upholding the principle of proportionality and accountability of controllers in the processing of data.

2. Definitions of SMEs and SMCs - Article 4(27) and (28)

The introduction of precise references to the definition of small and medium-sized enterprises and small mid-caps is an ordering measure that allows for a differentiated application of the provisions of the GDPR depending on the scale of the entity's activity. From a personal data protection perspective, such an approach may be justified as long as it does not lead to a weakening of protection standards.

3. Codes of conduct and certification mechanisms - Articles 40 and 42

Adding references to the SMC as a target group in the context of codes of conduct and certification mechanisms can facilitate the application of the GDPR in the operational reality of these entities. The DPO supports efforts to increase the availability of compliance tools for different categories of companies, while maintaining high data protection standards.

4. Editorial and legislative comments

Amendments to recitals (8) to (11) and Article 1(c) 2 are of a clarifying and orderly nature. In particular:

- Emphasising the need for a risk assessment by the data controller (recital 9) is in line with the principle of accountability.
- Clarification that the processing of special categories of data does not always represent a high risk (recital 10) may limit the over-interpretation of obligations by controllers.
- Any changes should rather reduce this threshold to 500 employees, which would take into account the position of the EDPB and the EDPS. Larger entities, due to the scale of their operations, should not have problems with the implementation of internal reporting obligations. This facilitates decision-making and identification of risk areas in information management in the organization.

Summary

We positively assess the direction of changes proposed to GDPR as part of the Omnibus IV package, provided that the obligation to keep a record of processing activities in the case of high-risk processing is clearly regulated in the normative content of Article 5 of GDPR. We believe that such a solution will provide greater transparency and legal certainty for data controllers and better protection of data subjects' rights.

Batteries Regulation

We express flexibility with regard to the DK Presidency proposal, i.e. amendments to recitals 18, 19, the addition of a new recital 19a and the amendment to Article 5 of the proposed Regulation, including the deletion of Article 74(5) of the EUBR.

In addition, we note changes to the reporting obligation – a return to the 3-year proposal with the addition of an obligation to review and publish policies if there is a significant change. For the sake of clarity of the wording in that regard, we propose to change the wording in Article 5 para. 2, as follows:

*‘The economic operator referred to in Article 48(1) shall, by the latest one year after the date specified in Article 48(1) and at least every three years thereafter, **and as well as** without undue delay **in each case** after a significant change occurs, review, and where necessary, update and make publicly available, including on the internet, a report on its battery due diligence policy.’.*

Comments concerning common specifications and digitalization

Common specifications: We maintain parliamentary reservation, however our assessment of the PRES's work's direction is positive. Our position is guided by two main principles: common specifications cannot be equivalent to or replace harmonized standards – it must be clear that they constitute an exception to the rule, hence they are not a common practice. Furthermore, their application should be limited in time. We support the approach of the Machine Regulation (the wording of this act is more precise than the one used in the Toy Safety Regulation).

Digitalisation: Poland submits a positive scrutiny reservation. We maintain also the parliamentary reservation.

Common specifications

The proposal to clarify the conditions for the use of common specifications is crucial. We would also like to emphasize that they should be used only in exceptional circumstances. In this context it would be useful to clarify what cases are meant to be covered by point 1a).

The proposal to take into account the opinions of stakeholders is another significant change in the development of implementing acts regarding the introduction of common specifications. The Commission should pay particular attention to the opinions of designated or appointed (assigned) expert groups and its obligation to consult the proposal with stakeholders. This last element is of particular importance, as common specifications should be developed by experts and should contain proven technical solutions, verified by the market and responding to its needs and expectations.

Another important issue is the provision allowing Member States to report justified concerns to the Commission if they consider that a common specification or parts thereof do not fully meet the specified essential requirements. To ensure legal certainty for businesses Poland believes that the provisions regarding common specifications should be as uniform as possible across all UE documents. This will minimize the risk of incorrect interpretation and application of the provisions depending on the subject matter.

Digitalization

1. Regarding „paper version of instruction” Poland believes, that instruction shall be provided with every product, to ensure it can be used. It's not possible without instruction. Therefore, any customer who buys a product and requests a paper version of the instruction, shall be provided with such a paper version at the time of purchase, not within 30 days. We also support the customer's right to request a paper version of instruction within 6 months after

the purchase of the product. The procedure for obtaining such a paper instruction shall be clearly explained in the text of directive/regulation. In this context it cannot be stated that the customer may contact the producer by post or via the Internet, as contact by post takes time and contact via the Internet is not appropriate for customer requesting a paper version of instruction.

2. Definition of Substantial Modification (definition No 16 in Machinery Regulation 2023/1230/UE) must be used also for another products:
 - a. (16) 'substantial modification' means a modification of machinery or a related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product, by creating a new hazard, or by increasing an existing risk, which requires:
 - (a) the addition of guards or protective devices to that machinery or related product the processing of which necessitates the modification of the existing safety control system; or
 - (b) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;

PORTUGAL

PT comments on small mid-caps - 04.09.2025

General:

- 1) We would prefer extending the transposition deadline to 18 months to ensure that Member States have sufficient time to implement the changes introduced by Omnibus IV into the sectoral legislation.

Batteries Regulation:

- 2) Recital 19 and Article 5: PT believes that the deadline set out in Article 52(3) of the Batteries Regulation should be aligned with Article 15 of the CSDDD, as both concern the assessment of companies' compliance with due diligence obligations. We therefore propose postponing this discussion until the deadline under the CSDDD has been established.
- 3) We support the inclusion of the concept of "significant changes" in the Batteries Regulation, as it provides greater clarity to the text.
- 4) Article 74(5): we support the proposed simplification.

ROMANIA

Please find below a RO text proposal on Omnibus IV, specifically on the 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) 2023/11542 and (EU) 2024/1781 as regards digitalisation and common specifications, specifically on Article 6 (4) - Amendments to Regulation (EU) 2023/1542:

(4) Article 38 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. When placing a battery on the market or putting it into service, including for the manufacturers’ own purposes, manufacturers shall ensure that the battery:

- (a) has been designed and manufactured in accordance with Articles 6 to 10 and Articles 12 and 14, and is, for stationary battery energy storage systems, accompanied by clear, understandable and readable instructions and safety information in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be placed on the market or put into service; and
- (b) is marked and labelled in accordance with Article 13.

The instructions and safety information for stationary battery energy storage systems may be provided in electronic form. In the case of stationary battery energy storage systems intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, the safety information.

When the instructions are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

The end-user may, at time of the purchase of the stationary battery energy storage systems, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to

the end-user, free of charge, **at the moment when the request is received**
~~within one month of receiving the request;'~~



SLOVENIA

We would like to emphasize the main points of our position, which we also expressed during the last AGS meeting on September 1, 2025:

- We believe that the transposition period for the directive of 1 year is certainly not long enough and call for at least 2 years.
- We're supportive of the PRE proposal regarding the definition of the common specifications which means that we can accept the proposed PRE wording from the recently adopted legislation on toy safety even though we were initially calling for the inclusion of the wording from the Machinery regulation.
- We would however like to express our reservation regarding the Commission's proposal on common specifications while we would still be interested in their further explanations of their proposal with concrete examples.
- We also remain supportive of the deletion of the regulation 765/2008 from the text

Written contribution of Slovenia
Omnibus IV - GDPR

General comment:

We took note of the interpretation of the Legal Service (CLS) that the references to non-legislative acts of the Commission within the definitions in EU Regulations are in principle not problematic. While such practice may occur in other areas of EU law, it is not so in the case of GDPR nor if the broader field of **fundamental rights**.

In our view, incorporating references to non-legislative acts — adopted by the executive branch — into the definitions of essential terms of a Regulation directly governing the exercise of a fundamental right is both legally questionable and institutionally inappropriate. Definitions in such an instrument form part of its essential elements, and therefore must adhere to the highest standards of legal certainty.

As we have already underlined in our previous written comments, the delegation of legislative powers to the Commission is strictly limited under the TFEU. Moreover, **legislative technique used in the GDPR should continue to be followed**: none of its definitions rely on references to external non-legislative acts. This method ensures legal clarity and predictability, which is indispensable in the regulation of fundamental rights.

Finally, we reiterate our concern that regulating matters with a impact on individuals' fundamental rights without a prior impact assessment is highly inappropriate.

Drafting proposals

In order to ensure clarity and the aim of the proposed simplification, Slovenia proposes the following amendments to the revised recitals 9 and 10:

(9) In order to reflect the above, it is necessary to amend Article 30(5) of Regulation (EU) 2016/679, by extending the scope of the derogation from the record-keeping obligation to **SMCs enterprises** and organisations with fewer than 750 employees to allow ~~also~~ them to ~~profit~~ **also benefit** from that derogation and by providing that the derogation applies unless the processing **of specific processing activities, upon assessment** in accordance Article 35 of Regulation (EU) 2016/679, is likely to result in a 'high risk' to data subjects' rights and freedoms. ~~within the meaning of Article 35 of Regulation (EU) 2016/679. In particular the processing of personal data referred to in paragraph 3 of that provision should be considered as requiring the data controller or the processor to maintain records of its those processing activities. The processing of personal data referred to in Article 35(3) of Regulation (EU) 2016/679 should be considered as requiring the keeping of records of processing activities, unless such obligation is excluded on the basis of a prior impact assessment carried out in accordance with Article 35 of Regulation (EU) 2016/679. Furthermore, it is clarified that enterprises and organisations carrying out high risk processing of personal data are only required to maintain a record of the specific processing activities likely to result in a 'high risk' to data subjects' rights and freedoms within the meaning of Article 35 of Regulation (EU) 2016/679.~~

(10) **The processing of special categories of personal data as referred to in Article 9(1) of Regulation (EU) 2016/679 and the processing of personal data relating to criminal convictions and offences as referred to in Article 10 of Regulation (EU) 2016/679 should as such require that records of processing activities be maintained unless an assessment indicates that the processing is likely not to result in a high risk. In this context,** ~~the processing of special categories of personal data which is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law, as referred to in Article 9(2), point (b), of Regulation (EU) 2016/679, would not always likely result in a high risk to data subjects, and should not as such require that records of processing activities be maintained unless an assessment indicates that the processing is likely to result in a high risk.~~

FINLAND

Omnibus IV - Digitalisation and common specifications / Antici Group on Simplification

Written comments from Finland on the IV Simplification Package, focusing on Presidency's proposals (Documents: ST 12226/25 + ST 12227/25) on digitalization and common specifications.

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. Please note that our positions are still preliminary.

General comments

Preliminary positions for the proposals:

- We mainly welcome the Omnibus IV proposal on digitalisation and common specifications. The proposals would support the simplification of regulation, digitalisation and lighten the regulatory burden on companies. We support the Commission's objectives of simplifying regulation and reducing the administrative burden. We aim to improve and reduce the burden of EU regulation.

Common specifications

- **We are positive and can in general support the Presidency's proposal for common specifications. It is very good that the Presidency proposes mainly the model from the Toy Safety Regulation here.**
- **In general, we are concerned that the references to the requirements in the Articles concerning Common Specifications are not correct. For example, in many cases the paragraph 1 refers to "essential safety requirements". However, many of the directives and regulations do not cover safety requirements. Please check the references. Also, in the last paragraph (6) the texts refer to requirements set out in Annex II. We believe that this is not a correct reference for many of the directives and regulations (it seems that this is copied from the Toy Safety Regulation, where requirements are in Annex II). Please check the references.**

COM new proposal 2608 (PDF), Common specifications

- **We do not support the Commission's new proposal for common specifications.**

- If the intention is to apply horizontally to all the sectors, we want to point out that the criteria are not sufficiently precise for the following reasons:
 - The criteria for developing a common specification should be clearly defined and foreseeable.
 - The criteria "urgent market concern" in the Commission proposal is more vague compared to Presidency's proposal and e.g. the agreement on the text of Toys Safety Regulation.
 - Also stakeholder participation would not be ensured in the Commission's proposal because paragraph 4 would not apply to the procedure in 1 b. 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 favour certain stakeholders, such as large manufacturers.

Comments on Specific Regulations

Regulations (Document st12227/25)

1) Article 3 - Amendments to Regulation (EU) 2016/425 (Personal Protective Equipment Regulation)

Comment 1 on Article 3, paragraph (2) (d), third subparagraph:

- **It would be good to emphasize the importance of the whole PPE Regulation Annex II 1.4 in Article 8 paragraph 7 subparagraph 7. by adding "all of":**

Please see under suggestion, insert in yellow:

7. In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in paragraph 1.4 of Annex II., **all of** which are related to the safe use of the PPE. Such information shall be easily visible and legible for consumers.

Background/ Reasoning. Economic operators tend to think that issues relating to safe use only mean PPE's donning instructions. Considering what is stated in new recital 9 about PPE's instructions ("the entirety of the instructions and information set out in point 1.4 of Annex II are related to the safe use of the product").

Comment 2 on Article 3, paragraph (7):

- **Proposed wording in Article 15 paragraph 5 states that where other Union legislation applicable to the PPE requires a digital product passport, the**

instructions referred to in Article 8(7) shall be provided only in that digital product passport. This is in contradiction with what is stated about paper format in Article 8 paragraph 7 subparagraph 7.

Background/ Reasoning:

According to new recital 9 about PPE's instructions and the requirement in Article 8 paragraph 7 subparagraph 7 that all information of PPE Annex II paragraph 1.4 shall be in paper format if PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them.

2) Article 6 - Amendments to Regulation (EU) 2023/1542 (Battery regulation)

- **Finland is concerned about proposal that manufacturers' obligations (Battery Regulation article 38.1) to provide instructions and safety information is limited to battery energy storages. Finland would like to hear justification for the proposal.**
- Finland considers that the manufacturers of batteries should provide instructions and safety information for all kind of batteries. Battery chemistries are developing rapidly and it is unclear whether safety concerns related to battery chemistry have been taken into account e.g. in the Low Voltage Directive or other legislation related to electric safety.
- Definition of battery in the Battery Regulation "*means any device delivering electrical energy generated by direct conversion of chemical energy, having internal or external storage, and consisting of one or more non-rechargeable or rechargeable battery cells, modules or of packs of them, and includes a battery that has been subject to preparation for re-use, preparation for repurposing, repurposing or remanufacturing*" meaning that as battery is also considered to be a single battery cell, assembled to a batteries of different battery categories. To our knowledge, most of the batteries (cells) are manufactured outside of EC.
- It is also a question of how producers (of extended producer responsibility system) can provide the information referred to in Article 74 of the Battery Regulation if manufacturers do not provide instructions and safety information in the battery supply chain.
- Also preparation for re-use, preparation repurposing, repurposing or remanufacturing make use of instructions and safety information from the original manufacturers of batteries.
- This information by manufacturers of batteries can be provided in electronic form, and for consumers as proposed in the draft.

- To our understanding also General Product Safety Regulation (EU) 2023/988 applies to batteries supplied to consumers.

Directives (Document st12226/25)

1) Article 2 - Amendments to Directive 2011/65/EU (ROHS-Directive)

Presidency's proposal

Article 2, paragraph (6):

in Article 13, the following paragraph 4 is added:

'4. Where other Union legislation applicable to EEE requires the economic operator to include the information that the product complies with the requirement set out in that legislation in a digital product passport or to upload the declaration of conformity in a digital product passport, the information required in Annex VI to be included in the EU declaration of conformity **or, as appropriate, the EU declaration of conformity, and the instructions and safety information** shall be provided only in that digital product passport.'

- There seems to be a new obligation in the RoHS directive about instructions and safety information. Currently, RoHS does not cover or set obligations for instructions.
- The electrical and electronic equipment put into the EU market (also those in the scope of the RoHS directive) do include instructions but the requirements for such instructions arise from EU regulations other than the RoHS directive. Is this new obligation intentional?
- Article 2, paragraph (7), first paragraphThe proposed new article 16a uses a term "essential safety requirements." The RoHS directive is environmental legislation and the directive does not set requirements/obligations for safety requirements.
- It seems that the intention is to seek for horizontal language across the directives for this new article but it is important to note that there seems to be a deviation from the legal basis of the RoHS directive.
- We suggest the following wording (in red):

In exceptional cases, the Commission may, ~~by means of~~ **adopt** implementing acts, ~~adopt establishing~~ common specifications ~~that enable compliance with the~~ **essential covering** requirements set out in Article 4 in any of ~~that~~ **provide a means to comply with the requirements set out in Article 4 applicable essential safety requirements**. Those implementing acts shall only be adopted where the following ~~cases~~ **conditions** are fulfilled:

2) Article 5 - Amendments to Directive 2014/30/EU (EMC- Directive)

Comment 1

- **We want to point out that the Articles, pointed here under, do not directly refer to safety requirements. We don't think it is entirely wrong, because you need to provide information so that the device can be used in accordance with its intended use.**
 - **The essential requirements** (EMC) are set out in Annex I to EMC Directive 2014/30/EU. The proposed amendment refers to the essential safety requirements in Article 5, paragraph (6) (new Article 13a). We suggest the following wording (in red) for Article 5, paragraph (6), first paragraph:

In exceptional cases, the Commission may, ~~by means of adopt~~ **adopt** implementing acts, ~~adopt establishing~~ **establishing** common specifications ~~that enable compliance with the essential covering requirements set out in Annex I in any of that provide a means to comply with the applicable requirements set out in Annex I~~ **essential safety requirements**. Those **implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

- Similar approach is in in Article 15.5, which States that the product passport must contain "the instructions and safety information referred to in Article 7(7) shall be provided only in the Digital product passport".

3) Article 6 – Amendments to Directive 2014/31/EU (Non-automatic weighing instruments Directive)

Article 6, point (6), paragraph 1:

- The Non-automatic weighing instruments Directive does not include essential safety requirements. Therefore, we suggest to change the wording in paragraph 1 to the following (suggestion in red):

In exceptional cases, the Commission may, ~~by means of adopt~~ **adopt** implementing acts, ~~adopt establishing~~ **establishing** common specifications ~~that enable compliance with the essential covering requirements set out in Annex I in any of that provide a means to comply with the requirements set out in Annex I~~ **applicable essential safety requirements**. Those **implementing acts shall only be adopted where** the following ~~eases~~ **conditions are fulfilled:**

4) Article 7 - Amendments to Directive 2014/32/EU (Measuring Instruments Directive)

Article 7, point (6)

Proposed change to MID 2014/32/EU, a new article 14a regarding Common Specifications

Article 7, point (6), paragraph 1:

- The Measuring Instruments Directive does not include essential safety requirements. Therefore, we suggest to change the wording in paragraph 1 to the following (suggestion in red):

In exceptional cases, the Commission may, by means of **adopt** implementing acts, ~~adopt~~ **establishing** common specifications ~~that enable compliance with the essential covering requirements set out in Annex I and in the relevant instrument-specific Annexes covered by~~ **that provide a means to comply with the requirements set out in Annex I and in the relevant instrument-specific Annexes applicable essential safety requirements**. Those parts of normative documents, in any ~~implementing acts shall only be adopted where~~ the following ~~cases~~ **conditions are fulfilled**:

Article 7, point (6), paragraph 2:

- The proposed new article 14a specifies condition that have to be fulfilled before the Commission may establish Common Specifications. In the proposed text, one of the conditions is that there is no Harmonised standard covering these products.
- An existing Normative Document would therefore NOT prevent establishing a Common Specification. This would alter the position of Normative Documents as described in Article 14.
- In the MID, normative documents have, in principle, the same status as harmonised standards in demonstrating the conformity of products (article 14). Normative documents are based on OIML Recommendations, that are commonly used as international standards in legal metrology.
- The proposed *Common Specifications* in the MID would put normative documents in a different position: *common specifications* could be drawn up under the new proposed Article 14a of the MID, despite the existence of a normative document published in the Official Journal. **We do not see this as a good development.**

Suggestion for alternative wording for proposed article 14a point 1 (a):

- (a) **there is no harmonised standard or normative document covering those requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of**

~~normative documents are not covered by harmonised standards, or parts thereof, the references~~ **the reference** of which have been published in the Official Journal of the European Union **and no such reference is expected to be published within a reasonable period;**

Finland Comments - Omnibus IV - Small mid-caps

- We welcome the opportunity to provide written comments. Please note that our positions are still preliminary.

Articles 1, 2, 3 and Recital 5 – Definition of Small Mid-Caps and Extension of Regulatory Relief

- For Articles 1 and 2
 - *We support the regulatory simplifications originally designed for SMEs to cover also SMCs. We recognise that SMCs are often innovative and agile but face more barriers to grow than larger firms.*
- Article 3
 - *No specific comment, but generally we generally support simplification and swift implementation of EU regulation.*
- Recital 5 – Extension of Regulatory Relief to SMCs
 - *We support extending regulatory and reporting reliefs to SMCs, but emphasize that the new definition should not undermine existing SME rights and not be used for financial support schemes.*

1) The Prospectus Regulation, MiFID II, the Anti-Subsidised Imports Regulation and the Anti-Dumping Regulation

- Articles 4, 7 and Recitals 8–11, 13, 16–17 – Amendments to Sectoral Regulations
 - Generally:
 - *We welcome these Presidency proposals, especially where they reduce reporting obligations and simplify procedures without compromising investor protection or data privacy.*
 - Article 4 and Recitals 8–9 – Thresholds for SMC Definition
 - *We support the use of the SMC definition from 250 to 749 employee companies and that the definition is used only for administrative simplification, not for financial instruments.*
- a. Recitals 14, 16, 17 - Prospectus Regulation
 - *We support the broadened scope of the shortened EU growth prospectus model to facilitate capital market access for SMEs and SMCs. And we also support*

the Presidency proposal to clarify exemptions related to bail-in instruments and to remove unnecessary references.

b. Article 1 and Recital 8 - Markets in Financial Instruments Directive II (MiFID II)

- *No specific comment, but generally we support tailoring regulation to company size and scope, but we highlight the potential impacts on smaller national markets.*

c. Recital 13 - Anti-Subsidised Imports Regulation and the Anti-Dumping Regulation

- *We support simplification and reduction of administrative burdens, especially for SMEs and support presidency's clarification.*

2) **Articles 5–6 and Recitals 18–20a – Battery Regulation, F-Gas Regulation and the General Data Protection Regulation (GDPR).**

a. Recitals 18–19 and Article 5 - Battery Regulation

- *We are in favour of PCY proposal to maintain the proposal from the Commission concerning the frequency of reporting (of Due Diligence obligations) at three years. We support insertion of the definition “significant change” to the text.*

- Article 74(5) – Battery Regulation

- *We can also support the new proposal from one MS to delete Article 74(5) from the Battery Regulation.*

b. Articles 6(1–2) and Recital 20 F-Gas Regulation

- *We support reducing reporting obligations and improving regulatory clarity.*

c. Recitals 8–11 and Article 1(2) and Article 30 (5) General Data Protection Regulation (GDPR)

- *We stress the need to ensure that the proposed amendments to Article 30(5) GDPR as well as the recital text will not lead to a situation where the current level of protection for special categories of personal data is compromised.*
- *We would still prefer to keep the wording “unless an assessment indicates that the processing is likely to result in a high risk” in recital 10, but we can be flexible in finding a compromise.*
- *In order to find a solution, we propose to amend the text in recitals 9 and 10 (highlighted below in yellow).*
- *If the “unless -- is likely to result in a high risk” must be deleted, we should add in recital 10 that it is “upon a data protection impact assessment” or at least “upon an assessment”. This would underline that the controller should carry out an appropriate assessment.*

- *In addition, we would prefer in recital 9 “a data protection impact assessment”.*
- *We would also like to point out that the simplest solution would be to delete recital 10 altogether, as the current text in recital 9 (see below) already clarifies the amendments proposed to Article 30(5) of the GDPR. We have concerns with recital 10, because the example might lead to a lower level of data protection for special categories of data, if understood incorrectly.*
- *Concerning the proposed amendments to recital 5, we have similar concerns than what the COM brought up yesterday. The amendments in recital 5 are problematic, because it could be understood that the level of data protection would be changed. This is not the aim and FI does not support amendments that would endanger the current level of data protection. Therefore we propose to delete some of the proposed texts in recital 5. The aim of the proposal is to reduce administrative burden.*

(5) Compared to SMEs, SMCs tend to demonstrate a higher pace of growth, and level of innovation and digitisation. Nevertheless, where administrative burden is concerned, they face similar challenges as SMEs, leading to a need for proportionality in legislation and for targeted support. To enable the smooth transition of SMEs into SMCs, it is important to address in a coherent manner the cliff-effect that may arise once they outgrow the segment of SMEs and are faced with rules that apply to large enterprises. In order to achieve the overarching objective of facilitating the operation of businesses and the internal market, with a particular focus on SMCs, a number of existing acts should be adjusted. ~~Each of these adjustments pursues the specific objective of adjusting the level of protection in the relevant Union act, thereby contributing to that overarching objective. In particular,~~ to make business easier for SMCs and reduce their administrative burden, a number of existing acts which provide for specific mitigating rules for SMEs should be adapted to extend the scope of those provisions and include SMCs, while still supporting the existing rights at European level for SMEs. In addition, certain other adjustments should be made with a view to reducing the burden on businesses, including in particular SMCs.

(9) In order to reflect the above, it is necessary to amend Article 30(5) of Regulation (EU) 2016/679, by extending the scope of the derogation from the record-keeping obligation to ~~SMC~~enterprises and organisations with fewer than 750 employees to allow also them to profitalso benefit from that derogation and by providing that the derogation applies unless the

processing, upon a data protection impact assessment, is likely to result in a 'high risk' to data subjects' rights and freedoms, within the meaning of Article 35 of Regulation (EU) 2016/679. In particular the processing of personal data referred to in paragraph 3 of that provision should be considered as requiring the data controller or the processor to maintain records of ~~the~~ those processing activities. Furthermore, it is clarified that enterprises and organisations carrying out high-risk processing of personal data are only required to maintain a record of the specific processing activities likely to result in a 'high-risk' to data subjects' rights and freedoms within the meaning of Article 35 of Regulation (EU) 2016/679.

(10) In this context, the processing of special categories of personal data which is necessary for the purposes of carrying out the obligations and exercising specific rights of the controller or of the data subject in the field of employment and social security and social protection law, as referred to in Article 9(2), point (b), of Regulation (EU) 2016/679, would not always, upon [a data protection impact] an assessment, likely result in a high risk to data subjects, and should not as such require that records of processing activities be maintained [unless an assessment indicates that the processing is likely to result in a high risk].

PUBLIC

SWEDEN

General Comment:

As previously expressed at the AGS, Sweden supports the initiative to simplify and digitalise the EU's product legislation. We favour amendments that are clear, technologically neutral, and consistent across the various legal acts, in line with the spirit of the New Legislative Framework (NLF).

On Common Specifications:

Sweden welcomes the Presidency's compromise proposal based on the Toy Safety Regulation. However, we are not in a position to go beyond this and therefore cannot support the Commission's proposal presented on 1 September.

Specific Comment on Article 6(4):

Could the Commission clarify the proposed amendment to Article 38 in the Battery Regulation concerning manufacturers' obligations, and explain why there are no corresponding changes to the requirements for importers and distributors under Articles 41 and 42? In the Commission's previous response, it is stated that other legislation is sufficient when it comes to instructions for use and safety information for battery types other than stationary battery systems. Is this possibility comprehensive, considering the exemption options available in, for example, the General Product Safety Regulation? Furthermore, how does the amendment to Article 38 align with the requirements for LMT batteries in Article 11.1, which presumably applies to all actors placing batteries on the market, including importers and distributors?
