

Brussels, 18 September 2025

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

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WORKING DOCUMENT

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

Subject:	Omnibus IV - MS compiled comments (Small mid-caps, digitalisation and common specifications)
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Delegations will find enclosed compilation of MS comments as received from BE, CZ, DE, ES, FR, IT, LT, HU, AT, PL, SI, FI and SE on the Omnibus IV (Small mid-caps, digitalisation and common specifications).

Omnibus IV
MS compiled comments (Small mid-caps, digitalisation and common specifications)
Deadline: 15 September 2025

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Brussels, 5 September 2025
(OR. en)

12523/25

Interinstitutional File:
2025/0134 (COD)

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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	12227/25
No. Cion doc.:	9318/25 + ADD 1
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 - Revised Presidency compromise text

Delegations will find in the Annex a revised Presidency compromise text in relation to the above proposal, for examination at the meeting of the Antici Group (Simplification) on 11 September 2025.

Additions to the previous Presidency compromise text as set out in document 12227/25 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) 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

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.

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, **harmonisation** 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

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 **in electronic form**. The manufacturer ~~will~~**should therefore** 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, **additional applications specific to the economic operator** or the obligation to register solely to access the EU declaration of conformity. *In the current state of the art, the use of email addresses seems to be the best solution for accessing the EU declaration of conformity/instructions electronically*

Commented [IV1]: Must this be still included as in recital 9 it is canceled

(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 becoming less important and not aligned with current technologies, the practices of consumers or 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 protect the safety of~~**specific safeguards for consumers should ensure that they, as lay persons, are still able to access and understand the information, in contrast to professional users, who are expected to possess the expertise and knowledge necessary for the correct use and handling of products.** ~~the Safety information, including instructions having an impact on product safety, should~~**the safe use of the products,**

Commented [IV2]: Lay persons ?

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.

might be provided in digital format where a product is used solely by professional users, namely persons acquiring the product as professional end users in the course of their industrial or professional activities. However, where it is reasonably foreseeable that a product, even if primarily intended for professional use, could also be used by consumers, manufacturers should provide the safety information in paper format or marked mark it directly on the product. The definition of ‘consumer’ forms part of the notion of ‘end user’ as laid down in Regulation (EU) 2019/1020 on market surveillance, which applies to the Regulations concerned, and refers to any natural person acting for purposes outside their trade, business, craft or profession. This requirement ensures that all consumers, including vulnerable consumers such as elderly persons, persons with disabilities or those with limited digital literacy, are able to access and understand the safety information. Such information should therefore be easily visible and legible, thereby guaranteeing a high level of consumer protection and safeguarding public safety. Instructions and safety information provided in digital format should be directly accessible in line with Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council¹¹ through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading an application, additional applications specific to the economic operator 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. 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 purchase and for a certain period of time after their purchase.

- (8a) 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

¹¹ Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70, ELI: <http://data.europa.eu/eli/dir/2019/882/oj>).

- (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~~**contact** economic operators directly, and should be accessible free of charge, without the ~~obligation to provide~~**need for providing any** personal data, ~~download~~**downloading** additional ~~specific~~ applications ~~specific to the economic operator~~ or the obligation to register solely to contact the economic operator. Importantly, the requirement should also exclude the use of third-party applications not operated by the economic operator (such as instant messaging services), in order to ensure that digital contact remains accessible through standard devices, typically preconfigured with an internet browser, without obliging users to install additional dedicated applications. Such digital contact may include, for example, an email address or ~~a contact form on a website~~**other direct means of digital communication without intermediate steps and allowing for traceability of exchanges**. 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~~**of the European Parliament and of the Council**¹², 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, 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,

¹² **Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/988/oj>).**

in paper or electronic form. The paper-based form is 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, **in particular SMEs**, 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 Council¹³, represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety requirements of the Regulations ~~amended by this Regulation~~ **concerned**. However, in the ~~absence~~ **absence** of relevant references to harmonised standards~~;~~, 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~~ **concerned**, 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 requirements of the Regulations ~~amended by this Regulation~~ **concerned**.
- (12) As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542¹⁴, 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

¹³ 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>).

¹⁴ 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>).

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.

- (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) 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) 2016/424, (EU) 2016/425, (EU) 2016/426, (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) 2016/424, (EU) 2016/425, (EU) 2016/426, (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 contacted without the need to register or to download additional specific applications for the purpose of this contact, whether they are operated by specific to the economic operator or not.~~ means any up-to-date and freely accessible online communication channel such as email addresses through which economic operators can be contacted or engaged without the need to register or to use an application ~~download additional applications specific to the economic operator.~~’

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

‘(19a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~specifications~~ **specification**, other than a standard, that provide means of complying with the essential requirements set out in Annex II of this Regulation applicable to a 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 of the subsystem or safety component 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 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 **directly** accessed without the need to register, to download a ~~specific~~ application, or to provide any personal information in any form, and by the instructions and safety information, in a language which can be easily understood by 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 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 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 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 without the need to register, to download a ~~specific~~ application, or to provide any personal information in any form.

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 **directly** access them ~~directly~~ and how to request them in paper format;
- (b) present them in a format that makes it possible for the user to print and download the instructions and safety information and save them on an electronic device without the need to register, to download a ~~specific~~

application, or to provide any personal information in any form so that the 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 user may, at time of the purchase of the subsystem or the safety component, at any time during the expected lifetime of the product or at least 10 years after that purchase or up to six months after that purchase, request the instructions or safety information in paper format and linked to the correct unit of the purchased subsystem or safety component. Where the user requests those instructions or safety information, the manufacturer shall provide them to the 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 **directly** accessed without the need to register, to download a specific ~~an~~ application, or to provide any personal information in any form 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).;

Commented [WV3]: This was deleted in comparison with the previous tekst. This should stay

(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 **directly** accessed without the need to register, to download a specific ~~an~~ application, or to provide any personal information in any form, 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 adopt implementing acts establishing common specifications ~~covering requirements~~ 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 conditions are fulfilled:
 - (a) there is no harmonised standard covering those requirements the reference of which is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;
 - (b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft or to revise European standards for those requirements 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 examination procedure referred to in Article 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 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:

- ‘5. Where other Union legislation applicable to the subsystem or safety 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 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 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 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 **directly** 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 contacted ~~or engaged~~ without the need to register or to download an application; **additional applications specific to the economic operator;**’

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

‘(10a) ‘common ~~specifications~~ **specification**’ means a ~~set of~~ technical ~~specifications~~ **specification**, other than a standard, that provides a means of complying with the essential requirements set out in Annex II of this Regulation applicable to 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 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 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 **directly** 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 without the need to register, to download an application, or to provide any personal information in any form 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 at any time during the expected lifetime of the product or at least 10 years after that purchase~~up to six months after that purchase~~, request the instructions and

information set out in point 1.4 of Annex II in paper format and linked to the correct unit of the purchased PPE. 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 **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:

(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 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 adopt implementing acts establishing common specifications covering requirements 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 conditions are fulfilled:
 - (a) there is no harmonised standard covering those requirements the reference of which is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;
 - (b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft or to revise European standards for those requirements 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 examination procedure referred to in Article 44(3).

2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential 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 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. **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).’

(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*, 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.

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 contacted ~~or engaged~~ without the need to register or to ~~use an application~~ **download additional applications specific to the economic operator;**

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

‘(23a) ‘common specifications specification’ means a ~~set of~~ technical ~~specifications~~ **specification**, other than a standard, that provides a means of complying with the essential requirements set out in Annex I of this Regulation applicable to 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 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 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 ~~an 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 **accessed and that it is accompanied by** 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 **or 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.’;’

- (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 **accessed** 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 **accessed** 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 **accessed**, 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 adopt implementing acts establishing common specifications ~~covering requirements~~ 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 requirements the reference of which is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;
 - (b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft or to revise European standards for those requirements 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 examination procedure referred to in Article 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 **accessed**.;

(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 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 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 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 **directly** accessed;’²

(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 contacted ~~or engaged~~ without the need to register or to ~~use an application~~ **download additional applications specific to the economic operator;**’

(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~~ **electronic form**, in accordance with Article 21 and affix the CE marking in accordance with Article 24.’

(aa) 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, website and 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:

‘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 **accessed**.;’

(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~~**electronic form**, 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~~**electronic form**, 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 **accessed**.;’

(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~~**electronic form**, 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~~**electronic form**, 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~~electronic form, 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 **directly** 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~~electronic form, 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~~electronic form, 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 required in Article 21 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).;~~’

(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 required in Article 22 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.’

(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~~ electronic form.;’

(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 contacted ~~or engaged~~ without the need to register or to ~~use an application.~~ **download additional applications specific to the economic operator;**

(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 **or 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:

(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 contacted ~~or engaged~~ without the need to register or to ~~use an application;~~ **download additional applications specific to the economic operator;**’
- (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.’

- (6a) 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~~30 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:

Commented [WV4]: Point 5.2 of Annex IV refers to a written EU declaration of Conformity. This needs to be modified

‘(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;’

~~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.’~~

(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

Commented [WV5]: Point 6.2 of Annex V refers to a ‘written’ declaration of conformity. This needs to be modified.

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.;;’

Commented [WV6]: Point 4.2 of Annex VI refers to a ‘written’ DoC. This needs to be modified

(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;;’

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

Commented [WV7]: Point 5.2 of Annex VII refers to a ‘written’ DoC. This needs to be modified

~~‘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 **directly** 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 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;’

~~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:

Commented [WV8]: + Point 6.2 of Annex VII refers to a ‘written’ EU DoC. This should be ‘digital’ EU DoC

Commented [WV9]: + Point 5.2 of Annex VIII refers to a ‘written’ EU DoC. This should be ‘digital’ EU DoC

‘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;’

~~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.’

(1) 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.’

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 **directly** 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;’

Commented [WV10]: + Point 5.2 of Annex IX refers to a ‘written’ EU DoC. Written should be deleted.

Commented [WV11]: + Point 5.2 of Annex X refers to a ‘written’ EU DoC. Written should be deleted.

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).’

Furthermore, I can share that BE can show flexibility on the DE request concerning the extension of the ESPR deadline. We might voice support in Coreper, if this would help consensus building

CZECHIA

Omnibus IV – digitalization and common specifications

Documents ST 12523/25 and ST 12524/25

For the Czech Republic, the wording of the text is **generally acceptable** in its submitted form.

In the case of **common specifications**, however, **we request** the relevant provisions to be aligned with the final version of the Toy Regulation after legal-linguistic revision, as specified below.

Furthermore, our comments concern the **transitional provisions**, and we propose **technical amendments** to the text of certain provisions, as outlined below.

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 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— is 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 **strongly supports** extending the deadline for the directive's entry into force to 24 months. Furthermore, **we consider it necessary** to add in the draft regulation's relevant article (Article 9 - Entry into force and application) its effective date—the date from which the regulation will be applied. "

Further technical amendments to the text of the draft Regulation

Article 3

Amendments to Regulation (EU) 2016/425

(2) Article 8 is amended as follows:

(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. **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."

Category 3 should be accessible in paper format; the use of these products can cause death.

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)

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

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

Basic requirements mentioned in annex of regulation (EU) 2016/426 relate also to fitting.

2) Article 7 is amended as follows:

(a)

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

‘Changes in appliance ~~or fitting~~ **or a 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.’

Removing 'or fitting' is inconsistent with the rest of the text in the paragraph.

Article 5

Amendments to Regulation (EU) 2023/1230

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

(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);’ ~~This does not affect the obligation to provide the safety information in paper format according to Article 10(7);~~ **This does not affect the obligation to provide the safety information in paper format according to Article 10(7);**

The final sentence is relevant and should be kept in the text to ensure the paragraph is not misunderstood to mean that the manufacturer will no longer have to provide safety information in paper form. This obligation, as regulated by Article 10(7) of Regulation 2023/1230, remains.

Article 7

Amendments to Regulation (EU) 2024/1781

The Czech Republic supports Germany’s request, endorsed by some other Member States, to amend Article 7 of the draft Regulation that modifies the ESPR, thereby extending the transitional period for Article 79(1) of the ESPR by two years.

Further technical amendments to the text of the draft Directive

Article 2

Amendments to Directive 2011/65/EU

(7) The following Article 16a is inserted:

‘Article 16a

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 conditions are fulfilled:

The current text of Directive 2011/65/EU does not include the term 'essential safety requirements'; it only refers to 'requirements'.

Article 5

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

(6) the following Article 13a is inserted:

‘Article 13a

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 conditions are fulfilled:

The current text of Directive 2014/30/EU does not include the term 'essential safety requirements'; it only refers to 'essential requirements'.

Article 8

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(2) Article 7 is amended as follows:

(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

Lifts are not being packed, so in this case the use of term 'on its packaging' is not accurate.

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

GDPR

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 activities¹⁵ 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 ~~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, **upon data protection impact 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.***

¹⁵ See Article 35(7) GDPR. EDPB Guidelines for DPIA are more than 20 pages long; EDPB position on Article 30(5) has two pages.

GERMANY

DE Proposals on Omnibus IV – 2nd Presidency compromise text from 08/09/25

1. On Art. 7 of the Omnibus (Art. 79 ESPR):

DE calls for a one-time extension of the transition period specified in Article 79(1)(a)(i) of the Ecodesign Regulation (EU) 2024/1781 by two years (until December 31, 2028). We have already distributed a one-pager on this subject, which sets out DEU's specific request and the reasons for it.

2. On the Battery-Regulation:

DE regrets that the provision in Article 74(5) is now to remain unchanged. From the German perspective, a provision on the indication of disposal costs, analogous to Article 14(1) of Directive 2012/19/EU, would have been a good compromise.

Nevertheless, DE can go along with the compromise text tabled by the PRES. With a view to our common objective of reducing administrative burdens, we hope that Article 74(5) BattVO will be revisited in the course of the trilogue or under the environmental omnibus.

3. On the Directive on non-automatic weighing instruments (NAWID):

DE calls to include the option of an electronic receipt in Directive 2014/31/EU.

SPAIN

1. Regulation (EU) 2016/424

Amendment (8) introduces a new paragraph in Article 19. It states that, when a subsystem or safety component is covered by another legislative act requiring the inclusion of the declaration of conformity and instructions in the digital product passport, the safety information referred to in Article 11.7 shall only be provided through that digital product passport.

Question: Does this mean that users will no longer be able to request the instructions in paper format within six months after purchase? Clarification is required.

General note: This issue affects all amended Regulations and Directives (except Directive 2000/14). All of them recognise the user's right to request information in paper format up to six months after purchase. However, if the product is subject to legislation requiring the digital product passport, it appears that the information may only be provided digitally. A consistent clarification is needed.

2. Regulation (EU) 2016/425

- **Art. 8.7:** establishes that, for products intended for consumers, certain instructions and safety information must be delivered in paper format.
- **Art. 15.5 (amendment 7):** states that, where the digital product passport applies, all information shall only be made available in that passport. Safety information in Annex II.1.4 is exempted, but instructions are not mentioned.

This contradicts Article 8.7 and recital 8a. Clarification is required.

3. Directive 2014/30/EU and others

Amendment (8) to Article 15 on the digital product passport does not provide the exception already included in other legislation (e.g. Directive 2014/29/EU or Regulation 2016/426), where the digital-only obligation does not apply to safety information that must be given in paper format when the product is intended for consumers.

The criterion should be uniform:

- If only safety information must be on paper → remove the obligation to also include instructions.
- If instructions must also be on paper → this should always apply, with or without a digital product passport.

Spain insists that, at a minimum, safety information must always be provided in paper format for products intended for consumers, regardless of the existence of a digital product passport.

4. Transposition deadlines

In Article 15 of the Directive: since the transposition deadline has been extended from 12 to 18 months (a measure we support), the second paragraph should also be amended accordingly for consistency.

5. Regulation (EU) 2016/425 on PPE – Observation on Article 8.7 and recital 8a

The Ministry of Labour has flagged a possible contradiction between Article 8.7, third paragraph, and recital 8a of the amended text.

- **Article 8.7, third paragraph:** provides that, in the case of PPE intended for consumers (or reasonably foreseeable to be used by them), the manufacturer must supply in paper format only the information related to safe use set out in Annex II, point 1.4, or make it visible on the packaging.
- **Recital 8a:** states that the entire content of Annex II, point 1.4, relates to safe use of the product, and therefore all of it should be provided in paper format or on the packaging when the PPE is intended for, or may foreseeably be used by, consumers.

This creates a discrepancy:

- The **Article** appears to limit the obligation to only part of point 1.4.
- The **Recital** interprets the whole of point 1.4 as safety information.

This generates legal uncertainty and risks divergent interpretations in the market.

Proposed correction:

It should be clarified whether:

- a) The entire content of Annex II, point 1.4, constitutes safety-related information (as recital 8a indicates), or
- b) Only part of Annex II, point 1.4, is considered “safety information” (as suggested by Article 8.7). In that case, the specific parts should be explicitly identified.

Spain considers it essential to resolve this contradiction in order to ensure legal certainty and avoid market distortions.

Comentarios de ES

1. Reglamento (UE) 2016/424

La modificación (8) introduce un nuevo párrafo en el artículo 19. Este dispone que, cuando un subsistema o componente de seguridad esté cubierto por otro acto legislativo que obligue a incluir la declaración de conformidad e instrucciones en el pasaporte digital del producto, la información de seguridad del artículo 11.7 solo se proporcionará a través de dicho pasaporte digital.

Duda: ¿significa esto que los usuarios ya no podrán solicitar las instrucciones en papel dentro de los seis meses posteriores a la compra? Se requiere una aclaración.

Nota general: Esta cuestión afecta a todos los reglamentos y directivas modificados (salvo la Directiva 2000/14). En todos ellos se reconoce el derecho del usuario a requerir la información en papel hasta seis meses después de la compra. Sin embargo, si el producto está sujeto a legislación que impone el pasaporte digital, parece que la información solo puede suministrarse en formato digital. Es necesaria una aclaración coherente.

2. Reglamento (UE) 2016/425

- Art. 8.7: establece que, para productos destinados a consumidores, determinadas instrucciones e información de seguridad deben entregarse en papel.
- Art. 15.5 (modificación 7): indica que, si aplica el pasaporte digital, toda la información estará únicamente en dicho pasaporte. Se exceptúa la información de seguridad del Anexo II.1.4, pero no se menciona a las instrucciones.

Esto entra en contradicción con el art. 8.7 y el considerando 8a. Se requiere aclaración.

3. Directiva 2014/30/UE y otras

En la modificación (8) del art. 15, sobre pasaporte digital, no se prevé la excepción ya recogida en otras normas (ej. 2014/29/UE o 2016/426), donde la obligación digital no se aplica a la información de seguridad que debe darse en papel cuando el producto se destina a consumidores.

El criterio debería ser uniforme:

- Si solo la información de seguridad va en papel → eliminar la obligación de incluir también las instrucciones.
- Si también deben ir las instrucciones → mantenerlo en todos los casos, con o sin pasaporte digital.

España defiende que, al menos, la información de seguridad siempre se proporcione en papel para productos destinados a consumidores, independientemente del pasaporte digital.

4. Plazos de transposición

En el artículo 15 de la Directiva: dado que el plazo de transposición ha pasado de 12 a 18 meses (medida que apoyamos), también debe modificarse el segundo párrafo en coherencia.

5. Reglamento (UE) 2016/425 sobre EPI – Observación sobre artículo 8.7 y considerando 8ª

El Ministerio de Trabajo nos traslada un comentario adicional que señala una posible **contradicción** entre el artículo 8.7, párrafo tercero, y el considerando 8a del texto modificado.

- **Artículo 8.7, párrafo tercero:** establece que, en el caso de EPI destinados a consumidores (o que puedan ser usados por ellos), el fabricante debe proporcionar en papel **solo la información relacionada con el uso seguro** recogida en el punto 1.4 del Anexo II, o bien hacerla visible en el embalaje.
- **Considerando 8a:** indica que **todo el contenido del punto 1.4 del Anexo II** está relacionado con el uso seguro del producto, por lo que debería proporcionarse íntegramente en formato papel o en el embalaje cuando el EPI vaya destinado a consumidores (o pueda ser usado por ellos).

En la práctica, esto genera una discrepancia:

- El **artículo** parece limitar la obligación solo a parte de la información del punto 1.4.
- El **considerando** entiende que la totalidad del punto 1.4 constituye información sobre seguridad.

Esto crea incertidumbre jurídica y riesgo de interpretaciones divergentes en el mercado.

Propuesta de corrección:

Debe aclararse si:

a) Todo el contenido del punto 1.4 del Anexo II es información relativa al uso seguro (como dice el considerando 8a), o

b) Solo una parte se considera “información de seguridad” (como sugiere el artículo 8.7). En este caso, sería necesario precisar qué parte concreta entra en esa categoría.

España considera imprescindible resolver esta contradicción para garantizar seguridad jurídica y evitar distorsiones en el mercado.

Finally, we do not have any further comments on Fluorinated Gases as we have understood the arguments of the COM and the juridical Service on art. 22 and we do not have either any further comments on the last version of the common specifications’ regulation.

FRANCE

Objet : Commentaires écrits des autorités françaises à la suite de la réunion du Groupe Antici Simplification Omnibus IV du 11 septembre.

Réf. : st12523.en25 et st12524.en25

1. Commentaires portant sur l'omnibus IV numérisation et spécification communes

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 11 septembre 2025 la Présidence a transmis ses deuxièmes 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 :

- **Sur la partie numérisation**, les autorités françaises souhaitent que les éléments suivants soient intégrés à ce deuxième compromis :

- **Définition du « digital contact »** : Les autorités françaises estiment que la nouvelle proposition de définition « digital contact » dans ce 2^{ème} compromis pourrait apparaître trop restrictive. En effet, le contact numérique devrait pouvoir être joint sans qu'il soit nécessaire d'utiliser ou de télécharger une application. La définition de ce 2ème compromis limite la restriction au cas du téléchargement d'une application propre à l'opérateur économique, alors qu'elle devrait s'appliquer de manière générique à toute application. À cet égard, les autorités françaises suggèrent de revenir à la rédaction proposée dans le premier compromis de la Présidence, en remplaçant le terme « download » par « use », qui offre une portée plus adaptée à l'objectif poursuivi.

'digital contact' means any up-to-date and freely accessible online communication channel such as email addresses through which economic operators can be contacted or engaged without the need to register **or to use an application download additional applications specific to the economic operator;**

- S'agissant **des notions d'instructions et d'informations relatives à la sécurité**, les autorités françaises soulignent l'importance de clarifier ce qui relève des instructions fournies sous format électronique et des informations de sécurité fournies sous format papier. Dans ce cadre, elles proposent de modifier le considérant 8 comme suit :

(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 becoming less important and not aligned with current technologies, the practices of consumers or 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 protect the safety of specific safeguards for consumers **should ensure that they, as lay persons, are still able to access and understand the information, in contrast to professional users, who are expected to possess the expertise and knowledge necessary for the correct use and handling of products.** the Safety information, **including instructions having an impact on product safety, should the safe use of the products, that is essential for installing and mounting, putting into service, using and maintaining the product safe way,** might be provided in digital format where a product is used solely by professional users, namely persons acquiring the product as professional end users in the course of their industrial or professional activities. However, where it is reasonably foreseeable that a product, even if primarily intended for professional use, could also be used by consumers, manufacturers should provide

- Enfin concernant le règlement 2016/425, les autorités françaises insistent sur 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 :

“ 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.”

- **Sur le volet des spécifications communes, les autorités françaises se déclarent favorables aux aménagements proposés par la Présidence dans ce deuxième compromis.** Celui-ci précise explicitement les conditions de recours aux spécifications communes en tant que solution de repli, tout en introduisant des dispositions visant à assurer la cohérence avec les normes harmonisées, ainsi que la définition proposée du terme « spécification commune ».

Concernant les articles relatifs aux spécifications communes, elles suggèrent toutefois que les ajustements suivants soient intégrés :

- Au point (2) les cas « *(b) do not comply with the request* » et « *(c) do not satisfy the requirements they aim to cover* » sont redondants, le cas (c) n'apportant pas de valeur ajoutée par rapport au (b) , les autorités françaises demandent sa suppression :

(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;~~

- Au point (6), les autorités françaises demandent d'ajouter la possibilité de supprimer, en plus d'amender, un acte d'exécution établissant des spécifications communes, lorsque tout ou partie de celui-ci a été signalé par un Etat Membre :

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 ~~or withdraw~~ the implementing act establishing the common specification in question.';

Enfin, la France ne souhaite pas étendre le champ de l'omnibus à d'autres textes, au-delà de l'objectif de numérisation et spécifications communes de la proposition de la Commission.

2. Commentaires portant sur l'omnibus IV volet small midcaps

Les autorités françaises remercient la Présidence pour la suppression de la disposition visant à supprimer l'article 74(5) du règlement batteries.

ITALY

DIGITALIZATION

COMMENT 1

Recital (12)

As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542¹⁴, it is essential to require economic operators to store the information contained in the EU declaration of conformity and ~~instructions~~ **compliance documents** 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~~ **compliance documents** 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.

COMMENT 2

GENERAL NEED FOR TEXT ALIGNMENT

The principle is that Italy would like that the end-user should be able to obtain **a paper copy at the time of purchase** should be preserved in all the subsequent articles, **as already stated in the recital 8.**

Recital (8)

[...] 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 purchase and for a certain period of time after their purchase.**

As an example of need for alignment:

Article 2 Amendments to Regulation (EU) 2016/424

Art. 2(d)(7)(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 user may, at time of the purchase of the subsystem or the safety component, or up to six months after that purchase, request the instructions or safety information in paper format. Where the user requests those instructions or safety information, the manufacturer shall provide them to the user, free of charge **at the time of the purchase and within one month of receiving the request;**

COMMENT 3 PROSPECTUS

It is a limited draft proposal which we believe could better clarify the scope of the exemption, which must be limited exclusively to intermediaries under resolution.

The **amendments to Article 1, paragraph 4 of the Prospectus Regulation** are as follows:

in the case of the offer:

(dc) an offer of securities resulting from the conversion or exchange of other securities, own funds or eligible liabilities by a resolution authority due to the exercise of a power referred to in Article 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or the exercise of a power referred to in Article 35(1), Article 39(2) or Article 42(1) of Directive (EU) 2025/1 of the European Parliament and of the Council () or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings, **provided that such an offer is carried out within a resolution action or within the exercise of the write down or conversion powers;***

for admission to listing (art.1, paragraph 5 of the Prospectus Regulation)

*(c) securities resulting from the conversion or exchange of other securities, own funds or eligible liabilities by a resolution authority due to the exercise of a power referred to in Article 53(2), Article 59(2) or Article 63(1) of Directive 2014/59/EU or the exercise of a power referred to in Article 35(1), Article 39(2) or Article 42(1) of Directive (EU) 2025/1 or by a relevant third-country authority due to the exercise of a comparable power in third-country resolution proceedings, **provided that the admission to trading on a regulated market of such securities is carried out within a resolution action or within the exercise of the write down or conversion powers;***

Recital (16)

[...] Equally, the existing exemption for the admission to trading on a regulated market of securities resulting from a conversion [...] should be extended to securities resulting from a conversion due to

the exercise of a comparable power in third-country resolution proceedings that implements those internationally agreed standards, clarifying that such an exemption, as well as the new exemption related to the public offer, could only be applied in the context of a resolution action, or in the context of the exercise of the write down or conversion powers.

LITHUANIA

Lithuanian comments on Omnibus IV (Digitalisation and Common specification) Directives and Regulations.

Additions are marked [with this color](#).

1. Suggestion for clarification in **Recital 8 for the Accessibility act** (both to regulation and directive):

-----The definition of ‘consumer’ forms part of the notion of ‘end user’ as laid down in Regulation (EU) 2019/1020 on market surveillance, which applies to the Regulations concerned, and refers to any natural person acting for purposes outside their trade, business, craft or profession. This requirement ensures that all consumers, including vulnerable consumers such as elderly persons, persons with disabilities or those with limited digital literacy, are able to access and understand the safety information. Such information should therefore be easily visible and legible, thereby guaranteeing a high level of consumer protection and safeguarding public safety.

Instructions and safety information provided in digital format should be directly accessible ~~in line with Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council~~² ~~through an internet address or a machine-readable code, free of charge, without the need for providing any personal data, downloading additional applications specific to the economic operator or the obligation to register solely to access the instructions and safety information, in particular by taking into account the requirements set out in Annex I of Directive (EU) 2019/882 of the European Parliament and of the Council, insofar as the products fall within the scope of that Directive, so as to ensure usability by all end-users, including persons with disabilities.~~

Instructions and safety information 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 additional applications specific to the economic operator 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 purchase and for a certain period of time after their purchase.

Justification: 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. Reference to an Accessibility Act in the recitals should remain, in regard of legislations which are amended by Proposal and regulating the products where Accessibility Act is applicable. Even if the Accessibility Act doesn't cover every product in Omnibus

IV, keeping it in the text ensures that manufacturers provide digital instructions in an inclusive way wherever the Accessibility Act applies. To reflect the fact, that Accessibility Act has limited scope in comparison to Proposal, we suggest stating this: “**insofar as the products fall within the scope of that Directive**”.

2. Suggestion for 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~~ an email address through which economic operators can be reached or ~~engaged~~ contacted without the need to register or to ~~use an application~~; download additional applications specific to the economic operator;’

Justification: In point 11a, the term “**email addresses**” (plural) is used, although in the amendment to Article 7(b) it is explained that “**digital contact shall indicate a single point**” (i.e., there should be only one email address). Therefore, it should be considered whether it would be more appropriate to use “**email address**” (singular) in point 11a. Also, it creates a burden as well as unreality to businesses having more than one email address.

It should be noted that the same applies to all other analogous amendments to directives and regulations.

HUNGARY

We thank the Danish Presidency for their work on the text. It's generally going to the right direction, although we would like to point out some points to clarify for the sake of consistency throughout the text:

- We propose to restore 'fittings' in Article 4(1), point (b) and Article 4(2), point (b) of the Regulation. Those text parts include fittings related not to the instructions, but to the essential requirements, and Regulation (EU) 2016/426 on appliances burning gaseous fuels does lay down essential requirements applicable to fittings too.
- We do not support the deletion of the last sentence in Article 5(9) of the Regulation. As we have indicated it in our previous written comments, we consider it as a useful clarification, and Article 10(7) of the Machinery Regulation lays down an obligation to provide safety information in paper format, so the presence of that sentence is relevant. Furthermore, we propose to introduce that sentence in every relevant paragraph of the Directive as well. We propose consistency. Based on our analysis, the paragraphs, where the sentence is relevant, are:
 - Article 3(7), point (b) of the Directive
 - Article 4(8) of the Directive (*the sentence is already present, no change needed*)
 - Article 5(8) of the Directive
 - Article 6(8) of the Directive
 - Article 7(9) of the Directive
 - Article 9(8) of the Directive
 - Article 10(7) of the Directive
 - Article 11(8), point (b) of the Directive
 - Article 12(9) of the Directive
 - Article 13(7) of the Directive
 - Article 3(7) of the Regulation (*the sentence is already present, no change needed*)
 - Article 4(9), point (b) of the Regulation (*the sentence is already present, no change needed*)
 - Article 5(9) of the Regulation (*reintroduction is necessary*)
- We do not understand, why normative documents are necessary in Article 6 of the Directive, as the text currently in force of Directive 2014/31/EU on non-automatic weighing instruments provides the assumption of conformity based only on harmonised standards. We suggest to double check it.
- Furthermore, we find it important to have a consistent wording in case of common specifications. For example, in the Regulation, the expression 'covering requirements' was deleted in case of some articles related to common specifications, but not everywhere. We propose to unify the texts both in the Regulation and the Directive.

AUSTRIA

Digi & Comspec

regarding 2013/53/EU, 2014/30/EU, 2014/34/EU, 2014/35/EU

- The proposed wording regarding Common Specifications, as contained in the second compromise text (12524/25 of September 5, 2025), should not be further changed.
- In its current form, the wording is considered a good compromise.

regarding 2014/31/EU, 2014/32/EU

- The compromise text is developing positively; particularly the consideration of normative documents in MID represents an important change.
- It seems, that the explanation we have provided concerning introduction of normative documents in NAWID was not sufficient.
- Therefore, the requirements in the compromise text are presumably inconsistent.
- AT therefore suggests the text amendments below.
- AT supports a further changes to achieve the digitisation goals in NAWID.
- With regard to the proposed text st12524 for MID and NAWID we see a need for the following changes:

Article 7 - Dir. 2014/32/EU Measuring instruments

- *In Article 14a the first sentence from our point of view should read:*
“In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the essential requirements set out in Annex I and in the relevant instrument-specific Annex covered by those parts of normative documents.”
- *Article 14a (2): The wording “...essential requirements set out in Article 6 and in the relevant instrument-specific Annexes covered...” of seems to be confusing. Probably one of these formulations would be better:*
“...~~essential~~ requirements set out in Article 6 ~~and in the relevant instrument-specific Annexes covered...~~” or
“...~~essential~~ requirements set out in Annex I and in the relevant instrument-specific Annexes covered...”
“...essential requirements set out in Annex I and the specific requirements in the relevant instrument-specific Annexes covered...”
- *Article 14a (6): We propose to add in the first sentence: “...does not entirely satisfy the essential **and/or** specific requirements...”*
- *(10) concerning Article 27(7), point (c): We propose to amend as follows: “...of the applicable harmonised standards and normative documents or common specifications...”*

Article 6 - Dir. 2014/31/EU Non-automatic weighing instruments

- (2) (b) Article 6 (b): Delete “or normative documents”

- (2) (d) Article 6 (7) (a): Delete “mark on the instrument, ~~or, where that is not possible, on its packaging or in an accompanying document,~~ how to access...”

On a non-automatic weighing instrument, it should always be possible to apply this link.

- (6) Article 12 1. (a): Delete “or normative document”

- Amend in Annex I No. 14, 4th sentence 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).**”

POLAND

PL comments on Omnibus IV following the AGS meeting on 11th September 2025

I. General comment

With regard to thresholds in the new definition of small mid-caps Poland will present its position during the Coreper II discussion on 17th September.

II. Comments on the new compromise text (12525/25) REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures – regarding changes to the battery regulation (EU) 2023/1542 / changes to due diligence reporting / Eng.

In the context of proposed changes to the Batteries Regulation (EU) 2023/1542 (as in the doc. 12525/25) we would like to highlight the following issues:

- With regard to the threshold for recognition as an SME (small and medium-sized enterprise) and the definition of a ‘group’, it is necessary to clearly specify whether the turnover threshold applies only to the parent company or whether it should be calculated at the consolidated level (IFRS/GAAP). Lack of clarity creates a significant risk of regulatory uncertainty.
- We propose to prepare standard report templates and support tools to help companies implement the requirements correctly and increase reporting consistency.
- We suggest considering raising the threshold for recognition as an SMC to EUR 250 million or limiting the turnover base to ‘turnover from battery activities’ (i.e. excluding segments not related to batteries/raw materials trading) so that the measure reflects the actual risk in the battery value chain.
- Recital 18 aims to achieve ‘proportionality’ and reduce the burden on SMCs; however, it appears that the EUR 150 million threshold alone does not reflect the specific nature of an industry with high material costs.
- With regard to the timing of the first report, we emphasise that companies should be given a realistic timeframe to carry out supplier audits, data digitalisation and laboratory verifications (especially for cathodes/anodes and critical raw materials), which is why we are considering extending the deadline from 12 to 18 months from the date specified in Article 48(1) of the Batteries Regulation.
- A ‘significant change’ should be defined, determining the need to prepare a due diligence report in the supply chain, taking into account the following factors: $\geq 20\%$ change in the volume of raw materials covered by the due diligence policy, addition/change of a country of origin with increased risk, entry/exit from the refining stage in the chain, acquisition/loss of a key Tier-1 supplier, significant change in the legal framework for due diligence in the country of origin.

The proposed text of recital 19:

“ [...] Operators should be required to review, and make publicly available their due diligence policy only every three years. **The first public report should be due within 18 months after the date specified in Article 48(1).** In between, operators should review and disclose **only upon a significant change, meaning a change reasonably likely to increase the severity or likelihood of adverse impacts**, including, inter alia, a $\geq 20\%$

change in the volume of covered raw materials, a change in the country-of-origin risk profile, entry into or exit from a refining/processing stage, or the replacement of a key Tier-1 supplier.”

The definition of ‘significant change’ and materiality thresholds would provide legal certainty and limit unnecessary ‘just in case’ updates.

The above proposals are consistent with the objective of the proposed simplifications to the SMC battery supply chain and take into account the maintenance of high standards of due diligence while reducing excessive administrative burdens.

The proposed text of art. 5(2):

“The economic operator referred to in Article 48(1) shall, by the latest **18 months** after the date specified in Article 48(1) and at least every three years thereafter, and without undue delay 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. **For the purposes of this paragraph, a ‘significant change’ means a change reasonably likely to increase the severity or likelihood of adverse impacts; it shall include, inter alia, (a) a $\geq 20\%$ change in the volume of covered raw materials; (b) a change in the country-of-origin risk profile; (c) entry into or exit from a refining/processing stage; (d) the replacement of a key Tier-1 supplier.**

PL comments on Omnibus IV following the AGS meeting on 11th September 2025

III. General comment

With regard to thresholds in the new definition of small mid-caps Poland will present its position during the Coreper II discussion on 17th September.

IV. Comments on the new compromise text (12525/25) REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/679, (EU) 2016/1036, (EU) 2016/1037, (EU) 2017/1129, (EU) 2023/1542 and (EU) 2024/573 as regards the extension of certain mitigating measures available for small and medium sized enterprises to small mid-cap enterprises and further simplification measures – regarding changes to the battery regulation (EU) 2023/1542 / changes to due diligence reporting / Eng.

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- Recital 18 aims to achieve ‘proportionality’ and reduce the burden on SMCs; however, it appears that the EUR 150 million threshold alone does not reflect the specific nature of an industry with high material costs.
- With regard to the timing of the first report, we emphasise that companies should be given a realistic timeframe to carry out supplier audits, data digitalisation and laboratory verifications (especially for cathodes/anodes and critical raw materials), which is why we are considering extending the deadline from 12 to 18 months from the date specified in Article 48(1) of the Batteries Regulation.
- A ‘significant change’ should be defined, determining the need to prepare a due diligence report in the supply chain, taking into account the following factors: $\geq 20\%$ change in the volume of raw materials covered by the due diligence policy, addition/change of a country of origin with increased risk, entry/exit from the refining stage in the chain, acquisition/loss of a key Tier-1 supplier, significant change in the legal framework for due diligence in the country of origin.

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The definition of ‘significant change’ and materiality thresholds would provide legal certainty and limit unnecessary ‘just in case’ updates.

The above proposals are consistent with the objective of the proposed simplifications to the SMC battery supply chain and take into account the maintenance of high standards of due diligence while reducing excessive administrative burdens.

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“The economic operator referred to in Article 48(1) shall, by the latest **18 months** after the date specified in Article 48(1) and at least every three years thereafter, and without undue delay 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. **For the purposes of this paragraph, a ‘significant change’ means a change reasonably likely to increase the severity or likelihood of adverse impacts; it shall include, inter alia, (a) a $\geq 20\%$ change in the volume of covered raw materials; (b) a change in the country-of-origin risk profile; (c) entry into or exit from a refining/processing stage; (d) the replacement of a key Tier-1 supplier.**

SLOVENIA

We would like to express **SI support for the DE proposal to extend the deadline** specified in Article 79(1)(a)(i) of the Regulation (EU) 2024/1781 (ESPR) **to 31 December 2028**.

We fully support the arguments expressed in the DE document from August 2025. The transitional period specified in Article 79(1)(a)(i) we estimate as not sufficient to adopt all the legal acts needed for the proper implementation of the ESPR.

ESPR is very complex piece of legislation this we believe that the member states as well as the Commission should have enough time to adopt all legal acts referred to ESPR.

In addition to that we would like to emphasize, that the transposition period for the directive of 1 year is certainly not long enough and call for at least 2 years. In SI we will have to amend the laws to implement the Directive. That involves the Parliamentary procedure and one year for the implementation is not enough.

FINLAND

Written comments from Finland on the IV Simplification Package, focusing on Presidency's proposals (Documents: ST 12523/25, ST 12524/25) on digitalization and common specifications.

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

We thank the Presidency for the hard work and progress made in this file. We see that the work is going in the right direction. 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.

Digitalisation

General Comment

- **Internal conflict regarding the digital product passport and information provided to consumers.** In some amendments (for example Article 10 of the Directive 2014/35/EU) it has been proposed to stipulate that when a digital product passport is required, the information should only be provided there. In order to avoid an internal conflict, we propose to specify and clarify the text in such a way that the information provided in the digital product passport does not affect what is regulated about the form of information provided to consumers.

As an example please see under suggestion Article 10

Amendments to Directive 2014/35/EU

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 with the exception of electrical equipment intended for consumer use for which safety information shall be provided with the product in paper form or marked on that product in accordance with Article 6(7).;'

Common specifications

- Presidency's **horizontal** approach is legal framework for common specifications from Toys Safety Regulation art. 14.
- **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.**
- **It is positive that most of the references to the articles on common specifications are now fixed. We have commented in writing some other articles as well in order to check the references (Art. 2 para seven (Directive 2011/65/EU) and Article 5 para 6 (2014/30/EU)).**

Positions on Specific Regulations

Regulations (Document st12523en25)

1) Art 6 Amendments to Battery Regulation (EU) 2023/1542

- **As regards Art 6 amendments to Battery Regulation, we have provided written comments. We are still concerned about proposal that manufacturers' obligations (Battery Regulation article 38.1) to provide instructions and safety information is limited to battery energy storages. Why the obligation is limited to battery energy storages?**

Background / groundings

- 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 st12524en25)

We have also sent written comments to articles 2 and 5. The Articles include a reference to essential safety requirements that is not included in the original legislation.

1) Article 2 - Amendments to Directive 2011/65/EU (ROHS-Directive)

Comment

- In article 2 para 7 about common specifications there is still reference to applicable safety requirements. The legal basis of the RoHS directive is the protection of human health and the environment and the directive does not set obligations for safety requirements. We have commented about this in previous written comments.

Please see under suggestion:

Article 16a

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 requirements set out in Article 4 ~~applicable essential safety requirements~~. Those implementing acts shall only be adopted where the following conditions are fulfilled:

2) Article 5 - Amendments to Directive 2014/30/EU (EMC Directive)

Comment

- In article 5 para 6 about common specifications there is still reference to essential safety requirements. We want to point out that the Directive does not directly refer to safety requirements. We have commented about this in previous written comments
- **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~~
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~~
requirements set out in Annex I essential safety requirements.

Those implementing acts shall only be adopted where the following
~~cases~~ **conditions are fulfilled:**

Background/ Reasoning:

The EMC Directive does not directly refer to safety requirements and therefore it states following: The information must be provided with the product.

- the specific precautions to be taken in connection with the assembly, installation, maintenance or operation of the appliance to ensure that the appliance complies with the essential requirements when put into service.
- if compliance with the essential requirements cannot be guaranteed in residential areas,
- necessary to enable the device to be used in accordance with its intended use.

3) Article 6 – Amendments to Directive 2014/31/EU (Non-automatic weighing instruments Directive)

Comment

- Proposed article 6 (amendments to directive 2014/31/EU) points 2 b and 6: changes made in the proposed article to include normative documents are **unnecessary**. Unlike the MID, the NAWI directive does not recognize normative documents.
- **Please see under suggestion:**

Proposed changes to art. 6, point 2 (b) and point 6:

(2) Article 6 is amended as follows:

...

(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 ~~or normative documents~~, 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.’

(6) the following Article 12a is inserted:

‘Article 12a

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 conditions are fulfilled:

(a) there is no harmonised standard ~~or normative document~~ covering those requirements the reference of which is published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period;

6) Article 13 Amendments to Directive 2014/90/EU

Comment

- We refer to our previous comments and concerns. We are still concerned about the administrative burden related to the new obligation on the manufacturer to upload the EU declaration of conformity to the database when the marine equipment is placed on board (Article 16(4)).
- We are still concerned that the proposed changes could weaken the access of ship's personnel to the same data, as ships may not be aware of the database and ships may not have access to the Internet. Ships are not required to have an internet connection.

Please see under suggestion:

1. When the manufacturer places marine equipment for distribution in its supply chain for the first time 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).

Background / groundings

- Finland supports the proposed amendments to the Marine Equipment Directive and the objectives of the amendments. However, Finland wants to ensure what is meant by the new obligation on the manufacturer to upload the EU declaration of conformity to the database when the marine equipment is placed on board (Article 16(4)). The wording of this Article can be interpreted as meaning that a certificate should be downloaded each time a marine equipment is put into service. This would place an administrative burden on manufacturers to find out when the marine equipment has been put into service and the document should be uploaded to the database. In reality, the manufacturers may not have means whatsoever to find out when the equipment is placed onboard. Is it intended, however, that the declaration of conformity be downloaded only once?

- A new obligation to upload the document to the database when the equipment is approved (Article 16(4)) would not be an unreasonable requirement and would facilitate the access of most operators to the necessary information. At present, the Marine Equipment Directive requires a copy of the EU declaration of conformity to be kept on board an EU ship. The proposed change that the document would in future only be in the database could weaken the access of ship's personnel to the same data, as ships may not be aware of the database and ships may not have access to the Internet. Finland considers that in the further preparation it should be assessed whether the obligation to keep a copy of the EU declaration of conformity on board should be maintained or how to ensure that users' information can otherwise be obtained.

- The recital justifies the digital format of documents such as instructions by EU household access to internet. However, ships are not required to have an internet connection. In addition, paragraph 12 of the recital addresses the availability of the European Maritime Safety Agency's database to Member States, flag states and market surveillance authorities. The access of the mariners and ships - the end users of the equipment - is not addressed.

SWEDEN

Small mid-Caps

SE suggestion to further improve recital 5 for your consideration.

Recital 5 in the regulation:

“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 **SMEs and maintaining** the existing rights at European level for SMEs ~~approach~~ **possibility to make targeted alleviations required for that category.**”

Recital 5 in the Directive:

“**In particular, to make business easier for SMCs and reduce their administrative burden, those acts** should be adapted to extend the scope of those provisions and include SMCs, while still supporting **SMEs and maintaining** the existing rights at European level for SMEs ~~approach~~ **possibility to make targeted alleviations required for that category.**”
