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WORKING DOCUMENT

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

Delegations will find enclosed a revised consolidated initial comments as received from BE, **BG**, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI and **SE** on the Omnibus IV proposal on REGULATION (Digitalisation and Common Specifications) (doc. 9318/25).

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) No 7651/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/1230, (EU) 2023/11542 and (EU) 2024/1781 as regards digitalisation and common specifications

Guidelines to be followed

Please kindly provide your contributions in the table below.

Drafting suggestions: you may use '**track changes**' or formatting (for example **bold-underline** for additions and ~~strike-through~~ for deletions, **where necessary, in a different colour**).

Name of document: please add the **two initials** of your delegation's country followed by a space (to the MS Word document name), followed by any optional text, for example, for Austria: **AT comments on … .docx**

Thank you for your cooperation!

Commission proposal	Drafting suggestions and Justifications
General comments	BG (Justifications): **Common specifications** The definition for common specification in Regulations 2016/424, 2016/425 and 2016/426 must be based on the term "technical specification". This term is defined in all these Regulations. The term "standard" is also defined as technical specification – see Regulation (EU) No 1025/2012. There is no need to introduce new terminology like "a set of technical requirements". As common specifications "provide means of complying with the essential requirements" and they cover only products, the definition of common specification must be limited to the relevant product and "device, service, process or system" must be deleted.

Commission proposal	Drafting suggestions and Justifications
	The new Articles introducing the common specifications must follow the model of the Toys Regulation, Machinery Regulation, Batteries Regulation and Ecodesign Regulation. Market surveillance provisions in Regulations 2016/424, 2016/425 and 2016/426 must cover also cases where non-compliance of products is attributed to shortcomings in the common specifications and the procedure to be followed in such cases – see Machinery Regulation. The Articles on presumption of conformity in the Emergency procedures Chapters added with the IMERA Omnibus must take into account not only the existence of harmonized standards but also the existence of common specifications established outside the internal market emergency mode. It is also necessary to make distinction between the two types of common specifications. We propose to designate the common specifications established under the internal market emergency mode as "crisis-relevant common specifications". We oppose to the proposed modifications in conformity assessment modules on quality management systems which add common specifications in the presumption of conformity for the quality system of the manufacturer. International standards (like ISO 9000) which are recognised also as harmonised standards must remain the only source of presumption of conformity for the quality system of the manufacturer. **Digitalisation** We identified additional provisions which must be amended in relation with the new requirement on electronic form of the EU declaration of conformity and instructions. In the obligations of importers and distributers as well as in some other parts of the Regulations there are still provisions

Commission proposal	Drafting suggestions and Justifications
	requiring products to be accompanied by instruction or by the EU declaration of conformity. The use of DPP must be optional and not an obligation – see the Toys Regulation. In all such provisions "shall" must be replaced by "may". In order to avoid confusion and contradictions, it is also necessary to add that when DPP is used the economic operators shall be deemed to fulfil the obligations for drawing up and keeping the EU declaration of conformity. LT (Justifications): We would like to get an assurance that the requirements set in the Omnibus, related to **safety information, is in correspondence to Council Directive 89/391/EEC** of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work. According to this directive, at any time worker has to have access to safety information. (see Art 10 Worker information 1. The employer shall take appropriate measures so that workers and/or their representatives in the undertaking and/or establishment receive, <...>, all the necessary information concerning: a) the safety <...>) **Definition of end user and / or consumer –** there is a need to make the definitions crystal clear: which subject(s) what obligations or rights has within different NLF. Detailed comments provided in the text bellow. Still on the definitions, we think that some NLF might require **that professional end-users and non-professional end-users in the context of this omnib**us (access to information) would be treated equally. Detailed comments provided next to the relevant NLF.

Commission proposal	Drafting suggestions and Justifications
	LT maintains scrutiny regarding the **choice for common specification framework - Medical Devices Regulation.** If this option remains, does the COM plan to accordingly change e.g. Toys regulation or Machinery regulation or IMERA, to ensure alignment? Why has COM decided not to include in the text a clear explanation on the application of the common specification v. harmonised standards (e.g. in case of the situation when harmonised standard is being adopted). Do we understand correctly that from the day following the publication of the harmonised standard, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the common specifications? If it is not the case, meaning that compliance can be confirmed by both documents, we ask the COM to explain the situation (possible duplication) in the text. The text could also benefit from the explanation how stakeholders will be involved in the process of drafting common specifications. Also, scrutiny regarding the third criteria – urgency: from our point of view, the urgency should stem or be indicated by either MSs or businesses. If decided that this criteria is to stay in the text, we would suggest a change which would assure that aforementioned subjects are included in the initial stage: *(c) where the Commission **based on the request provided by economic operators** considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.* We support request by other MSs to include a definition of "electronic form" or at least provide explanation of what is covered by this concept in the recitals. NL

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): The drafting suggestions provided in relation to the insertion of Article 17a on common specifications in Regulation (EU) 2016/424 are also **applicable to all other Regulations in this proposal where a corresponding article on common specifications is introduced**. NL (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation. SI (General comments) **We still believe that the common specification provisions should be harmonised in line with those set out in the Machinery regulation** and later used in other pieces of legislation (ESPR, AI, batteries, toys). **We could also agree** with the more specific and more recent outline of common specifications in the **legislation on toys.** SK (Drafting suggestions): A) digitalization • if digital contact, which is to be a means of contacting an economic operator online, according to the European Commission means any online

Commission proposal	Drafting suggestions and Justifications
	channel accessible without registration, we believe that the practice is dependent on the method chosen appropriately by the economic operator and therefore on its arbitrariness. Even if this concept is already to be used, we would consider it better for the future to have the term more precisely defined, or to have set limits for this channel. For example, in the proposal for a Regulation of the European Parliament and of the Council on the Safety of Toys and repealing Directive 2009/48/EC (hereinafter referred to as "the TSR"), although we do not directly have digital contact, we do have the following provision in Art. 7, paragraph 11 "manufacturers shall make publicly available communication channels such as a telephone number, an electronic address, a dedicated section of their website, ...". We also see a problem in the possibility of using a chat based on artificial intelligence, which should not be the exclusive communication channel, due to the perception of the need for direct involvement of the human factor. • We do not agree with the restriction for the manufacturer to provide the authorities with the necessary documentation only in digital form. The possibility of providing this documentation also in paper form should be maintained, for example, for cases where the technology simply fails and

Commission proposal	Drafting suggestions and Justifications
	it will be necessary to submit the documentation, or work with it as quickly as possible. In terms of supporting the idea of simplifying and digitalization of processes, we are in favour of a primarily digital form of providing documentation, but with a legally certain possibility of providing it in paper form in cases where it is not possible to provide it digitally. B) common specifications • the TSR solution provides greater certainty that common specifications are only a fallback option and limits the European Commission to more detailed and stricter conditions when adopting implementing acts, e.g. through binding to "exceptional cases" or expecting the adoption of the standard at a certain time. More detailed conditions and subsequent impacts of the adoption of implementing acts or new standards provide greater legal certainty for their correct application. We agree with the relevant MS that the basis for demonstrating conformity must be harmonised standards and the activities of national accreditation bodies.
(Text with EEA relevance)	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE **Updated: 27/06/2025 16:11**

Commission proposal	Drafting suggestions and Justifications
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 Committee[1],	
Acting in accordance with the ordinary legislative procedure,	
Whereas:	
(1) Reporting requirements play a key role in ensuring proper monitoring and correct enforcement of legislation. However, in order to ensure that they fulfil their intended purpose and to limit the administrative burden, it is important to streamline those requirements.	
(2) In its Communication on 'Long-term competitiveness of the EU: looking beyond 2030'[6], the Commission has committed to rationalise and simplify reporting requirements, with the aim to reduce such burdens by 25%, without undermining the related policy objectives.	
(3) In its Better regulation Guidelines [2], the Commission promotes the 'digital by default' principle to support digital transformations, by facilitating digital-ready policies which consider the fast-evolving world	

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.

Commission proposal	Drafting suggestions and Justifications
of digitalisation and technology, and which are digital, interoperable, future-proof and agile by default.	
(4) The increasing importance of digitalisation in simplifying regulatory frameworks necessitates the reduction and modernisation of reporting requirements and economic operators' obligations. In line with the efforts to accelerate digitalisation, it is essential to fully digitalise business-to-authority reporting and economic operators' obligations when they do not affect protection and safety of consumers. Embracing digitalisation will not only simplify compliance procedures but also enhance the overall efficiency of the regulatory framework, ultimately benefiting both businesses and authorities alike.	
(5) A number of sectoral Union legal acts lay down harmonised rules regarding the obligations of economic operators when placing a product on the market or putting it into service. Such legal acts include Regulations (EU) 2016/424[3], (EU) 2016/425[4], (EU) 2016/426[5], (EU) 2023/1230[6], (EU) 2023/1542[7] and (EU) 2024/1781[8] of the European	

[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).

Commission proposal	Drafting suggestions and Justifications
Parliament and of the Council (the 'Regulations concerned'). The Regulations concerned are based on the principles of the 'new approach' to technical harmonisation and are aligned with the reference provisions laid down in Decision No 768/2008/EC of the European Parliament and of the Council[9].	
(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 declaration of conformity accompanies the product. Considering the evolution of digitalisation, it is essential to modernise this obligation by requiring that such EU declaration of conformity electronically accompany the product. The manufacturer will make sure that the EU declaration of conformity is accessible through an internet address or a machine-readable code.	BG (Drafting suggestions): (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~~ is available in electronic form. The manufacturer ~~will~~ should therefore make sure that the EU declaration of conformity is accessible through an internet address or a machine-readable code and that this information accompanies the product.

[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).

Commission proposal	Drafting suggestions and Justifications
(8) Taking into account that in 2024 no less than 94% of EU households had access to internet[10], the paper format of the instructions accompanying the products under the scope of the Regulations concerned is outdated and not aligned with the current technologies, the practice of consumers nor with green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Regulations concerned. This will allow manufacturers to provide instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to still protect the safety of consumers, the safety information, including instructions having impact on product safety, should be provided in paper format or marked on the product. Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of the purchase and for a certain period of time after their purchase.	CZ (Drafting suggestions): ~~Taking into account that in 2024 no less than 94% of EU households had access to internet[11], the paper format of the instructions accompanying the products under the scope of the Regulations concerned is outdated and not aligned with the current technologies, the practice of consumers nor with green objectives. Consequently, the possibility for a digital format of the instructions should be introduced in the Regulations concerned. This will allow m~~**M**anufacturers **should be allowed** to provide instructions in digital format, if they wish to do so. Where manufacturers choose to provide instructions in digital format, in order to still protect the safety of consumers, the safety information, including instructions having impact on product safety, should be provided in paper format or marked on the product. Moreover, end-users should be able to obtain a paper copy of the instructions for use or safety information, upon request – at the time of the purchase and for a certain period of time after their purchase. CZ (Justifications): Taking into the number of the EU population, 6% is a significant part of population. CZ would therefore propose that the recital be amended as indicated. HU (Justifications):

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

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

Commission proposal	Drafting suggestions and Justifications
	Even if internet access is available, consumers who are not familiar with digital technologies might face serious difficulties due to the lack of paper-based instructions. It does not seem feasible to make them wait 1 month for the printed instructions to arrive from the manufacturers/distributors. Furthermore, instructions in paper format are usable more practically in many cases, for example if only a device with a small screen (e.g. a smartphone) is available as a digital tool.
(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 digital contact should be defined in the Regulations concerned.	
(10) The Regulations concerned require that economic operators provide, on a reasoned request from a competent national authority, all information and documentation necessary to demonstrate the conformity of the concerned products with the respective Regulations, in paper or electronic form. The paper-based form is an outdated requirement, while electronic communication enhances interaction between authorities and businesses, streamlining processes and reducing administrative burdens. In order to achieve the digitalisation of reporting requirements and to reduce administrative burden for economic operators and competent authorities, the economic operators should be required to provide the	

Commission proposal	Drafting suggestions and Justifications
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 Council[12], represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety or other requirements. However, where no harmonised standards exist or where they are insufficient, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety or other requirements, as an exceptional fall-back solution to facilitate the manufacturer's obligation to comply with those health and safety or other requirements.	DE (Drafting suggestions): The current EU standardisation framework which is based on the New Approach principles set out in Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards (14) and on Regulation (EU) No 1025/2012 represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety requirements of this Regulation. **European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus.** However, in the absence of relevant references to harmonised standards ~~or where they are insufficient~~, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety requirements of this Regulation, **provided that in doing so it duly respects the role and functions of standardisation organisations**, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with those health and safety requirements**, when the standardisation process is**

[12] 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).

Commission proposal	Drafting suggestions and Justifications
	blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications. (Machinery Regulation, rec. 45) DE (Justifications): In principle, we welcome Common Specifications, provided that priority is given to harmonized standards and that the role and function of Standardization Organizations is duly respected in a clear and transparent process. We would prefer having a single legal basis allowing for the implementation of Common Specifications, e.g. as part of the revision of the EU Standardisation Regulation or the revision of the New Legislative Framework (NLF). However, if a more "granular" approach is chosen, it is of major important that the consistency amongst the new respective legal acts, as well as consistency with existing harmonised product legislation is ensured (e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation). SE (Drafting suggestions): The current Union standardisation framework, which is based on Regulation (EU) No 1025/2012 of the European Parliament and of the

Commission proposal	Drafting suggestions and Justifications
	Council , represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential health and safety or other requirements. ~~However, where no harmonised standards exist or where they are insufficient, the Commission should be able to adopt implementing acts establishing common specifications for the essential health and safety or other requirements, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with those health and safety or other requirements.~~ However, in the 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, provided that in doing so it duly respects the role and functions of standardisation organisations, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with those health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications. SE (Justifications): Reference to common specifications should be in line with existing EU-legislation, such as regulation (EU) 2023/1230 and the toy safety regulation. Important that the wording reflects the fact that common specifications should be an exceptional fall-back option.

Commission proposal	Drafting suggestions and Justifications
(12) As the digital product passport is foreseen in certain EU legislation, such as Regulation (EU) 2023/1542, it is essential to require economic operators to store the information contained in the EU declaration of conformity and instructions in the digital product passport where a product is covered by multiple pieces of legislation. This approach would reduce the administrative burden on manufacturers, as they would no longer need to maintain separate storage locations for compliance documents. 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) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be	BG (Drafting suggestions): (14) To ensure a smooth and effective transition, to minimize disruptions, and to provide a reasonable timeframe for industries to

Commission proposal	Drafting suggestions and Justifications
deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.	adjust to the new requirements amendments to Regulations ~~(EU) 765/2008,~~ (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009,~~ (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation should be deferred. Amendments to Regulation (EU) 2023/1230 should apply from the date of application of that Regulation.
(15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with those Regulations in their version applicable before that date.	BG (Drafting suggestions): (15) In order to enable economic operators to supply stock of products that have been placed on the market before the date of application of amendments to Regulations ~~(EU) 765/2008,~~ (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009,~~ (EU) 2023/1542 and (EU) 2024/1781 concerning digitalisation, it is necessary to provide for reasonable transitional arrangements that do not impede the making available on the market of products that have been placed on the market in accordance with those Regulations in their version applicable before that date.
(16) Regulations (EU) 765/2008, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,	BG (Drafting suggestions): (16) Regulations ~~(EU) 765/2008,~~ (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009,~~ (EU) 2023/1230, (EU) 2023/1542 and (EU) 2024/1781 should therefore be amended accordingly,

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
HAVE ADOPTED THIS REGULATION:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE **Updated: 27/06/2025 16:11**

Article 1	BG (Drafting suggestions): deleted BG (Justifications): **BG insists on deleting this Article – this is a red line for us.** Now EU industry benefits from recognition of test reports and certificates issued by accredited conformity assessment bodies not only at EU level but globally. This is due to the fact that conformity assessment bodies issuing that test reports and certificates are assessed and monitored on the basis of international standards, recognised as harmonised standards, which are used globally. National accreditation bodies in the Union also meet requirements of international standards, recognized as harmonized standards, conformity with which is ensured by regular peer evaluations. Common specifications cannot provide such global recognition. If EU policies and legislation require additional requirements to be met by conformity assessment bodies the Commission can even now request EA – the body recognized under Article 14, to develop sectoral accreditation schemes (see Article 13(2) of Regulation 765/2008). For these reasons there is no need to introduce common specifications in Regulation 765/2008, as an alternative solution already exists. Establishing a parallel accreditation system based on common specifications and valid only in the Union will bring tremendous administrative burden and costs for economic operators, conformity assessment bodies and national accreditation bodies and will undermine competitiveness of EU economy. CZ (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	Deletion of the whole Article 1 CZ (Justifications): CZ has serious concerns regarding the impacts of the adoption of the common specifications in area of accreditation in the international context.
Amendments to Regulation (EU) 765/2008	BG (Drafting suggestions): deleted LT (Justifications): We would like to point out to two different situations: 1. **Accreditation according to harmonised standards** (alongside which there is an intention to mention common specifications), which is carried out by accreditation bodies. This is related to the amendment of Article 2 of the Regulation, and the justification of the proposal relates to this as well. The fallback option could be justified specifically in these cases. 2. **What the accreditation bodies themselves must comply with** (Articles 10 and 11 of the Regulation, where, in addition to the harmonised standard applicable to national accreditation bodies, there is also an intention to include common specifications) – through EA peer evaluations, a group of representatives from other countries' accreditation bodies assesses national accreditation bodies for compliance with the harmonised standard 17011. However, this is not considered accreditation. Standard 17011 is

Commission proposal	Drafting suggestions and Justifications
	published in the Official Journal (OJ), it is harmonised, and in our opinion, **no fallback option is needed for it**. **For this reason we have a very strong plea to delete amendments to Art 11 and 11 of the Regulation (EU) 765/2008.** HU (Justifications): These amendments mean a fundamental change in the concept of accreditation, they even amend its definition. We are concerned that if common specifications differ from standards, their application could lead to the exclusion of national accreditation bodies from the global accreditation system. National accreditation bodies assess conformity assessment bodies based on international reference standards (e.g. ISO/IEC 17025 for laboratories, ISO 9001 for quality assurance) and harmonised European Standards (hENs). That supports the global acknowledgement of assessments and inspection reports through systems such as ILAC, IAF and EA MLA. We are concerned that if the reference standards and widely used hENs are replaced by common specifications, then it will weaken acknowledgement of European conformity assessment bodies outside the Union, or their costs and workload will increase, if they still want to comply with both common specifications and international standards. Common specifications might solve the absence of hENs within the Union, but they can reduce the competitiveness of European enterprises on the global market. This would lead to the opposite of the objectives we try to achieve, even if legal compliance within the EU can be maintained. Therefore, we have the following questions to the Commission:

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
	What objective does the Commission try to achieve with the amendments of Regulation (EU) 765/2008? Has it made an impact assessment about this new concept? Is there any estimation, how much these amendments would increase the workload of national accreditation bodies?
Regulation (EU) 765/2008 is amended as follows:	BG (Drafting suggestions): deleted
(1) Article 2 is amended as follows:	BG (Drafting suggestions): deleted
(a) the following point (9a) is inserted:	BG (Drafting suggestions): deleted
'(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;';	BG (Drafting suggestions): deleted SE (Justifications): Important to ensure consistency with definitions of common specifications in existing legislation.
(b) paragraph 10 is replaced by the following:	BG (Drafting suggestions): deleted

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'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;';	BG (Drafting suggestions): deleted SE (Justifications): Important to ensure consistency with definitions of common specifications in existing legislation.
(2) in Article 10, paragraph 5 is replaced by the following:	BG (Drafting suggestions): deleted LT (Drafting suggestions): ~~(2) in Article 10, paragraph 5 is replaced by the following:~~ LT (Justifications): Please see arguments above.
'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.';	BG (Drafting suggestions): deleted LT (Drafting suggestions): ~~5. Peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 8, taking into account~~

Commission proposal	Drafting suggestions and Justifications
	~~the relevant harmonised standards or common specifications referred to in Article 11.';~~
(3) in Article 11, paragraph 1 is replaced by the following:	BG (Drafting suggestions): deleted LT (Drafting suggestions): ~~(3) in Article 11, paragraph 1 is replaced by the following:~~ LT (Justifications): Please see arguments above.
'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.'.	BG (Drafting suggestions): deleted LT (Drafting suggestions): '~~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.'.~~

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
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 accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';	BE (Drafting suggestions): We would like the definition of "digital contact" to be clarified to avoid it referring to a simple webpage or to other elements that do not allow for direct, effective, and traceable communication. Instead, it should imply a truly functional means of communication — an email address being one of the most illustrative examples. This would also help prevent confusion regarding acceptable formats or communication channels. BE (Justifications): As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and

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	potentially inaccessible or unavailable due to changes to the relevant website. A mere mention of a website compels consumers or Market Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should for instance take the form of an email address that is directly accessible without intermediate steps. This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address.
(b) the following point (19a) is inserted:	
'(19a) 'common specifications' means a set of technical requirements, other than a standard, that provide means of complying with the essential requirements applicable to a product, device, service, process or system;';	BG (Drafting suggestions): '(19a) 'common specification~~s~~' means a ~~set of technical requirements~~ technical 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 ~~product, device, service, process or system~~;'; BG (Justifications): See general comments. SE

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	(Justifications): Important to ensure consistency with definitions of common specifications in already existing legislation.
(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, in electronic form, and affix the CE marking.';	BE (Drafting suggestions): 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 the EU declaration of conformity referred to in Article 19, in electronic form, and affix the CE marking referred to in Article 20. BE (Justifications): Align with the other texts
(b) in paragraph 4, first subparagraph, the second sentence is replaced by the following:	
'Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.';	BE (Drafting suggestions): Changes in the 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.

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	BE (Justifications): Align with the other texts
(c) in paragraph 6, the first and second sentences are replaced by the following:	
'Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the subsystem or safety component. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.';	
(d) paragraph 7 is replaced by the following:	
'7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information, in a language which can be easily understood by end-users, 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.	BE (Drafting suggestions): '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 an application, or to provide any personnal information in any form,** and by the instructions and safety information, in a language which can be easily understood by end-users, as determined by the Member State concerned. The instructions and safety information may be provided in electronic form. Such instructions and safety information shall be clear, understandable and intelligible. BE (Justifications):

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	MSA's should therefore be able to directly access the conformity documents without registration or the provision of any personal information. BG (Drafting suggestions): '7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information, in a language which can be easily understood by ~~end~~ users, 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. BG (Justifications): The term used in this Regulation is "user" and not "end-user". LT (Justifications): The term "end-users", under Regulation 2019/1020 would suit both professional and non-professional users. (See justifications below or in extra comments document)
The manufacturer shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information. When drafting the safety information, the manufacturers shall take account of the intended use and	BE (Drafting suggestions):

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foreseeable misuse by the end-user, as well as the role which the instructions play for ensuring safety.	The manufacturer shall take into account the intended use and the foreseeable end-user of the subsystem or the safety component when deciding the specific format for the instructions and safety information. When drafting the instructions and 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. BE (Justifications): Everywhere the terminology 'the subsystem or the safety component is used' This is also valid for the instructions BG (Drafting suggestions): The manufacturer shall take into account the intended use and the foreseeable ~~end~~ user of the ~~product~~ subsystem or the safety component when deciding the specific format for the instructions and safety information. 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.
However, where a large number of subsystems or safety components are delivered to a single economic operator or end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of conformity can be accessed.	BE (Drafting suggestions): However, where a large number of subsystems or safety components are delivered to a single economic operator or end-user, the batch or consignment concerned may be accompanied by a single internet address or machine-readable code through which the EU declaration of

Commission proposal	Drafting suggestions and Justifications
	conformity can be ***directly*** *accessed* ***without the need to register, to download an application, or to provide any personnal information in any form***. BE (Justifications): MSA's should therefore be able to directly access the conformity documents without registration or the provision of any personal information. BG (Drafting suggestions): However, where a large number of subsystems or safety components are delivered to a single economic operator or ~~end-~~user, the batch or consignment concerned may be accompanied by a single document containing the internet address or machine-readable code through which the EU declaration of conformity can be accessed.
When the instructions, referred to in the first subparagraph, are provided in electronic form the manufacturer shall:	BE (Drafting suggestions): When the instructions and safety information, referred to in the first subparagraph, are provided in electronic form the manufacturer shall: BE (Justifications): This is also valid for the safety information

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	BG (Drafting suggestions): When the instructions and safety information, referred to in the first subparagraph, are provided in electronic form the manufacturer shall:
(a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;	BE (Drafting suggestions): (a) mark on the subsystem or the safety component, or, where that is not possible, on its packaging or in an accompanying document, how to access them via a direct link and how to request them in paper format; BE (Justifications): It is well known that users are often reluctant to consult the manual before using certain products. Making instructions available only online requires additional steps for users to consult them and will possibly result in even fewer actual manuals being consulted. In order to try to limit this negative impact of digitalisation, it is necessary to provide a direct link to the instructions for end users
(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions are embedded in the software of the subsystem or the safety component;	BE (Drafting suggestions): (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 without the need to register, to download an application, or to provide any personal information in any form so that the

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	end-user can directly 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; BE (Justifications): This is also valid for the safety information No information or data should be required from users to access electronic instructions. End-users should therefore be able to access the instructions without registration or the provision of any personal information. BG (Drafting suggestions): (b) present them in a format that makes it possible for the ~~end~~ user to print and download the instructions and save them on an electronic device so that the ~~end~~ user can access them at all times, in particular during a breakdown of the subsystem or the safety component; this requirement also applies where the instructions are embedded in the software of the subsystem or the safety component;
(c) make them accessible online during the expected lifetime of the subsystem or the safety component and for at least 30 years after the placing on the market of the subsystem or the safety component.	
However, the end-user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the end-user requests those	BE (Drafting suggestions):

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instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.’;	However, the end-user may, at time of the purchase of the subsystem or the safety component, or at any time during the expected lifetime of the product or at least 10 years 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 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.’ BE (Justifications): Everywhere the terminology ‘the subsystem or the safety component is used’ The possibility for end-users to request a paper version within six months of purchasing the product is overly restrictive without considering all possible practical scenarios. This time period should be extended to account for practical considerations. If the product is transferred or given to another person, the end-user may be penalized by such a short time limit, which may already have expired by the time they receive the product. Since electronic instructions must remain accessible online during the expected lifetime of the product, it would be reasonable for end-users to be able to request a paper version from the manufacturer for the same duration. Different versions of the same product can exist, meaning the end-user should be able to receive instructions specific to the version they purchased. BG

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	(Drafting suggestions): However, the ~~end~~ user may, at time of the purchase of the product, or up to six months after that purchase, request the instructions or safety information in paper format. Where the ~~end~~ user requests those instructions or safety information, the manufacturer shall provide them to the ~~end~~ user, free of charge, within one month of receiving the request.'; FR (Drafting suggestions): However, the end-user may, at time of the purchase of the product, ~~or up to six months after that purchase~~, request the instructions or safety information in paper format. Where the end-user requests those instructions or safety information, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.'; FR (Justifications): The six-month period imposes administrative burdens that appear misaligned with the objectives of the Omnibus Regulation. The French authorities recommend aligning the provisions with those set out in the Machinery Regulation, whereby the request would be submitted at the time of purchase. LT (Justifications): The term "end-users", under Regulation 2019/1020 would suit both professional and non-professional users. (See justifications below or in extra comments document)

Commission proposal	Drafting suggestions and Justifications
(e) paragraph 9 is replaced by the following:	
'9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.';	
(3) in Article 12(2), point (b) is replaced by the following:	
'(b) further to a reasoned request from a competent national authority, provide that authority, in electronic form, with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component;';	
(4) Article 13 is amended as follows:	
(a) in paragraph 2, first subparagraph, the second sentence is replaced by the following:	
'They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and by the instructions and safety information and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).';	BE (Drafting suggestions): '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 an application, or to provide any personnal information in any form** and

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	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).' BG (Drafting suggestions): 'They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed ~~and by the instructions and safety information~~ and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).'; BG (Justifications): Instructions and safety information are covered by paragraph 4 of this Article – see proposed modification below.
(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.';	BG (Drafting suggestions): '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.';

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	(b1) paragraph 4 is replaced by the following: '4. Importers shall ensure that the instructions and safety information **are available in accordance with Article 11(7)**, in a language which can be easily understood by users, as determined by the Member State concerned.'; BG (Justifications): New point (b1) is added amending paragraph 4 to avoid contradictions with Article 11(7)
(c) paragraph 9 is replaced by the following:	
'9. Importers shall, further to a reasoned request from a competent national authority, provide it, in electronic form, with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.';	BG (Drafting suggestions): '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 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.';
(5) Article 14 is amended as follows:	
(a) in paragraph 2, the first subparagraph is replaced by the following:	

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

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	BG (Justifications): Modified to avoid contradictions with Article 11(7)
(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.';	BG (Drafting suggestions): '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 with this Regulation. 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***	EL (Justifications): The provisions proposed by the European Commission concerning the Common Specifications (Articles 2(6)(1)(1), 3(6)(1), 4(7)(1) of the omnibus Regulation) do not seem to provide the necessary safeguards for delimiting the delegation of power to the European Commission to adopt implementing acts, and the proportionality of the provisions does not seem to be ensured, in line with the following reasoning:

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	The proposed provisions give a broad empowerment to the European Commission to adopt common specifications both where they are not covered by harmonised standards and where they are covered by harmonised standards. This proposal may call into question the benefits arising from the use of harmonised standards, such as those relating to competitiveness on international markets and the active involvement of stakeholders in the formulation of standards. It is not clear and circumscribed in which cases and by which criteria the "result in non-compliance" is demonstrated. There are no means of proof (e.g. proven after a thorough study by the European Commission), nor a threshold above which the European Commission will have the right to intervene. It is not defined according to which criteria the European Commission decides that a need is urgent "considers that there is a need to address an urgent concern", nor is the activation linked to existing relevant legislation (e.g. IMERA Regulation). In addition, the advisory procedure for the adoption of the enabling act is proposed and it may be necessary to assess whether we should propose the adoption of the examination procedure, which provides more assurance to the Member States and is more binding on the European Commission. In the light of the above, we have a scrutiny reservation on the provisions relating to common specifications for both the omnibus proposal for regulation and the omnibus proposal for directive.
Common Specifications	BG (Justifications): See general comments.

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1. The Commission may by means of implementing acts adopt common specifications that enable compliance with the essential requirements set out in Annex II in any of the following cases:	BE (Drafting suggestions): 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: BE (Justifications): We prefer the text as negotiated in the new Toy Safety Regulation: BG (Drafting suggestions): 1. The Commission may by means of implementing acts ~~adopt~~ establish common specifications ~~that enable compliance with the essential requirements set out in Annex II in any of~~ where the following ~~cases~~ conditions are fulfilled: CZ (Drafting suggestions): 1. The Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications that enable compliance with the essential requirements set out in Annex II ~~in any of~~ **where** the following ~~cases~~ **conditions are fulfilled**: CZ

Commission proposal	Drafting suggestions and Justifications
	(Justifications): CZ, in general, support the introduction of harmonised rules for adopting common specifications across sectoral legislation. However, the common specifications must remain a fallback option to the harmonised standards. Thus, the conditions for triggering the empowerment of the Commission to adopt the common specification must be well-defined and limited to situations where the harmonised standard is not available, or it is apparent that it will not be available within a reasonable period. DE (Drafting suggestions): 1**. <u>In exceptional cases</u>**, the Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Article 4. ~~in any of the following cases:~~ **<u>Those implementing acts shall only be adopted where the following conditions are fulfilled:</u>** DE (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation. FR (Drafting suggestions): 1. The Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set

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	out in Annex II ~~in any of the following cases~~ **Those implementing acts shall only be adopted where the following conditions are fulfilled :** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be achieved and will call for the wording used in the ESPR Regulation to be reinstated. HU (Drafting suggestions): 1. Subsystems and safety components which are in conformity with the common specifications referred to in paragraph 2 of this Article or parts thereof shall be presumed to be in conformity with the essential requirements set out in Annex II to the extent that those requirements are covered by those common specifications or parts thereof. HU (Justifications):

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	As regards to the introduction of common specifications, we find it important to keep harmonised standards a priority. Adoption of common specifications should happen only as a fallback option, based on reasonable criteria, in case standards are not available. The proposed text does not reflect this principle properly. Therefore, we prefer using a text based on the Toy Safety Regulation and Machinery Regulation, as they are more detailed and ensure priority of standards and exceptionality of common specifications. Using those texts would also facilitate the horizontally uniform handling of common specifications. These texts also provide legal clarity what happens when a reference of a harmonised standard is published in the OJEU after common specifications had been adopted. Furthermore, they clarify what Member States should be if they have concerns of a common specification. NL (Drafting suggestions): 1**. <u>In exceptional cases</u>**, the Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex II. ~~in any of the following cases:~~ **<u>Those implementing acts shall only be adopted where the following conditions are fulfilled:</u>** NL (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation

Commission proposal	Drafting suggestions and Justifications
	SE (Drafting suggestions): The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential requirements set out in Annex II in any of the following cases. Those implementing acts shall only be adopted where the following conditions are fulfilled: (a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex II. (i) the request has not been accepted; or (ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or (iii) the harmonised standards do not comply with the request; and (b) no reference to harmonised standards covering the relevant essential requirements set out in Annex II has been published in the Official Journal of the European Union in accordance with Regulation (EU) No

Commission proposal	Drafting suggestions and Justifications
	1025/2012 and no such reference is expected to be published within a reasonable period. SE (Justifications): Reference to common specifications should be in line with existing EU-legislation, such as regulation (EU) 2023/1230 and the toy safety regulation. Important that the wording reflects the fact that common specifications should be an exceptional fall-back option.
(a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;	BE (Drafting suggestions): 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 BG (Drafting suggestions): (a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* and no such reference is expected to be published within a reasonable period; (a1) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European

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	standardisation organisations to draft or to revise European standards for the essential requirements set out in Annex II and: (i) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or (ii) 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: — are not delivered within the deadline set in the request; — do not comply with the request; or — do not satisfy the requirements they aim to cover. CZ (Drafting suggestions): (a) ~~requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex II and:** **(i) the request has not been accepted; or**

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	(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or **(iii) the harmonised standards do not comply with the request; and** DE (Drafting suggestions): ~~(b) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;~~ **(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or** **(iii) the harmonised standards do not comply with the request; and** DE (Justifications): Ensure consistency with existing harmonised product legislation (see above). FR (Drafting suggestions): **(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for essential requirements ; and:** **(i) the request has not been accepted;**

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	(ii) the harmonised standard addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or **(iii) the harmonised standard does not comply with the request; and** ~~(a~~ **b**) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* ;**in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be achieved and will call for the wording used in the ESPR Regulation to be reinstated.

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	HU (Drafting suggestions): 2. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the applicable essential 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: (i) are not delivered within the deadline set in the request; (ii) do not comply with the request; or (iii) do not satisfy the requirements they aim to cover. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

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	NL (Drafting suggestions): ~~(a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;~~ **(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex II and:** **(i) the request has not been accepted; or** **(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or** **(iii) the harmonised standards do not comply with the request; and** NL (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation.
(b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex II; or	BE (Drafting suggestions): 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

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	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. BG (Drafting suggestions): deleted CZ (Drafting suggestions): (b) ~~requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex II; or~~ **no reference to harmonised standards covering the relevant essential requirements set out in Annex II has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.** DE (Drafting suggestions): (~~b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in~~

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	~~the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex II; or~~ DE (Justifications): Ensure consistency with existing harmonised product legislation (see above). FR (Drafting suggestions): ~~(b)~~ **c)** requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of a product with the essential requirements set out in Annex II **and those harmonised standards, or parts thereof, have been subject to a decision referred to in paragraph 1 article 11 of Regulation (EU) No 1025/2012** FR (Justifications): The French authorities support the use of common specifications when harmonised standards do not fully meet the relevant requirements, provided that such standards have been subject to a formal objection in accordance with Article 11 of Regulation (EU) No 1025/2012 on formal objections.

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	They therefore wish for the Omnibus IV Regulation to explicitly mention this possibility, in order to clarify its application and its consistency with the mechanism provided for in Article 11 of the Regulation. HU (Drafting suggestions): 3. Before preparing the draft implementing act referred to in paragraph 2, 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 2 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the relevant bodies and expert groups, and shall duly consult all relevant stakeholders. NL (Drafting suggestions): ~~(b) requirements set out in Article II are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of a product with the essential requirements set out in Article II; or~~ **(b) no reference to harmonised standards covering the relevant essential requirements set out in Annex II has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.**

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	NL (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation
(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.	BE (Drafting suggestions): delete BE (Justifications): This should be first addressed by the regular standardisation system BG (Drafting suggestions): deleted CZ (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~ CZ (Justifications): CZ does not agree with the condition set out in this provision. It would provide the Commission with extensive empowerment, which is not

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	clearly defined and which undermines the requested fallback nature of the common specifications. DE (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant materials, components and EEE.~~ DE (Justifications): Ensure consistency with existing harmonised product legislation (see above) FR (Drafting suggestions): *pending clarification by the Commission]* FR (Justifications): The French authorities are asking for more details and illustrative examples of the "urgent concern" raised and wonder how they relate to the provisions already adopted in the sectoral texts covered by Omnibus IMERA. HU (Drafting suggestions):

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	4. 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 the harmonised 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 2, or parts thereof which cover the same essential requirements set out in Annex II as those covered by that harmonised standard. NL (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~ NL (Justifications): It is not clear what 'an urgent concern' exactly is. Point a) and b) cover the necessary conditions to establish common specifications if necessary.
Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).	BG (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure referred to in Article 44(~~2~~3). 1a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred

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	to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant expert group and shall duly consult all relevant stakeholders. CZ (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 44(~~2~~**3**). **1a. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **1b. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** CZ (Justifications): CZ insists on adopting the implementing acts establishing the common specification in accordance with the examination procedure.

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	CZ also insists that the Committee on Standards established under Regulation 1025/2012 must be informed that the Commission considers the conditions in paragraph 1 to have been fulfilled. The drafts of the implementing acts should be properly consulted with all relevant stakeholders. DE (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory procedure referred to in Article 44(2)~~ **examination procedure, as in Article 5 of Regulation 182/2011**. **2. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **3. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** DE (Justifications): Besides ensuring consistency with existing harmonised product legislation (see above), we would like to highlight that the Member States need to be able to examine and if necessary modify the implementing acts during the adoption process. Besides, we would like to emphasize the

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	need for transparency and clearly defined process involving all relevant stakeholders. HU (Drafting suggestions): 5. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex II, 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. NL (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory procedure referred to in Article 44(2)~~ **examination procedure referred to in Article 44 (3)**. **2. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **3. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** NL (Justifications):

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	Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation. AT (Drafting suggestions): Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). AT (Justifications): Similar to art 20 of the regulation on machinery 2023/1230 and art 14 of the latest proposal of the regulation on the safety of toys (COM(2023) 462 final), the task of the committee on cableway installations must be changed from advisory to examination procedure for common specifications. Otherwise, the regulations on machinery and the safety of toys would be more restrictive than the regulation on cableway installations. This would contradict the horizontal Omnibus approach.
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.’;	BE (Drafting suggestions): + add: Before preparing the draft implementing act referred to in paragraph 2, 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 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the Expert Group on **** and shall duly

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	consult all relevant stakeholders. 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 the harmonised 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 2, or parts thereof which cover the same essential safety requirements as those covered by that harmonised standard. When a Member State considers that a common specification does not entirely satisfy the essential requirements, 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. BE (Justifications): Important to add the repeal or amendment, otherwise there will be a parallel circuit BG (Drafting suggestions): 2. Subsystems and safety components that are in conformity with common specifications referred to in paragraph 1 or parts thereof shall be presumed to be in conformity with essential requirements set out in Annex II covered by those common specifications or parts thereof~~, set out in Annex II~~.

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	2a. Where a European 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. 2b. 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.'; CZ (Drafting suggestions): 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. **2a. 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**

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	European Union, the Commission shall assess the harmonised 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 essential requirements as those covered by that harmonised standard. **2b. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex II, 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.**'; CZ (Justifications): CZ insists on addressing situations where a harmonised standard covering the same essential requirements is published in the Official Journal of the EU after the adoption of the common specification to avoid duplication. FR

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	(Drafting suggestions): 2. Subsystems and safety components that are in conformity with common specifications or parts thereof shall be presumed to be in conformity with essential requirements covered by those specifications or parts thereof, set out in Annex II.'; **3. Before preparing the draft of the implementing acts referred to in paragraph 1 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 the harmonised standard in accordance with Regulation (EU) No 1025/2012. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1 or the parts thereof which cover the same requirements** **6. Where a Member State or the European Parliament considers that a common specification does not entirely satisfy requirements, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation**

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	and, if appropriate, may amend the implementing act establishing the common specification in question. FR (Justifications): The French authorities consider it essential to ensure consistency between common specifications and harmonised standards. They have several questions regarding the proposed process and request that further clarifications be included in the texts of Omnibus IV, some of which already appear in the regulations that provide for the use of this mechanism. Indeed, the Machinery, AI, and ESPR Regulations have established satisfactory framing conditions; these should serve as a minimum reference framework to ensure a coherent European approach and to uphold the intended objective of simplification. HU (Drafting suggestions): ***Deleted*** NL (Drafting suggestions): 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.’;

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	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 the harmonised 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 3, or parts thereof which cover the same essential health and safety requirements as those covered by that harmonised standard. **6. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex III, 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.** NL (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation.

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	A common specification is a temporary fall-back solution in exceptional cases. Include that the existing implementing act shall be repealed in the situation where harmonised standards are adopted and published in OJEU that cover the same essential requirements as covered by the common specifications. Include the obligation for member states to inform the Commission if the common specifications do not satisfy the essential requirements. AT (Drafting suggestions): 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. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall assess whether the implementing acts referred to in paragraph 1 of this Article, which cover the same essential requirements, need to be repealed or amended. AT (Justifications): Similar to art 14 of the latest proposal of the regulation on the safety of toys (COM(2023) 462 final), paragraph 3 must be added. This also agrees with art 20, para 7 of the regulation on machinery 2023/1230.

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	Otherwise, the regulations on machinery and the safety of toys would be more restrictive than the regulation on cableway installations. This would contradict the horizontal Omnibus approach.
(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:	BG (Drafting suggestions): (8) ~~in~~ Article 19~~, the following paragraph 5 is added~~ is amended as follows: (a) in paragraph 2, the second sentence is replaced by the following: 'It shall be translated into the language or languages required by the Member State in which the subsystem or the safety component is placed or made available on the market. **The subsystem and the safety component shall be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed**.'; (b) the following paragraph 5 is added:

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	BG (Justifications): New point is added – the EU declaration of conformity is in electronic form and does not accompany the product.
'5. Where other Union legislation applicable to subsystem or a safety component requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in in Annex IX to be included in the EU declaration of conformity and referred to in Article 11(7) shall be provided only in that digital product passport.';	BE (Drafting suggestions): '5. Where other Union legislation applicable to the subsystem or ~~a~~ safety component requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in ~~in~~ Annex IX to be included in the EU declaration of conformity and referred to in Article 11(7) shall be provided only in that digital product passport.'; BG (Drafting suggestions): '5. Where other Union legislation applicable to a subsystem or a safety component requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in ~~in Annex IX~~ paragraph 2 of this Article to be included in the EU declaration of conformity and the instructions referred to in Article 11(7) ~~shall~~ may be provided only in that digital product passport. Where the information required in paragraph 2 of this Article to be included in the EU declaration of conformity is provided in the digital product

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	passport economic operators shall be deemed to fulfil their obligations related to drawing up and keeping the EU declaration of conformity under Article 11(2) and (3), Article 12(2)(a), Article 13(8), point 5.2 of Annex IV, point 6.2 of Annex V, point 4.2 of Annex VI and point 5.2 of Annex VII.'; BG (Justifications): See general comments.
(9) in Article 26, paragraph 7, point (c) is replaced by the following:	
'(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';	BG (Drafting suggestions): '(c) appropriate knowledge and understanding of the essential requirements set out in Annex II, of the applicable harmonised standards ~~or~~ and common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';
(10) in Article 34, paragraph 3 is replaced by the following:	
'3. Where a notified body finds that the essential requirements set out in Annex II or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.';	BG (Drafting suggestions): '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

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	shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.'; (10a) in Article 40(5) the following point (c) is added: '(c) shortcomings in the common specifications referred to in Article 17a conferring a presumption of conformity.'; (10b) in Article 41, paragraph 3 is replaced by the following: '3. Where the national measure is considered justified and the non-compliance of the subsystem or safety component is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Regulation **or the common specifications referred to in point (c) of Article 40(5) of this Regulation**, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 **or in Article 17a(2b) of this Regulation respectively**.'; BG (Justifications): New points (10a) and (10b) are added - shortcomings in the common specifications (see general comments).
(11) in Article 43(1), point (d) is replaced by the following:	
'(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;'.	BG (Drafting suggestions): '(d) the subsystem or safety component is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;'.

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	(11a) Article 43d is amended as follows: (a) the title is replaced by the following: 'Article 43d Presumption of conformity based on standards and **crisis-relevant** common specifications'; (b) paragraph 1 is replaced by the following: '1. Where subsystems and safety components have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing **crisis-relevant** common specifications for such subsystems and safety components to cover the applicable essential requirements set out in Annex II to this Regulation in the following cases: (a) where a reference to harmonised standards covering the applicable essential requirements set out in Annex II to this Regulation has not been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period, **and common specifications referred to in Article 17a covering the essential requirements set out in Annex II to this Regulation have not been established and are not expected to be established within a reasonable period**; or (b) where severe disruptions to the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 18 of Regulation (EU) 2024/2747, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover

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	the applicable essential requirements set out in Annex II to this Regulation and the references of which have already been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 **or of the common specifications referred to in Article 17a of this Regulation**.'; (c) in paragraph 2, the second sentence is replaced by the following: 'To that end, references of European standards or references of relevant applicable national or international standards may be published in those implementing acts or, if there is no European standard or relevant applicable national or international standard, **crisis-relevant** common specifications may be established by those implementing acts.'; (d) paragraphs 5, 6 and 7 are replaced by the following: '5. Without prejudice to **Articles 17 and 17a**, subsystems and safety components that are in conformity with the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article, or parts thereof, shall be presumed to be in conformity with the applicable essential requirements set out in Annex II that are covered by those standards, **crisis-relevant** common specifications or parts thereof. From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the standards or the **crisis-relevant** common specifications referred to in **or established by** the implementing acts referred to in paragraph 1 of this Article. 6. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components, covered by the standards or **crisis-relevant** common

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	specifications referred to in paragraph 1 of this Article, present a risk to the health or safety of persons, the subsystems or safety components that are in conformity with those standards or **crisis-relevant** common specifications and which have been placed on the market, shall be deemed to be in conformity with the applicable essential requirements set out in Annex II after the expiry or repeal of an implementing act adopted pursuant to paragraph 3 of this Article and after the expiry or deactivation of the internal market emergency mode. 7. When a Member State considers that a standard or **crisis-relevant** common specification referred to in paragraph 1 does not entirely satisfy the applicable essential requirements set out in Annex II, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend or repeal the implementing act listing the standard or establishing the **crisis-relevant** common specification in question.'; BG (Justifications): New point (11a) is added - crisis-relevant common specifications (see general comments).
(12) Annexes III to IX are amended in accordance with Annex I to this Regulation.	
Article 3	
Amendments to Regulation (EU) 2016/425	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

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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 accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';	BE (Drafting suggestions): We would like the definition of "digital contact" to be clarified to avoid it referring to a simple webpage or to other elements that do not allow for direct, effective, and traceable communication. Instead, it should imply a truly functional means of communication — an email address being one of the most illustrative examples. This would also help prevent confusion regarding acceptable formats or communication channels. BE (Justifications): As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and potentially inaccessible or unavailable due to changes to the relevant website. A mere mention of a website compels consumers or Market

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	Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should for instance take the form of an email address that is directly accessible without intermediate steps. This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address DE (Drafting suggestions): '(8a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be ~~reached or engaged~~ **contacted** without the need to register or to download an application;'; DE (Justifications): It is unclear what is meant by "reached or engaged". According to our understanding the intention is that the economic operators can be contacted.
(b) the following point (10a) is inserted:	
'(10a) 'common specifications' means a set of technical requirements, other than a standard, that provides a means of complying with the	BG

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essential requirements applicable to a product, device, service, process or system;’;	(Drafting suggestions): ‘(10a) ‘common specification~~s~~’ means a ~~set of technical requirements~~ technical specification, other than a standard, that provides a means of complying with the essential health and safety requirements set out in Annex II of this Regulation applicable to PPE ~~a product, device, service, process or system~~;’; BG (Justifications): See general comments. SE (Drafting suggestions): See comment above.
(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	

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technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.’;	
(c) in paragraph 6, the first and second sentences are replaced by the following:	
‘Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the PPE. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached.’;	DE (Drafting suggestions): ‘Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact or, where that is not possible, on its packaging or in a document accompanying the PPE. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~reached~~ **contacted**.’; DE (Justifications): It is unclear what is meant by “reached or engaged”. According to our understanding the intention is that the economic operators can be contacted.
(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.	LT (Justifications): Why are these two terms (“***consumers and other end-users”)*** present separately since “end user” defines both? According to Article 3(21) of Regulation 2019/1020 (Market Surveillance and Conformity of Products): ‘end user’ means any natural or legal person residing or established in the Union, to whom a product has been

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	made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities, i.e. this term includes both non-professional consumers and professional end-users, and the term 'end-user' refers to both of them together.
The manufacturer shall take into account the intended use and the foreseeable end-user of the PPE when deciding the specific format for the instructions and information set out in point 1.4 of Annex II.	
In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II.. Such information shall be easily visible and legible for consumers.	DE (Drafting suggestions): ~~In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II.. Such information shall be easily visible and legible for consumers.~~ **In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or make them visible on the packaging, the safety information needed to use the PPE correctly. Such information shall be easily visible and legible for consumers.** DE (Justifications):

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	As in the other sectors, the obligation for paper form should be related to safety information. Otherwise, most PPE would be excluded from the benefits of a digital solution. FR (Drafting suggestions): ~~In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them,~~ **.The** manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II.. Such information shall be easily visible and legible for ~~consumers~~ **end users** FR (Justifications): The French authorities welcome all proposals aimed at facilitating the transfer of information between economic operators and authorities, and at harmonizing this transfer through electronic means rather than on paper. They believe that such measures are likely to eliminate redundancies and create more efficient processes for all stakeholders. However, they would like to make the following comments: Such a principle should not prevent the legislator from providing for more restrictive provisions in favor of physical formats (in particular paper), where sector-specific security concerns justify it LT (Justifications): Given the potential for limited digital literacy, we believe that there may be difficulties in accessing, navigating or fully understanding digital

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	instructions, which may lead to misuse or safety risks. The dependence on electronic devices (smartphones, tablets, computers) means that if the device breaks down, is lost or the battery runs out, access to instructions may be disrupted at critical moments. Also, the amount of information, digital interfaces may make it difficult for users to quickly find and interpret critical safety instructions/information, especially under stress. In this regard, we would suggest assessing the potential risks and considering the provisions of Regulation 2023/1230 (Machinery) and Regulation 2016/425 (Personal Protective Equipment) that safety-related information is provided immediately in paper format only to a non-professional user, while a professional has to wait up to 1 month. We believe that such information should be provided immediately in paper format upon purchase of the item, regardless of the type of user. According to Article 3(21) of Regulation 2019/1020 (Market Surveillance and Conformity of Products): 'end user' means any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities, i.e. this term includes both non-professional consumers and professional end-users, and the term 'end-user' refers to both of them together. The term "consumers", under Regulation 2019/1020 would suit non-professional users.
When drafting the instructions and information set out in point 1.4 of Annex II, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.	DE (Drafting suggestions):

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	~~When drafting the instructions and information set out in point 1.4 of Annex II, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.~~ **When drafting the instructions, information set out in point 1.4 of Annex II or safety information, the manufacturers shall take account of the intended use and foreseeable misuse by the end-user.**
When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:	BE (Drafting suggestions): When the instructions and safety information, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall: BE (Justifications): This is also valid for the safety information BG (Drafting suggestions): When the instructions and information, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall: DE (Drafting suggestions): When the instructions **or safety information**, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall: DE

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	(Justifications): For PPE that are not intended for consumers and are not used by consumers even under reasonably foreseeable conditions, safety information may be provided in electronic form. In that case, requirements of points (a) to (c) should also apply to that safety information.
(a) mark on the PPE, 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;	BE (Drafting suggestions): (a) mark on the PPE, or, where that is not possible, on its packaging or in an accompanying document, how to access them via a direct link and how to request them in paper format; BE (Justifications): It is well known that users are often reluctant to consult the manual before using certain products. Making instructions available only online requires additional steps for users to consult them and will possibly result in even fewer actual manuals being consulted. In order to try to limit this negative impact of digitalisation, it is necessary to provide a direct link to the instructions for end users
(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the PPE; this requirement also applies where the instructions are embedded in the software of the PPE;	BE (Drafting suggestions): (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 without the need to register, to download an application, or to provide any personal information in any form so that the

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	end-user can access them at all times, in particular during a breakdown of the PPE; this requirement also applies where the instructions and safety information are embedded in the software of the PPE; BE (Justifications): This is also valid for the safety information No information or data should be required from users to access electronic instructions. End-users should therefore be able to access the instructions without registration or the provision of any personal information. DE (Drafting suggestions): (b) present them in a format that makes it possible for the end-user to print and download the instructions **or 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 PPE; this requirement also applies where the instructions **or safety information** are embedded in the software of the PPE; DE (Justifications): For PPE that are not intended for consumers and are not used by consumers even under reasonably foreseeable conditions, safety information may be provided in electronic form. In that case, requirements of points (a) to (c) should also apply to that safety information.

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(c) make them accessible online during the expected lifetime of the PPE and for at least 10 years after the placing on the market of the PPE.	
However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.	BE (Drafting suggestions): 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 request the instructions or safety information in paper format and linked to the correct unit of the purchased PPE, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request. BE (Justifications): The possibility for end-users to request a paper version within six months of purchasing the product is overly restrictive without considering all possible practical scenarios. This time period should be extended to account for practical considerations. If the product is transferred or given to another person, the end-user may be penalized by such a short time limit, which may already have expired by the time they receive the product. Since electronic instructions must remain accessible online during the expected lifetime of the product, it would be reasonable for end-users to be able to request a paper version from the manufacturer for the same duration. Different versions of the same product can exist, meaning the

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	end-user should be able to receive instructions specific to the version they purchased. DE (Drafting suggestions): ~~However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request.~~ However, the end-user may, at time of the purchase of the PPE, or up to six months after that purchase, request the instructions, information set out in point 1.4 of Annex II **and safety information** in paper format. Where the end-user requests those instructions, information set out in point 1.4 of Annex II **and safety information**, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request. DE (Justifications): For PPE that are not intended for consumers and are not used by consumers even under reasonably foreseeable conditions, safety information may be provided in electronic form. In that case, requirements of points (a) to (c) should also apply to that safety information. FR

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	(Drafting suggestions): However, the end-user may, at time of the purchase of the PPE, o~~r up to six months after that purchase,~~ request the instructions and information set out in point 1.4 of Annex II in paper format. Where the end-user requests those instructions and information set out in point 1.4 of Annex II, the manufacturer shall provide them to the end-user, free of charge, within one month of receiving the request. FR (Justifications): The six-month period imposes administrative burdens that appear misaligned with the objectives of the Omnibus Regulation. The French authorities recommend aligning the provisions with those set out in the Machinery Regulation, whereby the request would be submitted at the time of purchase. LT (Justifications): Which user does the term “end-user” imply? Because non-professional users (“consumer”) has to receive all the information during the purchase.
8. The manufacturer shall provide the internet address or machine-readable code through which the EU declaration of conformity can be accessed with the PPE.’;	BG (Drafting suggestions): 8. The manufacturer shall ~~provide~~ ensure that the PPE is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed ~~with the PPE~~.’;

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(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:	BG (Drafting suggestions): (4) Article 10 is amended as follows: (a0) in paragraph 2, first subparagraph, the second sentence is replaced by the following: 'They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied **by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and** by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).'; BG (Justifications):

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	New point (a0) is added to clarify that the PPE must be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed.
(a) in paragraph 3, the first sentence is replaced by the following:	
'Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be reached or, where that is not possible, on its packaging or in a document accompanying the PPE.';	BG (Drafting suggestions): 'Importers shall indicate, on the PPE, their name, registered trade name or registered trademark as well as their postal address and digital contact through which they can be reached or, where that is not possible, on its packaging or in a document accompanying the PPE.'; (a1) paragraph 4 is replaced by the following: '4. Importers shall ensure that the instructions and information set out in point 1.4 of Annex II **are available in accordance with Article 8(7)** in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.'; BG (Justifications): New point (a1) is added amending paragraph 4 to avoid contradictions with Article 8(7)
(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	BG (Drafting suggestions):

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documentation necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority.’;	‘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:	BG (Drafting suggestions): (5) ~~in~~ Article 11~~(5) the first sentence is replaced by the following~~ is amended as follows: (a) in paragraph 2, the first subparagraph is replaced by the following: ‘Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by **the internet address or machine-readable code through which the EU declaration of conformity can be accessed and** by the required documents, **that** the instructions and information set out in point 1.4 of Annex II **are available in accordance with Article 8(7)** in a language which can be easily understood by consumers and other end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.’; (b) in paragraph 5, the first sentence is replaced by the following: BG (Justifications):

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	New point (a) is added amending paragraph 2 to clarify that the PPE must be accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and to avoid contradictions with Article 8(7).
'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	BG (Justifications): See general comments.
1. The Commission may by means of implementing acts adopt common specifications that enable compliance with essential requirements set out in Annex II in any of the following cases:	BE (Drafting suggestions): 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: BE (Justifications): We prefer the text as negotiated in the new Toy Safety Regulation: BG (Drafting suggestions):

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	1. The Commission may by means of implementing acts ~~adopt~~ establish common specifications ~~that enable compliance with essential requirements set out in Annex II in any of~~ where the following ~~cases~~ conditions are fulfilled: CZ (Drafting suggestions): 1. The Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications that enable compliance with the essential requirements set out in Annex II ~~in any of~~ **where** the following ~~cases~~ **conditions are fulfilled**: CZ (Justifications): CZ, in general, support the introduction of harmonised rules for adopting common specifications across sectoral legislation. However, the common specifications must remain a fallback option to the harmonised standards. Thus, the conditions for triggering the empowerment of the Commission to adopt the common specification must be well-defined and limited to situations where the harmonised standard is not available, or it is apparent that it will not be available within a reasonable period. DE (Drafting suggestions): 1. **In exceptional cases**, the Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex II. ~~in any of the following cases:~~

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	Those implementing acts shall only be adopted where the following conditions are fulfilled: DE (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation. FR (Drafting suggestions): 1. The Commission may by means of implementing acts adopt common specifications that enable compliance with the essential requirements set out in in Annex II. ~~in any of the following cases~~ **Those implementing acts shall only be adopted where the following conditions are fulfilled :** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be

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	achieved and will call for the wording used in the ESPR Regulation to be reinstated. HU (Drafting suggestions): 1. PPE which is in conformity with the common specifications referred to in paragraph 2 of this Article or parts thereof shall be presumed to be in conformity with the essential requirements set out in Annex II to the extent that those requirements are covered by those common specifications or parts thereof. HU (Justifications): As regards to the introduction of common specifications, we find it important to keep harmonised standards a priority. Adoption of common specifications should happen only as a fallback option, based on reasonable criteria, in case standards are not available. The proposed text does not reflect this principle properly. Therefore, we prefer using a text based on the Toy Safety Regulation and Machinery Regulation, as they are more detailed and ensure priority of standards and exceptionality of common specifications. Using those texts would also facilitate the horizontally uniform handling of common specifications. These texts also provide legal clarity what happens when a reference of a harmonised standard is published in the OJEU after common specifications had been adopted. Furthermore, they clarify what Member States should be if they have concerns of a common specification.

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	SE (Drafting suggestions): See comment above. SE (Justifications): See comment above - Reference to common specifications should be in line with existing EU-legislation, such as regulation (EU) 2023/1230 and the toy safety regulation. Important that the wording reflects the fact that common specifications should be an exceptional fall-back option.
(a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;	BE (Drafting suggestions): 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 BG (Drafting suggestions): (a) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* and no such reference is expected to be published within a reasonable period; (a1) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European

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	standardisation organisations to draft or to revise European standards for the essential health and safety requirements set out in Annex II and: (i) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or (ii) 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: — are not delivered within the deadline set in the request; — do not comply with the request; or — do not satisfy the requirements they aim to cover. CZ (Drafting suggestions): (a) ~~requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex II and:** **(i) the request has not been accepted; or**

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	(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or **(iii) the harmonised standards do not comply with the request; and** DE (Drafting suggestions): (~~a) requirements set out in Annex II are not covered by harmonised standards, or partsthereof, the references of which have been published in the *Official Journal of the European Union*~~; **(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or** **(iii) the harmonised standards do not comply with the request; and** DE (Justifications): See above, ensure consistency FR (Drafting suggestions): **(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for essential requirements ; and:** **(i) the request has not been accepted;**

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	(ii) the harmonised standard addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or **(iii) the harmonised standard does not comply with the request; and** ~~(a~~ **b**) requirements set out in Annex II are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* ;**in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be achieved and will call for the wording used in the ESPR Regulation to be reinstated.

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	HU (Drafting suggestions): 2. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the applicable essential 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: (i) are not delivered within the deadline set in the request; (ii) do not comply with the request; or (iii) do not satisfy the requirements they aim to cover. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

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(b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of PPE with the requirements set out in Annex II, or	BE (Drafting suggestions): 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. BG (Drafting suggestions): deleted CZ (Drafting suggestions): (b) ~~requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of PPE with the requirements set out in Annex II, or~~ **no reference to harmonised standards covering the relevant essential requirements set out in Annex II has been published in the Official Journal of the European Union in accordance with Regulation (EU)**

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	No 1025/2012 and no such reference is expected to be published within a reasonable period. DE (Drafting suggestions): ~~b) requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex II; or~~ DE (Justifications): See above, ensure consistency. FR (Drafting suggestions): ~~(b)~~ **c)** requirements set out in Annex II are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of PPE with the requirements set out in Annex II **and those harmonised standards, or parts thereof, have been subject to a decision referred to in paragraph 1 article 11 of Regulation (EU) No 1025/2012** FR (Justifications):

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	The French authorities support the use of common specifications when harmonised standards do not fully meet the relevant requirements, provided that such standards have been subject to a formal objection in accordance with Article 11 of Regulation (EU) No 1025/2012 on formal objections. They therefore wish for the Omnibus IV Regulation to explicitly mention this possibility, in order to clarify its application and its consistency with the mechanism provided for in Article 11 of the Regulation. HU (Drafting suggestions): 3. Before preparing the draft implementing act referred to in paragraph 2, 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 2 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the relevant bodies and expert groups, and shall duly consult all relevant stakeholders.
(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant PPE.	BE (Drafting suggestions): delete BE (Justifications): This should be first addressed by the regular standardisation system

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	BG (Drafting suggestions): deleted CZ (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant PPE.~~ CZ (Justifications): CZ does not agree with the condition set out in this provision. It would provide the Commission with extensive empowerment, which is not clearly defined and which undermines the requested fallback nature of the common specifications. DE (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant materials, components and EEE.~~ DE (Justifications): See above, ensure consistency. FR (Drafting suggestions): *pending clarification by the Commission]*

Commission proposal	Drafting suggestions and Justifications
	FR (Justifications): The French authorities are asking for more details and illustrative examples of the "urgent concern" raised and wonder how they relate to the provisions already adopted in the sectoral texts covered by Omnibus IMERA. HU (Drafting suggestions): 4. 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 the harmonised 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 2, or parts thereof which cover the same essential requirements set out in Annex II as those covered by that harmonised standard.
Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 44(2).	BG (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure referred to in Article 44(~~2~~3).

Commission proposal	Drafting suggestions and Justifications
	1a. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant expert group and shall duly consult all relevant stakeholders. CZ (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 44(~~2~~**3**). **1a. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **1b. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** CZ (Justifications): CZ insists on adopting the implementing acts establishing the common specification in accordance with the examination procedure.

Commission proposal	Drafting suggestions and Justifications
	DE (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory procedure referred to in Article 44(2)~~ **examination procedure, as in Article 5 of Regulation 182/2011**. **2. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **3. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** DE (Justifications): See above, ensure consistency. HU (Drafting suggestions): 5. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex II, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if

Commission proposal	Drafting suggestions and Justifications
	appropriate, amend the implementing act establishing the common specification in question.
2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II.’;	BE (Drafting suggestions): + add: Before preparing the draft implementing act referred to in paragraph 2, 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 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the Expert Group on **** and shall duly consult all relevant stakeholders. 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 the harmonised 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 2, or parts thereof which cover the same essential safety requirements as those covered by that harmonised standard. When a Member State considers that a common specification does not entirely satisfy the essential safety requirements, 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. BE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): Important to add the repeal or amendment, otherwise there will be a parallel circuit BG (Drafting suggestions): 2. PPE that is in conformity with common specifications referred to in paragraph 1 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof~~, set out in Annex II~~. 2a. Where a European 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. 2b. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential health and safety requirements set out in Annex II which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed

Commission proposal	Drafting suggestions and Justifications
	explanation and may, if appropriate, amend the implementing act establishing the common specification in question.'; CZ (Drafting suggestions): 2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II. **2a. 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 the harmonised 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 essential requirements as those covered by that harmonised standard.** **2b. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex II, 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.**';

Commission proposal	Drafting suggestions and Justifications
	CZ (Justifications): CZ insists on addressing situations where a harmonised standard covering the same essential requirements is published in the Official Journal of the EU after the adoption of the common specification to avoid duplication. DE (Drafting suggestions): ~~PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II.';~~ **3. Before preparing the draft implementing act referred to in paragraph 2, 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 2 have been fulfilled.** **4. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.**

Commission proposal	Drafting suggestions and Justifications
	5. A product within the scope of this Regulation which is in conformity with the common specifications established by implementing acts referred to in paragraph 2, or parts thereof, shall be presumed to be in conformity with the requirements set out in Annex II covered by those common specifications or parts thereof. **6. 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 the harmonised 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 2, or parts thereof which cover the same requirements as those covered by that harmonised standard.** **7. When a Member State considers that a common specification does not entirely satisfy the requirements set out in Annex II, 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.** FR (Drafting suggestions): 2. PPE that is in conformity with common specifications or parts thereof shall be presumed to be in conformity with the essential

Commission proposal	Drafting suggestions and Justifications
	requirements covered by those specifications or parts thereof, set out in Annex II.'; **3. Before preparing the draft of the implementing acts referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article are fulfilled.** **4. When preparing the draft of the implementing acts referred to in paragraph 1, the Commission shall take into account the views of the 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 the harmonised standard in accordance with Regulation (EU) No 1025/2012. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1 or the parts thereof which cover the same requirements** **6. Where a Member State or the European Parliament considers that a common specification does not entirely satisfy requirements, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, if appropriate, may amend the implementing act establishing the common specification in question.**

Commission proposal	Drafting suggestions and Justifications
	FR (Justifications): The French authorities consider it essential to ensure consistency between common specifications and harmonised standards. They have several questions regarding the proposed process and request that further clarifications be included in the texts of Omnibus IV, some of which already appear in the regulations that provide for the use of this mechanism. Indeed, the Machinery, AI, and ESPR Regulations have established satisfactory framing conditions; these should serve as a minimum reference framework to ensure a coherent European approach and to uphold the intended objective of simplification. HU (Drafting suggestions): ***Deleted***
(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 and the instructions referred to in Article 8(7) shall be provided only in that digital product passport.';	BG (Drafting suggestions): '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~~ paragraph 2 of this Article to be included in the EU declaration of conformity and the

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	instructions referred to in Article 8(7) ~~shall~~ may be provided only in that digital product passport. Where the information required in paragraph 2 of this Article to be included in the EU declaration of conformity is provided in the digital product passport economic operators shall be deemed to fulfil their obligations related to drawing up and keeping the EU declaration of conformity under Article 8(2) and (3), Article 9(2)(a), Article 10(8), point 4.2 of Annex IV, point 3.2 of Annex VI, point 6.2 of Annex VII and point 5.2 of Annex VIII.'; BG (Justifications): See general comments. DE (Drafting suggestions): '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 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 safety information in paper format according to Article 8 (7).**'; DE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): To ensure the safety of consumers the safety information in paper format must not be replaced by the digital product passport. FI (Drafting suggestions): '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 ~~and the instructions referred to in Article 8(7)~~ shall be provided only in that digital product passport.'; FI (Justifications): The deleted part is in contradiction with what is proposed for article 7: In the case of PPE intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, *the manufacturer shall provide, in paper format, or make them visible on the packaging, the instructions and information set out in point 1.4 of Annex II*
(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.';	BE (Drafting suggestions): ~~Where applicable~~, the manufacturer shall provide to the notified body carrying out the conformity assessment procedure all the information and

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	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’;	BG (Drafting suggestions): ‘(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards ~~or~~ and common specifications, and of the relevant provisions of Union harmonisation legislation and of national legislation’;
(10) Article 25 is replaced by the following:	BG (Drafting suggestions): deleted
‘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 cover those requirements.’;	BG (Drafting suggestions): deleted BG (Justifications): Presumption of conformity for conformity assessment bodies must be based only on harmonised standards. According to the definition common specifications provide means of complying with the essential requirements and they apply to products, not to CABs. FI

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): '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.'; FI (Justifications): In the proposal "harmonised standards or common specifications" go hand in hand, so it seems "or common specifications" is lacking in the end of Article 25.
(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.'	BG (Drafting suggestions): '3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards, or common specifications, or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.' (11a) in Article 38(5) the following point (c) is added: '(c) shortcomings in the common specifications referred to in Article 14a conferring a presumption of conformity.';

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	(11b) in Article 39, paragraph 3 is replaced by the following: '3. Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation **or the common specifications referred to in point (c) of Article 38(5) of this Regulation**, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 **or in Article 14a(2b) of this Regulation respectively**.'; (11c) Article 41d is amended as follows: (a) the title is replaced by the following: 'Article 41d Presumption of conformity based on standards and **crisis-relevant** common specifications'; (b) paragraph 1 is replaced by the following: '1. Where PPE has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing **crisis-relevant** common specifications for such PPE to cover the applicable essential health and safety requirements set out in Annex II to this Regulation in the following cases: (a) where a reference to harmonised standards covering the applicable essential health and safety requirements set out in Annex II to this Regulation has not been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be

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	published within a reasonable period, **and common specifications referred to in Article 14a covering the essential health and safety requirements set out in Annex II to this Regulation have not been established and are not expected to be established within a reasonable period**; or (b) where severe disruptions to the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 18 of Regulation (EU) 2024/2747, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the applicable essential health and safety requirements set out in Annex II to this Regulation and the references of which have already been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 **or of the common specifications referred to in Article 14a of this Regulation**.'; (c) in paragraph 2, the second sentence is replaced by the following: 'To that end, references of European standards or references of relevant applicable national or international standards may be published in those implementing acts or, if there is no European standard or relevant applicable national or international standard, **crisis-relevant** common specifications may be established by those implementing acts.'; (d) paragraphs 5, 6 and 7 are replaced by the following: '5. Without prejudice to **Articles 14 and 14a**, PPE that is in conformity with the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article, or parts thereof, shall be presumed to be in conformity with the applicable essential health and safety requirements set

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	out in Annex II that are covered by those standards, **crisis-relevant** common specifications or parts thereof. From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the standards or the **crisis-relevant** common specifications referred to in **or established by** the implementing acts referred to in paragraph 1 of this Article. 6. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article presents a risk to the health or safety of persons, the PPE that is in conformity with those standards or **crisis-relevant** common specifications and which has been placed on the market shall be deemed to be in conformity with the applicable essential health and safety requirements set out in Annex II after the expiry or repeal of an implementing act adopted pursuant to paragraph 3 of this Article and after the expiry or deactivation of the internal market emergency mode. 7. When a Member State considers that a standard or **crisis-relevant** common specification as referred to in paragraph 1 does not entirely satisfy the applicable essential health and safety requirements set out in Annex II, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend or repeal the implementing act listing the standard or establishing the **crisis-relevant** common specification in question.'; BG

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	(Justifications): New points (11a) and (11b) are added - shortcomings in the common specifications (see general comments). New point (11c) is added - crisis-relevant common specifications (see general comments).
(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 accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;'	BE (Drafting suggestions): We would like the definition of "digital contact" to be clarified to avoid it referring to a simple webpage or to other elements that do not allow for direct, effective, and traceable communication. Instead, it should imply a truly functional means of communication — an email address being one of the most illustrative examples. This would also help prevent confusion regarding acceptable formats or communication channels. BE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and potentially inaccessible or unavailable due to changes to the relevant website. A mere mention of a website compels consumers or Market Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should for instance take the form of an email address that is directly accessible without intermediate steps. This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address. DE (Drafting suggestions): ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be ~~**reached or engaged**~~ **contacted** without the need to register or to download an application;’ DE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): It is unclear what is meant by "reached or engaged". According to our understanding the intention is that the economic operators can be contacted.
(b) the following point (23a) is inserted:	
'(23a) 'common specifications' means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements applicable to a product, device, service, process or system;';	BG (Drafting suggestions): '(23a) 'common specifications' means a ~~set of technical requirements~~ technical 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 ~~a product, device, service, process or system~~;'; BG (Justifications): See general comments. SE (Drafting suggestions): See comment above.
(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	

Commission proposal	Drafting suggestions and Justifications
first subparagraph, manufacturers shall draw up an EU declaration of conformity, in electronic form, and affix the CE marking.'; (b) in paragraph 4, first subparagraph, the second sentence is replaced by the following: 'Changes in appliance or fitting design or characteristics and changes in the harmonised standards or in the common specifications or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.'; (c) paragraphs 6 and 7 are replaced by the following: '6. Manufacturers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.	BE (Drafting suggestions): 'Changes in **the design or characteristics of the** 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.'; BE (Justifications): Align with the other texts DE (Drafting suggestions): Manufacturers shall indicate on the appliance their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the appliance. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~**reached**~~ **contacted**. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities. DE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): It is unclear what is meant by "reached". According to our understanding the intention is that the manufacturer can be contacted.
Manufacturers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached. 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.	DE (Drafting suggestions): Manufacturers shall indicate on the fitting their name, registered trade name or registered trademark, as well as their postal address and digital contact or, where that is not possible, on the packaging or in a document accompanying the fitting. The postal address and digital contact shall indicate a single point through which the manufacturer can be ~~**reached**~~ **contacted**. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities. DE (Justifications): It is unclear what is meant by "reached". According to our understanding the intention is that the manufacturer can be contacted.
Manufacturers shall take into account the intended use and the foreseeable end-user of the product when deciding the specific format for the instructions and safety information.	BG (Drafting suggestions): Manufacturers shall take into account the intended use and the foreseeable end-user of the ~~product~~ appliance when deciding the specific format for the instructions and safety information.
In the case of appliance or fitting intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or	BG (Drafting suggestions):

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mark on the equipment, the safety information. Such safety information shall be easily visible and legible for consumers.	In the case of appliance ~~or fitting~~ intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the ~~equipment~~ appliance, the safety information. Such safety information shall be easily visible and legible for consumers. BG (Justifications): Instructions for incorporation are not a separate document. They are part of the content of the EU declaration of conformity for fittings – see Article 15(3) and point 8 of Annex V to Regulation 2016/426. FR (Drafting suggestions): ~~In the case of appliance or fitting intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them~~, **The** manufacturer shall provide, in paper format, or mark on the equipment, the safety information **for putting the product into service and for using it safe way**. Such safety information shall be easily visible and legible for ~~consumers~~ **end-users.** FR (Justifications): The French authorities welcome all proposals aimed at facilitating the transfer of information between economic operators and authorities, and at harmonizing this transfer through electronic means rather than on paper. They believe that such measures are likely to eliminate redundancies and create more efficient processes for all stakeholders.

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	However, they would like to make the following comments: Such a principle should not prevent the legislator from providing for more restrictive provisions in favor of physical formats (in particular paper), where sector-specific security concerns justify it
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.	BE (Drafting suggestions): *When drafting the* ***markings and instructions*** ~~*safety information*~~*, the manufacturers shall take account of the intended use and foreseeable* ***(mis)****use by the end-user, as well as the role which the instructions play for ensuring safety.* BE (Justifications): "Safety information" is distinguished from other instructions and information without specifying what this term encompasses. This could create ambiguous situations in practice, as it is not always clear what constitutes safety-related content or what may be perceived as such. Moreover, applicable standards generally refer more broadly to "markings and instructions" without making such distinctions. Given the current state of the proposal, it is therefore necessary to define the concept of "safety information."
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 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	BE (Drafting suggestions): *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* ***directly*** *accessed* ***without the need to register, to***

Commission proposal	Drafting suggestions and Justifications
appliance manufacturers, as determined by the Member State concerned. The instructions may be provided in electronic form.	***download an application, or to provide any personnal information in any form*** *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.* ***Except for the safety instructions,*** *the instructions may be provided in electronic form.* BE (Justifications): No information or data should be required from users or MSA's to access electronic instructions. End-users should therefore be able to access the instructions without registration or the provision of any personal information. Since GAR-related instructions are invariably linked to safety considerations, and safety instructions represent manufacturers' final recourse when design measures alone cannot sufficiently minimize risks, it is essential to ensure that these safety instructions are provided in physical format to guarantee end-user safety. The current proposal creates confusion; therefore, it should be clearly specified that digital instructions constitute an additional option rather than an alternative to paper-based instructions. Digital instructions create additional steps for end-users to access safety instructions, which will likely result in fewer people reading these critical safety materials. BG (Drafting suggestions): 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. The EU declaration of conformity shall

Commission proposal	Drafting suggestions and Justifications
	contain, inter alia, ~~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.~~ BG (Justifications): Instructions for incorporation are not a separate document. They are part of the content of the EU declaration of conformity for fittings – see Article 15(3) and point 8 of Annex V to Regulation 2016/426.
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 accessed.	BE (Drafting suggestions): *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* ***without the need to register, to download an application, or to provide any personnal information in any form****.* BE (Justifications): No information or data should be required from users or MSA's to access electronic instructions. End-users should therefore be able to access the instructions without registration or the provision of any personal information.

Commission proposal	Drafting suggestions and Justifications
	BG (Drafting suggestions): However, where a large number of fittings are delivered to a single ~~end~~ user, the batch or consignment concerned may be accompanied by a single document containing the internet address or machine-readable code through which the EU declaration of conformity can be accessed.
When the instructions, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:	BE (Drafting suggestions): *When the **other** instructions **and safety information**, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall:* BE (Justifications): To avoid misunderstanding and maintain consistency with the amendments in the first subparagraph, a clear reference is necessary. This is also valid for the safety information BG (Drafting suggestions): When the instructions and safety information, referred to in the first subparagraph, are provided in electronic form, the manufacturer shall: DE (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	When the instructions **or safety information**, referred to in the first **or fifth** subparagraph, are provided in electronic form, the manufacturer shall: DE (Justifications): For appliances that are not intended for consumers and are not used by consumers even under reasonably foreseeable conditions, safety information may be provided in electronic form. In that case, requirements of points (a) to (c) should also apply to that safety information. Requirements of points (a)-(c) shall also apply to instructions for fittings. Fittings are not covered by the first subparagraph but the fifth subparagraph.
(a) mark on the appliance or fitting, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format;	BE (Drafting suggestions): *(a) mark on the appliance or fitting, or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format* ***by providing a direct link to the instructions;*** BE (Justifications): It is well known that users are often reluctant to consult the manual before using certain products. Making instructions available only online requires additional steps for users to consult them and will possibly result in even fewer actual manuals being consulted.

Commission proposal	Drafting suggestions and Justifications
	In order to try to limit this negative impact of digitalisation, it is necessary to provide a direct link to the instructions for end users. BG (Drafting suggestions): (a) mark on the appliance ~~or fitting,~~ or, where that is not possible, on its packaging or in an accompanying document, how to access them and how to request them in paper format; BG (Justifications): Instructions for incorporation are not a separate document. They are part of the content of the EU declaration of conformity for fittings – see Article 15(3) and point 8 of Annex V to Regulation 2016/426.
(b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the appliance or fitting;	BE (Drafting suggestions): *(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* ***without the need to register, to download an application, or to provide any personnal information in any form*** *so that the end-user can* ***directly*** *access them at all times, in particular during a breakdown of the* appliance or fitting*;* ***this requirement also applies where the instructions*** ***and safety information*** ***are embedded in the software of the gas appliance*** BE (Justifications):

Commission proposal	Drafting suggestions and Justifications
	No information or data should be required from users to access electronic instructions. End-users should therefore be able to access the instructions without registration or the provision of any personal information. Consistency on the requirements should be ensured between directives and regulations, such as between LVD and GAR This is also valid for the safety information BG (Drafting suggestions): (b) present them in a format that makes it possible for the end-user to print and download the instructions and save them on an electronic device so that the end-user can access them at all times, in particular during a breakdown of the appliance ~~or fitting~~; BG (Justifications): See the comment above. DE (Drafting suggestions): (b) present them in a format that makes it possible for the end-user to print and download the instructions **or 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; DE (Justifications):

Commission proposal	Drafting suggestions and Justifications
	For appliances that are not intended for consumers and are not used by consumers even under reasonably foreseeable conditions, safety information may be provided in electronic form. In that case, requirements of points (a) to (c) should also apply to that safety information.
(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.	BG (Drafting suggestions): (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~~. BG (Justifications): See the comment above. SE (Drafting suggestions): (d) keep records of the different versions instructions in electronic form. SE (Justifications): Under 10 years or more the instructions may be changed several times. To be able to assess which version of the instructions the consumer had access to the manufacturer should keep records of the different versions of the instructions.
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	BE

Commission proposal	Drafting suggestions and Justifications
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.';';	(Drafting suggestions): *However, the end-user may, at time of the purchase of* the appliance or fitting*, or* ***at any time during the expected lifetime of the product or at least 10 years after that purchase****, request the instructions or safety information in paper format* ***and linked to the correct version/batch of the purchased appliance****. 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.* BE (Justifications): The possibility for end-users to request a paper version within six months of purchasing the product is overly restrictive without considering all possible practical scenarios. This time period should be extended to account for practical considerations. If the product is transferred or given to another person, the end-user may be penalised by such a short time limit, which may already have expired by the time they receive the product. Since electronic instructions must remain accessible online during the expected lifetime of the product, it would be reasonable for end-users to be able to request a paper version from the manufacturer for the same duration. Different versions of the same appliance can exist, meaning the end-user should be able to receive instructions specific to the version they purchased to ensure safe use and installation of the appliance. BG (Drafting suggestions): 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

Commission proposal	Drafting suggestions and Justifications
	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.';~~',~~ BG (Justifications): See the comment above. FR (Drafting suggestions): 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 FR (Justifications): The six-month period imposes administrative burdens that appear misaligned with the objectives of the Omnibus Regulation. The French authorities recommend aligning the provisions with those set out in the Machinery Regulation, whereby the request would be submitted at the time of purchase
(d) in paragraph 9, the first sentence is replaced by the following:	BG (Drafting suggestions): (d) in paragraph 9, the first and second sentences are ~~is~~ replaced by the following:

Commission proposal	Drafting suggestions and Justifications
	DE (Drafting suggestions): (d) in paragraph 9, the first **and second** sentence**s** ~~**is**~~ **are** replaced by the following: DE (Justifications): In accordance with the current version of the second sentence of paragraph 9, the information and documents may be submitted **in paper or electronic form**. Since, according to our understanding, only electronic transmission should apply in the future, the sentence 2 would have to be deleted.
'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:	BG

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): (a) ~~in~~ paragraph 2~~, second subparagraph, the second sentence is replaced by the following~~ is amended as follows: (i) in the first subparagraph, the second sentence is replaced by the following: 'They shall ensure that the manufacturer has drawn up the technical documentation, that the appliance bears the CE marking, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).'; (ii) in the second subparagraph, the second sentence is replaced by the following: BG (Justifications): New point (i) is added amending paragraph 2 to avoid overlapping and contradictions with paragraph 4 in relation to instructions and safety information.
'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 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).';	BE (Drafting suggestions): *They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking, ~~and~~ is accompanied by 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)., **and is accompanied** the internet address and machine-readable*

Commission proposal	Drafting suggestions and Justifications
	code through which the EU declaration of conformity can be ***directly*** *accessed* ***without the need to register, to download an application, or to provide any personnal information in any form*** ~~*and by, inter alia,*~~ BE (Justifications): Due to the amendments done for the manufacturer requirements, consistency has to be ensured. Plus the requirements order had to be revised to avoid any misunderstanding on which part has to physically accompany the fitting. BG (Drafting suggestions): '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 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).'; BG (Justifications): Modification proposed in order to avoid overlapping and contradictions with paragraph 4 in relation to EU declaration of conformity and instructions for incorporation..
(b) paragraph 3 is replaced by the following:	

Commission proposal	Drafting suggestions and Justifications
'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:	BG (Drafting suggestions): (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 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.';	BE (Drafting suggestions): *Importers shall ensure that the fitting is accompanied by instructions for incorporation or assembly, adjustment, operation and 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 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 an application, or to provide any personnal information in any form****.*

Commission proposal	Drafting suggestions and Justifications
	BE (Justifications): Due to the amendments done for the manufacturer requirements, consistency has to be ensured. Plus the requirements order had to be revised to avoid any misunderstanding on which part has to physically accompany the fitting. BG (Drafting suggestions): '4. Importers shall ensure that the instructions and safety information in accordance with point 1.5 of Annex I **are available in accordance with Article 7(7)**, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Importers shall ensure that the fitting is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed and ~~by~~ that the EU declaration of conformity contains, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.'; BG (Justifications): The first subparagraph of paragraph 4 must be amended in order to avoid contradictions with Article 7(7).

Commission proposal	Drafting suggestions and Justifications
	The second subparagraph must be modified to clarify that the instructions for incorporation are included in the EU declaration of conformity.
(d) in paragraph 9, the first sentence is replaced by the following:	BG (Drafting suggestions): (d) in paragraph 9, the first and second sentences are ~~is~~ replaced by the following: DE (Drafting suggestions): (d) in paragraph 9, the first **and second** sentence**s** ~~**is**~~ **are** replaced by the following: DE (Justifications): In accordance with the current version of the second sentence of paragraph 9, the information and documents may be submitted **in paper or electronic form.** Since, according to our understanding, only electronic transmission should apply in the future, the sentence 2 would have to be deleted.
'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:	

Commission proposal	Drafting suggestions and Justifications
(a) in paragraph 2, the second subparagraph is replaced by the following:	BG (Drafting suggestions): (a) in paragraph 2, the first and second subparagraphs are ~~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, 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.';	BE (Drafting suggestions): *'Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking,* ***is accompanied by*** *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* ~~*that it*~~ ***and*** *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 an application, or to provide any personnal information in any form. The distributors shall also verify*** *that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.'* ~~*and by, inter alia*~~*.* BE (Justifications): Due to the amendments done for the manufacturer requirements, consistency has to be ensured. Plus the requirements order had to be revised to avoid any misunderstanding on which part has to physically accompany the fitting.

Commission proposal	Drafting suggestions and Justifications
	BG (Drafting suggestions): 'Before making an appliance available on the market, distributors shall verify that the appliance bears the CE marking, **that the** instructions and safety information in accordance with point 1.5 of Annex I **are available in accordance with Article 7(7)**, in a language which can be easily understood by consumers and other end-users, as determined by the Member State in which the appliance is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively. Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking, ~~and~~ that it is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed, ~~and by~~ that the EU declaration of conformity contains, inter alia, the instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.'; BG (Justifications): The first subparagraph of paragraph 2 must be amended in order to avoid contradictions with Article 7(7).

Commission proposal	Drafting suggestions and Justifications
	The second subparagraph must be modified to clarify that the instructions for incorporation are included in the EU declaration of conformity.
(6) in paragraph 5, the first sentence is replaced by the following:	BG (Drafting suggestions): (~~6~~b) in paragraph 5, the first and second sentences are ~~is~~ replaced by the following: DE (Drafting suggestions): (6) in paragraph 5, the first **and second** sentence**s** ~~**is**~~ **are** replaced by the following: DE (Justifications): In accordance with the current version of the second sentence of paragraph 5, the information and documents may be submitted **in paper or electronic form.** Since, according to our understanding, only electronic transmission should apply in the future, the sentence 2 would have to be deleted.
'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***	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
Common Specifications	BG (Justifications): See general comments.
1. The Commission may by means of implementing acts adopt common specifications that enable compliance with essential requirements set out in Annex I in any of the following cases:	BE (Drafting suggestions): *1.* ***In exceptional cases, t****~~T~~he Commission may, by means of implementing acts, adopt common specifications* ***covering technical requirements*** *that enable compliance* with essential requirements set out in Annex I *~~in any of the following cases:~~* ***Those implementing acts shall only be adopted where the following conditions are fulfilled:*** BE (Justifications): We prefer the text as negotiated in the new Toy Safety Regulation BG (Drafting suggestions): 1. The Commission may by means of implementing acts ~~adopt~~ establish common specifications ~~that enable compliance with essential requirements set out in Annex I in any of~~ where the following ~~cases~~ conditions are fulfilled: CZ (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	1. The Commission may ~~by means of~~ **adopt** implementing acts ~~adopt~~ **establishing** common specifications that enable compliance with the essential requirements set out in Annex I ~~in any of~~ **where** the following ~~cases~~ **conditions are fulfilled**: CZ (Justifications): CZ, in general, support the introduction of harmonised rules for adopting common specifications across sectoral legislation. However, the common specifications must remain a fallback option to the harmonised standards. Thus, the conditions for triggering the empowerment of the Commission to adopt the common specification must be well-defined and limited to situations where the harmonised standard is not available, or it is apparent that it will not be available within a reasonable period. DE (Drafting suggestions): 1**. In exceptional cases**, the Commission may, by means of implementing acts, adopt common specifications that enable compliance with the essential requirements set out in Annex I. ~~in any of the following cases:~~ **Those implementing acts shall only be adopted where the following conditions are fulfilled:** DE (Justifications): Ensure consistency with existing harmonised product legislation, e.g. see article 20 of the Machinery Regulation (Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery) or Article 14 of the proposed Toy Safety Regulation

Commission proposal	Drafting suggestions and Justifications
	FR (Drafting suggestions): 1. The Commission may by means of implementing acts adopt common specifications that enable compliance with the essential requirements set out in Annex I ~~in any of the following cases~~ **Those implementing acts shall only be adopted where the following conditions are fulfilled :** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be achieved and will call for the wording used in the ESPR Regulation to be reinstated. HU (Drafting suggestions): 1. Appliances and fittings which are in conformity with the common specifications referred to in paragraph 2 of this Article or parts thereof shall be presumed to be in conformity with the essential requirements set

Commission proposal	Drafting suggestions and Justifications
	out in Annex I to the extent that those requirements are covered by those common specifications or parts thereof. HU (Justifications): As regards to the introduction of common specifications, we find it important to keep harmonised standards a priority. Adoption of common specifications should happen only as a fallback option, based on reasonable criteria, in case standards are not available. The proposed text does not reflect this principle properly. Therefore, we prefer using a text based on the Toy Safety Regulation and Machinery Regulation, as they are more detailed and ensure priority of standards and exceptionality of common specifications. Using those texts would also facilitate the horizontally uniform handling of common specifications. These texts also provide legal clarity what happens when a reference of a harmonised standard is published in the OJEU after common specifications had been adopted. Furthermore, they clarify what Member States should be if they have concerns of a common specification. SE (Drafting suggestions): See comment above. SE (Justifications): Reference to common specifications should be in line with existing EU-legislation, such as regulation (EU) 2023/1230 and the toy safety regulation.

Commission proposal	Drafting suggestions and Justifications
	Important that the wording reflects the fact that common specifications should be an exceptional fall-back option.
(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;	BE (Drafting suggestions): ~~*(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;*~~ **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** BE (Justifications): Strict conditions should be clearly defined and align with the existing established framework. BG (Drafting suggestions): (a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* and no such reference is expected to be published within a reasonable period; (a1) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European

Commission proposal	Drafting suggestions and Justifications
	standardisation organisations to draft or to revise European standards for the essential requirements set out in Annex I and: (i) the request has not been accepted by any of the European standardisation organisations to which the request was addressed; or (ii) 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: — are not delivered within the deadline set in the request; — do not comply with the request; or — do not satisfy the requirements they aim to cover. CZ (Drafting suggestions): (a) ~~requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union;~~ **the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex I and:** **(i) the request has not been accepted; or**

Commission proposal	Drafting suggestions and Justifications
	(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or **(iii) the harmonised standards do not comply with the request; and** DE (Drafting suggestions): ~~(a) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*;~~ DE (Justifications): Ensure consistency, see above FR (Drafting suggestions): **(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for essential requirements ; and:** **(i) the request has not been accepted;** **(ii) the harmonised standard addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or** **(iii) the harmonised standard does not comply with the request; and**

Commission proposal	Drafting suggestions and Justifications
	~~(a~~ **b**) requirements set out in Annex I are not covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union* ;**in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.** FR (Justifications): The fallback condition is not formulated clearly enough in the Omnibus proposal, unlike in other texts (such as the Ecodesign Regulation (ESPR), the Machinery Regulation, or the AI Regulation), which already foresee the use of such specifications under conditions that the French authorities consider to be adequately framed. The French authorities will express their concern that the objectives pursued by the Commission in this part of the Omnibus may not be achieved and will call for the wording used in the ESPR Regulation to be reinstated. HU (Drafting suggestions): 2. In exceptional cases, the Commission may adopt implementing acts establishing common specifications covering requirements that provide a means to comply with the applicable essential requirements set

Commission proposal	Drafting suggestions and Justifications
	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: (i) are not delivered within the deadline set in the request; (ii) do not comply with the request; or (iii) do not satisfy the requirements they aim to cover. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).
(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of appliances and fittings with the requirements set out in Annex I, or	BE (Drafting suggestions): ~~*(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those*~~

Commission proposal	Drafting suggestions and Justifications
	~~*standards or parts thereof result in non-compliance of appliances and fittings with the requirements set out in Annex I, or*~~ **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.** BE (Justifications): Strict conditions should be clearly defined and align with the existing established framework. BG (Drafting suggestions): deleted CZ (Drafting suggestions): (b) ~~requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts~~

Commission proposal	Drafting suggestions and Justifications
	~~thereof result in non-compliance of appliances and fittings with the requirements set out in Annex I, or~~ **no reference to harmonised standards covering the relevant essential requirements set out in Annex I has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.** DE (Drafting suggestions): ~~(b) requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union, but application of those standards or parts thereof result in non-compliance of a product with the essential requirements set out in Annex I; or~~ DE (Justifications): Ensure consistency, see above FR (Drafting suggestions): ~~(b)~~ **c)** requirements set out in Annex I are covered by harmonised standards, or parts thereof, the references of which have been published in the *Official Journal of the European Union*, but application of those standards or parts thereof results in non-compliance of appliances and fittings with the requirements set out in Annex I **and those harmonised**

Commission proposal	Drafting suggestions and Justifications
	standards, or parts thereof, have been subject to a decision referred to in paragraph 1 article 11 of Regulation (EU) No 1025/2012 FR (Justifications): The French authorities support the use of common specifications when harmonised standards do not fully meet the relevant requirements, provided that such standards have been subject to a formal objection in accordance with Article 11 of Regulation (EU) No 1025/2012 on formal objections. They therefore wish for the Omnibus IV Regulation to explicitly mention this possibility, in order to clarify its application and its consistency with the mechanism provided for in Article 11 of the Regulation. HU (Drafting suggestions): 3. Before preparing the draft implementing act referred to in paragraph 2, 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 2 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the relevant bodies and expert groups, and shall duly consult all relevant stakeholders.

Commission proposal	Drafting suggestions and Justifications
(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.	BE (Drafting suggestions): ~~*(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.*~~ BE (Justifications): As explained, the adoption of common specifications should be accompanied by robust safeguards, such as those already provided for in Regulation (EU) 2023/1230 on machinery. Indeed, for regulatory harmonisation purposes, it would be consistent to align the procedures for all legislation under the NLF, including machinery legislation already revised. BG (Drafting suggestions): deleted CZ (Drafting suggestions): ~~(c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant subsystems and safety components.~~ CZ (Justifications): CZ does not agree with the condition set out in this provision. It would provide the Commission with extensive empowerment, which is not clearly

Commission proposal	Drafting suggestions and Justifications
	defined and which undermines the requested fallback nature of the common specifications. DE (Drafting suggestions): ~~c) where the Commission considers that there is a need to address an urgent concern with regard to non-compliant materials, components and EEE.~~ DE (Justifications): Ensure consistency, see above FR (Drafting suggestions): *pending clarification by the Commission]* FR (Justifications): The French authorities are asking for more details and illustrative examples of the "urgent concern" raised and wonder how they relate to the provisions already adopted in the sectoral texts covered by Omnibus IMERA. HU (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	4. 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 the harmonised 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 2, or parts thereof which cover the same essential requirements set out in Annex I as those covered by that harmonised standard.
Those implementing acts shall be adopted in accordance with the advisory procedure as provided for in Article 42(2).	BE (Drafting suggestions): *Those implementing acts shall be adopted in accordance with the* ***examination procedure*** *referred to in Article 42(3).* BG (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ examination procedure as provided for in Article 42(~~2~~3). 1a. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant expert group and shall duly consult all relevant stakeholders.

Commission proposal	Drafting suggestions and Justifications
	CZ (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 42(~~2~~**3**). **1a. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **1b. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** CZ (Justifications): CZ insists on adopting the implementing acts establishing the common specification in accordance with the examination procedure. CZ also insists that the Committee on Standards established under Regulation 1025/2012 must be informed that the Commission considers the conditions in paragraph 1 to have been fulfilled. The drafts of the implementing acts should be properly consulted with all relevant stakeholders.

Commission proposal	Drafting suggestions and Justifications
	DE (Drafting suggestions): Those implementing acts shall be adopted in accordance with the ~~advisory procedure as provided for in Article 42(2)~~ **examination procedure, as in Article 5 of Regulation 182/2011**. **2. Before preparing the draft implementing act referred to in paragraph 1, 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 have been fulfilled.** **3. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.** DE (Justifications): Ensure consistency, see above The same wording from the Machinery Regulation (Regulation 2023/1230) must be used ensure that harmonised standards are the first choice. It is not acceptable for us, that common specifications become an equal instrument to harmonised standards. Furthermore, we desire to introduce common specifications by a horizontal legislation. HU (Drafting suggestions): 5. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex I, it shall

Commission proposal	Drafting suggestions and Justifications
	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.
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 specifications or parts thereof, set out in Annex I.’;	BE (Drafting suggestions): **+ add: Before preparing the draft implementing act referred to in paragraph 2, 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 have been fulfilled. When preparing the draft implementing act referred to in paragraph 2, the Commission shall take into account the views of the Expert Group on **** and shall duly consult all relevant stakeholders. 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 the harmonised 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 2, or parts thereof which cover the same essential safety requirements as those covered by that harmonised standard. When a Member State considers that a common specification does not entirely satisfy the Important to add the repeal or amendment, otherwise there will be a parallel circuit**

Commission proposal	Drafting suggestions and Justifications
	Commission proposal Drafting suggestions Justifications essential safety requirements, 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. BE (Justifications): **Important to add the repeal or amendment, otherwise there will be a parallel circuit** BG (Drafting suggestions): 2. Appliances and fittings that are in conformity with common specifications referred to in paragraph 1 or parts thereof shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof~~, set out in Annex I~~. 2a. Where a European 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.

Commission proposal	Drafting suggestions and Justifications
	2b. When a Member State considers that a common specification or parts thereof does not entirely satisfy the essential requirements set out in Annex I which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.'; CZ (Drafting suggestions): 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 specifications or parts thereof, set out in Annex I. **2a. 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 the harmonised 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 essential requirements as those covered by that harmonised standard.** **2b. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex I, it**

Commission proposal	Drafting suggestions and Justifications
	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.**'; CZ (Justifications): CZ insists on addressing situations where a harmonised standard covering the same essential requirements is published in the Official Journal of the EU after the adoption of the common specification to avoid duplication. DE (Drafting suggestions): ~~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 specifications or parts thereof, set out in Annex I.';~~ **5. An appliance or fitting within the scope of this Regulation which is in conformity with the common specifications established by implementing acts referred to in paragraph 2, or parts thereof, shall be presumed to be in conformity with the requirements set out in Annex I covered by those common specifications or parts thereof.** **6. 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**

Commission proposal	Drafting suggestions and Justifications
	European Union, the Commission shall assess the harmonised 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 2, or parts thereof which cover the same requirements as those covered by that harmonised standard. **7. When a Member State considers that a common specification does not entirely satisfy the requirements set out in Annex I, 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.** DE (Justifications): The same wording from the Machinery Regulation (Regulation 2023/1230) must be used ensure that harmonised standards are the first choice. It is not acceptable for us, that common specifications become an equal instrument to harmonised standards. Furthermore, we desire to introduce common specifications by a horizontal legislation. FR (Drafting suggestions): 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 specifications or parts thereof, set out in Annex I.’;

Commission proposal	Drafting suggestions and Justifications
	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 the harmonised standard in accordance with Regulation (EU) No 1025/2012. When references of a harmonised standard are published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 1 or the parts thereof which cover the same requirements** **6. Where a Member State or the European Parliament considers that a common specification does not entirely satisfy requirements, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, if appropriate, may amend the implementing act establishing the common specification in question.** FR

Commission proposal	Drafting suggestions and Justifications
	(Justifications): The French authorities consider it essential to ensure consistency between common specifications and harmonised standards. They have several questions regarding the proposed process and request that further clarifications be included in the texts of Omnibus IV, some of which already appear in the regulations that provide for the use of this mechanism. Indeed, the Machinery, AI, and ESPR Regulations have established satisfactory framing conditions; these should serve as a minimum reference framework to ensure a coherent European approach and to uphold the intended objective of simplification. HU (Drafting suggestions): ***Deleted***
(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:	

Commission proposal	Drafting suggestions and Justifications
'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.';	SE (Drafting suggestions): 6. The manufacturer shall make the certificate issued by the notified body available to the market surveillance authority through internet address or machine-readable code SE (Justifications): To simplify the communication between the manufacturer and the market surveillance authorities review.
(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.';	BE (Drafting suggestions): *6. The fitting shall be 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 an application, or to provide any personnal information in any form*** BE (Justifications): Due to the amendments done for the manufacturer requirements, consistency has to be ensured
(b) the following paragraph 7 is added:	

Commission proposal	Drafting suggestions and Justifications
'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 II to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) shall be provided only in that digital product passport.';	BG (Drafting suggestions): '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 II~~ paragraphs 2 and 3 of this Article to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) ~~shall~~ may be provided only in that digital product passport. Where the information required in paragraphs 2 and 3 of this Article to be included in the EU declaration of conformity is provided in the digital product passport economic operators shall be deemed to fulfil their obligations related to drawing up and keeping the EU declaration of conformity under Article 7(2) and (3), Article 8(2)(a), Article 9(8), points 2.4.2, 3.5.2, 4.5.2, 5.6.2 and 6.5.2 of Annex III.'; BG (Justifications): See general comments. CZ (Drafting suggestions): '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

Commission proposal	Drafting suggestions and Justifications
	product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in ~~Annex II~~ **Annex V** to be included in the EU declaration of conformity and the instructions referred to in Article 7(7) shall be provided only in that digital product passport. ’ CZ (Justifications): The structure of Declaration of conformity is set in Annex V – EU declaration of conformity. Annex II sets out the content of the Member States communications of the gas supply conditions. The text therefore needs to be amended. DE (Drafting suggestions): ‘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 II to be included in the EU declaration of conformity and the instructions 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).;** DE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): To ensure the safety of consumers the safety information in paper format must not be replaced by the digital product passport.
(10) in Article 23(7), point (c) is replaced by the following:	
'(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards or common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';	BG (Drafting suggestions): '(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards ~~or~~ and common specifications and of the relevant provisions of Union harmonisation legislation and of national legislation;';
(11) in Article 31, paragraph 3 is replaced by the following:	
'3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.'	BG (Drafting suggestions): '3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or common specifications or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.' (11a) in Article 37(5) the following point (c) is added: '(c) shortcomings in the common specifications referred to in Article 13a conferring a presumption of conformity.'; (11b) in Article 38, paragraph 3 is replaced by the following:

Commission proposal	Drafting suggestions and Justifications
	‘3. Where the national measure is considered justified and the non-compliance of the appliance or fitting is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Regulation **or the common specifications referred to in point (c) of Article 37(5) of this Regulation**, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 **or in Article 13a(2b) of this Regulation respectively**.’; BG (Justifications): New points (11a) and (11b) are added - shortcomings in the common specifications (see general comments).
(12) in Article 40(1), point (f) is replaced by the following:	
‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’;	BE (Drafting suggestions): *(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* ***without the need to register, to download an application, or to provide any personnal information in any form*** BE (Justifications): Due to the amendments done for the manufacturer requirements, consistency has to be ensured BG

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): ‘(f) the fitting is not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed;’; (12a) Article 40d is amended as follows: (a) the title is replaced by the following: ‘Article 40d Presumption of conformity based on standards and **crisis-relevant** common specifications’; (b) paragraph 1 is replaced by the following: ‘1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing **crisis-relevant** common specifications for such appliances or fittings to cover the applicable essential requirements set out in Annex I to this Regulation in the following cases: (a) where a reference to harmonised standards covering the applicable essential requirements set out in Annex I to this Regulation has not been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period, **and common specifications referred to in Article 13a covering the essential requirements set out in Annex I to this Regulation have not been established and are not expected to be established within a reasonable period**; or

Commission proposal	Drafting suggestions and Justifications
	(b) where severe disruptions to the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 18 of Regulation (EU) 2024/2747, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the applicable essential requirements set out in Annex I to this Regulation and the references of which have already been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 **or of the common specifications referred to in Article 13a of this Regulation**.'; (c) in paragraph 2, the second sentence is replaced by the following: 'To that end, references of European standards or references of relevant applicable national or international standards may be published in those implementing acts or, if there is no European standard or relevant applicable national or international standard, **crisis-relevant** common specifications may be established by those implementing acts.'; (d) paragraphs 5, 6 and 7 are replaced by the following: '5. Without prejudice to **Articles 13 and 13a**, appliances or fittings that are in conformity with the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article, or parts thereof, shall be presumed to be in conformity with the applicable essential requirements set out in Annex I that are covered by those standards, **crisis-relevant** common specifications or parts thereof. From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the standards or the **crisis-relevant** common specifications

Commission proposal	Drafting suggestions and Justifications
	referred to in **or established by** the implementing acts referred to in paragraph 1 of this Article. 6. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings that are in conformity with those standards or **crisis-relevant** common specifications and which have been placed on the market or used for the manufacturer's own purposes shall be deemed to be in conformity with the applicable essential requirements set out in Annex I after the expiry or repeal of an implementing act adopted pursuant to paragraph 3 of this Article and after the expiry or deactivation of the internal market emergency mode. 7. When a Member State considers that a standard or **crisis-relevant** common specification as referred to in paragraph 1 does not entirely satisfy the applicable essential requirements set out in Annex I, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend or repeal the implementing act listing the standard or establishing the **crisis-relevant** common specification in question.'; BG (Justifications): New point (12a) is added - crisis-relevant common specifications (see general comments). SE

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): (f) a copy of the EU declaration of conformity does not accompany the fitting used by consumers, or other fitting not accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed; SE (Justifications): According to article 15.3 shall the EU declaration of conformity for a fitting state the characteristics of the fitting and shall contain instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance. The proposed article 7 requests in the case of appliance or fitting intended for consumers or that can, under reasonably foreseeable conditions, be used by consumers, even if not intended for them, the manufacturer shall provide, in paper format, or mark on the equipment, the safety information. Therefore should article 40(1), point (f) be revised as the instructions for consumers on how the fitting should be incorporated into an appliance or assembled to constitute an appliance are very important.
(13) Annexes III and V are amended in accordance with Annex III to this Regulation.	BE (Drafting suggestions): All references to 'digital contact' have to be changed into 'electronic address' BE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and potentially inaccessible or unavailable due to changes to the relevant website. A mere mention of a website compels consumers or Market Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should by default take the form of an email address that is directly accessible without intermediate steps. This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address. BG (Drafting suggestions): (13) Annexes I, III and V are amended in accordance with Annex III to this Regulation. BG

Commission proposal	Drafting suggestions and Justifications
	(Justifications): See comments on 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 accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.';	BE (Drafting suggestions): We would like the definition of "digital contact" to be clarified to avoid it referring to a simple webpage or to other elements that do not allow for direct, effective, and traceable communication. Instead, it should imply a truly functional means of communication — an email address being one of the most illustrative examples. This would also help prevent confusion regarding acceptable formats or communication channels. Also add definition of common specification like for the other texts 'common specifications' means a set of technical requirements, other than a standard, that provides a means of complying with the essential requirements applicable to a product, device, service, process or system;'; BE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): As it stands, the definition of digital contact allows for interpretation regarding the nature of online communication channels that may be utilized. For example, this could take the form of an online contact form, which does not ensure that copies of exchanges are retained, nor enable users to track communications, nor provide clear identification of the correspondent. Such channels risk being anonymous, untraceable, and potentially inaccessible or unavailable due to changes to the relevant website. A mere mention of a website compels consumers or Market Surveillance Authorities (MSAs) to locate the appropriate section independently, thereby hindering immediate access to contact information. Therefore, digital contact should for instance take the form of an email address that is directly accessible without intermediate steps. This communication method ensures traceability of exchanges and compatibility with requirements for documentation and follow-up, both for users and market surveillance authorities. It also guarantees consistency and continuity with the initial requirement of being able to contact the economic operator through direct communication via a complete physical address DE (Drafting suggestions): ‘digital contact’ means any up-to-date and accessible online communication channel through which economic operators can be ~~**reached or engaged**~~ **contacted** without the need to register or to download an application.’;

Commission proposal	Drafting suggestions and Justifications
	DE (Justifications): It is unclear what is meant by "reached or engaged". According to our understanding the intention is that the economic operators can be contacted.
(2) Article 10 is amended as follows:	
(a) in paragraph 2, the second subparagraph is replaced by the following:	DE (Drafting suggestions): 'Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.'; **(b) paragraph 6, the first sentence is replaced by the following:** **Manufacturers shall indicate their name, registered trade name or registered trade mark, and the postal address and website, e-mail address or other digital contact at which they can be contacted, on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product.** DE

Commission proposal	Drafting suggestions and Justifications
	(Justifications): To ensure coherence with other legislation only the "digital contact" should be mentioned. Thus the "website, e-mail address" should be deleted.
'Where compliance of machinery or a related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity, in digital format, in accordance with Article 21 and affix the CE marking in accordance with Article 24.';	BE (Drafting suggestions): Why digital format here and not electronic form like in the other texts? + change paragraph 6: Manufacturers shall indicate their name, registered trade name or registered trade mark, ~~and the~~ as well as their postal address and ~~website, e-mail address or other~~ digital contact ~~at which they can be contacted~~, on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product. The postal address and digital contact shall indicate a single point through which the manufacturer can be reached BE (Justifications): **Also to the same for art 11 (6), art 13 (3), art 14 (3)** FI (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	in paragraph 7, the third subparagraph is replaced by the following: However, at the request of the user at the time of the purchase or up to six months after that purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month. FI (Justifications): The requirement to provide paper instructions upon request by the customer at the time of purchase or at least six months after the time of purchase is in line with the requirements of other regulations. In any case, manufacturers will have to prepare for sending paper instructions to the customer, and the additional costs are minimal.
(b) in paragraph 8, the first subparagraph is replaced by the following:	BE (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	The requirements for the instructions in article 10, paragraph 7 are not aligned with the other proposals in the Omnibus
'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.';	CZ (Drafting suggestions): '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. **A person who manufactures machinery or related products for his or her own use is considered as to be a manufacturer and should be required to fulfil all the related obligations. In that case, the machinery or related product is not placed on the market, since it is not made available by the manufacturer to another person but is used by the manufacturer itself. Manufacturers does not ensure that such machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity can be accessed.** CZ (Justifications): CZ considers it necessary to add this provisio for the cases when the machinery or related product is not placed on the market, but is used by the manufacturer itself. It does not make sense to accompany such machinery by the internet address or machine-readable code through which the EU declaration of conformity can be accessed.
(c) in paragraph 10, the first sentence is replaced by the following:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
'Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority.'; (3) Article 11 is amended as follows: (a) in paragraph 2, the second subparagraph is replaced by the following: 'Where compliance of partly completed machinery with the relevant essential health and safety requirements set out in Annex III has been demonstrated in the technical documentation set out in Part B, of Annex IV, manufacturers shall draw up the EU declaration of incorporation, in digital format, in accordance with Article 22.'; (b) in paragraph 8, the first subparagraph is replaced by the following: 'Manufacturers shall ensure that the partly completed machinery is accompanied by the internet address or machine-readable code through	BE (Drafting suggestions): 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.' BE (Justifications): Align with other texts BE (Drafting suggestions): Change to electronic form BE (Justifications): Align with other texts

Commission proposal	Drafting suggestions and Justifications
which the EU declaration of incorporation set out in Part B of Annex V can be 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, 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.’;	BE (Drafting suggestions): Replace by ‘electronic form’ BE (Justifications): Align with other texts
(4) in Article 12(2), point (b) is replaced by the following:	
‘(b) further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation;’;	BE (Drafting suggestions): Replace by ‘electronic form’ BE (Justifications): Align with other texts
(5) in Article 13(9), the first sentence is replaced by the following:	BG (Drafting suggestions): (5) ~~in~~ Article 13~~(9), the first sentence is replaced by the following~~ is amended as follows: (a) paragraph 4 is replaced by the following:

Commission proposal	Drafting suggestions and Justifications
	‘4. Importers shall ensure that the instructions for use and the information **set out in Annex III are available in accordance with Article 10(7) in a language which can be easily understood by users, as determined by the Member State concerned**.’; (b) in paragraph 9, the first sentence is replaced by the following: BG (Justifications): New point (a) is added amending paragraph 4 to avoid contradictions with Article 10(7).
‘9. Importers shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority.’;	BE (Drafting suggestions): Replace by ‘electronic form’ BE (Justifications): Align with other texts
(6) in Article 14(8), the first sentence is replaced by the following:	BG (Drafting suggestions): (6) ~~in~~ Article 14~~(8), the first sentence is replaced by the following~~ is amended as follows: (a) paragraph 4 is replaced by the following: ‘4. Importers shall ensure that the assembly instructions **set out in Annex XI are available in accordance with Article 11(7) in a language which can be easily understood by the person who incorporates the partly**

Commission proposal	Drafting suggestions and Justifications
	completed machinery, as determined by the Member State concerned.’;
	(b) in paragraph 8, the first sentence is replaced by the following:
	BG (Justifications): New point (a) is added amending paragraph 4 to avoid contradictions with Article 11(7).
‘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.’;	BE (Drafting suggestions): Replace by ‘electronic form’ BE (Justifications): Align with other texts
(7) Article 15 is amended as follows:	
(a) in paragraph 2, point (b) is replaced by the following:	BG (Drafting suggestions): (a) in paragraph 2, points (b) and (c) are ~~is~~ replaced by the following:
‘(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be accessed;’;	BG (Drafting suggestions):

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	‘(b) the machinery or related product is accompanied by the internet address or machine-readable code through which the EU declaration of conformity referred to in Article 10(8) can be accessed; (c) the instructions for use and the information **set out in Annex III are available in accordance with Article 10(7)**, and that they are in a language which can be easily understood by users, as determined by the Member State in which the machinery or related product is to be made available on the market;’; BG (Justifications): Article 15(2), point (c) must be modified to avoid contradictions with Article 10(7).
(b) in paragraph 6, the first sentence is replaced by the following:	
‘Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be easily understood by that authority.’;	BE (Drafting suggestions): Replace by ‘electronic form’ BE (Justifications): Align with other texts
(8) in Article 16(6), the first sentence is replaced by the following:	BG (Drafting suggestions):

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	(8) ~~in~~ Article 16~~(6), the first sentence is replaced by the following~~ is amended as follows: (a) in paragraph 2, points (a) and (b) are replaced by the following: '(a) the partly completed machinery is accompanied by **the internet address or machine-readable code through which** the EU declaration of incorporation referred to in Article 11(8) **can be accessed**; (b) the assembly instructions **set out in Annex XI are available in accordance with Article 11(7)**, and that they are in a language which can be easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market;'; (b) in paragraph 6, the first sentence is replaced by the following: BG (Justifications): New point (a) is added to modify Article 16(2), points (a) and (b) to take account of electronic EU declaration of conformity and to avoid contradictions with Article 11(7).
'Distributors shall, further to a reasoned request from a competent national authority, provide that authority, in digital format, with all the information and documentation necessary to demonstrate the conformity of the partly completed machinery with this Regulation.';	BE (Drafting suggestions): Replace by 'electronic form' BE (Justifications): Align with other texts

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(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 Part~~s~~ A of Annex V to be included in the EU declaration of conformity and the instructions referred to in Article 10(7) shall be provided only in that digital product passport.';	BG (Drafting suggestions): '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~~ paragraph 2 of this Article to be included in the EU declaration of conformity and the instructions referred to in Article 10(7) ~~shall~~ may be provided only in that digital product passport. Where the information required in paragraph 2 of this Article to be included in the EU declaration of conformity is provided in the digital product passport economic operators shall be deemed to fulfil their obligations related to drawing up and keeping the EU declaration of conformity under Article 10(2) and (3), Article 12(2)(a), Article 13(8), point 4.2 of Annex VI, point 3.2 of Annex VIII, point 5.2 of Annex IX and point 5.2 of Annex X.'; BG (Justifications): See general comments. DE (Drafting suggestions):

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	Where other Union legislation applicable to machinery or related products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of conformity or instructions in a digital product passport, the information required in Parts A of Annex V to be included in the EU declaration of conformity and the instructions referred to in Article 10(7) shall be provided only in that digital product passport.'; **<u>This does not affect the obligation to provide the safety information in paper format according to Article 10(7).;</u>** DE (Justifications): To ensure the safety of consumers the safety information in paper format must not be replaced by the digital product passport.
(10) in Article 22, the following paragraph 5 is added:	BG (Drafting suggestions): deleted
'5. Where other Union legislation applicable to machinery or related products requires the economic operator to include the information that the product complies with the requirements set out in that legislation in a digital product passport or to upload the EU declaration of incorporation or instructions in a digital product passport, the information required in Part~~s~~ B of Annex V to be included in the EU declaration of incorporation and the instructions referred to in Article 11(7) shall be provided only in that digital product passport.';	BG (Drafting suggestions): deleted

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(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.';	BE (Drafting suggestions): Replace by 'electronic form' + add 'Article 31 is replaced by *Article 31* **Presumption of conformity of notified bodies** 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 30 insofar as the applicable harmonised standards cover those requirements." BE (Justifications): Align with other texts Align with other texts BG (Drafting suggestions): '6. Where applicable, the manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information

Commission proposal	Drafting suggestions and Justifications
	and documentation relating to conformity assessment procedures in digital format.'; (11a) Article 25d is amended as follows: (a) the title is replaced by the following: 'Article 25d Presumption of conformity based on standards and **crisis-relevant** common specifications'; (b) paragraph 1 is replaced by the following: '1. Where machinery or related products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing **crisis-relevant** common specifications for such machinery or related products to cover the applicable essential health and safety requirements set out in Annex III to this Regulation in the following cases: (a) where a reference to harmonised standards covering the applicable essential health and safety requirements set out in Annex III to this Regulation has not been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period, **and common specifications referred to in Article 20(6) covering the essential health and safety requirements set out in Annex III to this Regulation have not been established and are not expected to be established within a reasonable period**; or

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	(b) where severe disruptions to the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 18 of Regulation (EU) 2024/2747, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the applicable essential health and safety requirements set out in Annex III to this Regulation and the references of which have already been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 **or of the common specifications referred to in Article 20(6) of this Regulation**.'; (c) in paragraph 2, the second sentence is replaced by the following: 'To that end, references of European standards or references of relevant applicable national or international standards may be published in those implementing acts or, if there is no European standard or relevant applicable national or international standard, **crisis-relevant** common specifications may be established by those implementing acts.'; (d) paragraphs 5, 6 and 7 are replaced by the following: '5. Without prejudice to Article 20, machinery and related products that are in conformity with the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article, or parts thereof, shall be presumed to be in conformity with the applicable essential health and safety requirements set out in Annex III that are covered by those standards, **crisis-relevant** common specifications or parts thereof. From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the standards or the **crisis-relevant**

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	common specifications referred to in **or established by** the implementing acts referred to in paragraph 1 of this Article. 6. By way of derogation from Article 25a(3), first subparagraph, unless there is sufficient reason to believe that the machinery and the related products covered by the standards or **crisis-relevant** common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the machinery and the related products that are in conformity with those standards or **crisis-relevant** common specifications and which have been placed on the market or put into service shall be deemed to be in conformity with the applicable essential health and safety requirements set out in Annex III after the expiry or repeal of an implementing act adopted pursuant to paragraph 3 of this Article and after the expiry or deactivation of the internal market emergency mode. 7. When a Member State considers that a standard or **crisis-relevant** common specification referred to in paragraph 1 does not entirely satisfy the applicable essential health and safety requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend or repeal the implementing act listing the standard or establishing the **crisis-relevant** common specification in question.'; BG (Justifications): New point (11a) is added - crisis-relevant common specifications (see general comments).

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(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 accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.';	BG (Drafting suggestions): '(23a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application.'; (1a) in Article 16 the following paragraph 4 is added: '4. When a Member State considers that a common specification or parts thereof does not entirely satisfy the requirements laid down in Articles 9, 10, 12, 13, 14 and 78 which it covers, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.'; BG (Justifications):

Commission proposal	Drafting suggestions and Justifications
	New point (1a) is added amending Article 16 to add objection procedure for common specifications – see Toys Regulation, Machinery Regulation and Ecodesign Regulation.
(2) Article 17 is amended as follows:	
(a) paragraph 4 is replaced by the following:	
'4. Records and correspondence relating to the conformity assessment procedures of batteries shall be drawn up, in electronic form, in the official language or languages of the Member State where the notified body carrying out the conformity assessment procedures is established, or in one or more languages accepted by that body.';	
(b) the following paragraph 5 is added:	
'5. The manufacturer shall provide the notified body carrying out the conformity assessment procedure with all the information and documentation relating to conformity assessment procedures in electronic form.';	
(3) in Article 18(2), the third sentence is replaced by the following:	
'It shall be drawn up in electronic form.';	
(4) Article 38 is amended as follows:	
(a) paragraph 1 is replaced by the following:	
'1. When placing a battery on the market or putting it into service, including for the manufacturers' own purposes, manufacturers shall ensure that the battery:	

Commission proposal	Drafting suggestions and Justifications
(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	BG (Drafting suggestions): (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 BG (Justifications): The deleted text is better placed in the second subparagraph as the requirement for instructions and safety information is limited to stationary battery energy storage systems. DE (Drafting suggestions): (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~~ **where applicable**, 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 DE (Justifications):

Commission proposal	Drafting suggestions and Justifications
	It is unclear why the scope has been changed. This amendment will change the scope of application so that only stationary battery energy storage systems will have to be accompanied by instructions and safety information. At least Article 11 Par 1 Subpar 3 states that, for portable batteries, there need to be instructions and safety information on the removal of batteries incorporated into products. It is therefore unclear as to why the scope has been changed towards stationary battery energy storage systems only. Also, no changes have been made for Art. 41 (1c) regarding the obligations for importers to verify the existence of instructions and safety information. Therefore, there is a general obligation for importers to check for instructions and safety information regardless of the battery category. LT (Justifications): We do support the question, raised by DE: why the instructions is going to be made available only for stationary battery energy storage system? FI (Drafting suggestions): 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 FI

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Commission proposal	Drafting suggestions and Justifications
	(Justifications): Finland considers that also other battery types than battery energy storage systems -should be accompanied by clear, understandable and readable instructions and safety information. Battery manufacturer has the best knowledge of the characteristics of its battery product and the manufacturer is best able to evaluate the need and content of instructions and safety information -and, consequently, prepare instructions and safety information for the product.
(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.	BG (Drafting suggestions): When placing a stationary battery energy storage system on the market manufacturers shall ensure that it is 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 stationary battery energy storage system is to be placed on the market or put into service. 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. BG (Justifications):

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	See comment above. DE (Drafting suggestions): **Where applicable, t**~~T~~he 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. DE (Justifications): See above. FR (Drafting suggestions): 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 **for putting the product into service and for using it safe way**. FR (Justifications): The French authorities welcome all proposals aimed at facilitating the transfer of information between economic operators and authorities, and

Commission proposal	Drafting suggestions and Justifications
	at harmonizing this transfer through electronic means rather than on paper. They believe that such measures are likely to eliminate redundancies and create more efficient processes for all stakeholders. However, they would like to make the following comments: Such a principle should not prevent the legislator from providing for more restrictive provisions in favor of physical formats (in particular paper), where sector-specific security concerns justify it FI (Drafting suggestions): The instructions and safety information for ~~stationary battery energy storage systems~~ batteries 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. FI (Justifications): Instructions and safety information should be provided for all batteriers and they may be provided in electronic form.
When the instructions are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.	BG (Drafting suggestions): When the instructions and safety information are provided in electronic form, the manufacturer shall mark on the battery, or, where that is not possible, on its packaging or in an accompanying document, that they are accessible in the battery passport and how to request them in paper format.

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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.’;	FR (Drafting suggestions): 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.’; FR (Justifications): The six-month period imposes administrative burdens that appear misaligned with the objectives of the Omnibus Regulation. The French authorities recommend aligning the provisions with those set out in the Machinery Regulation, whereby the request would be submitted at the time of purchase.
(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.’;	

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(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:	BG (Drafting suggestions): (7) Article 41 is amended as follows: (a0) in paragraph 2, first subparagraph, point (c) is replaced by the following: '(c) the battery is accompanied by the documents required pursuant to Articles 6 to 10 and Articles 12, 13 and 14, **and that** the instructions and safety information **for stationary battery energy storage systems are available in accordance with Article 38(1)** in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be made available on the market; and'; BG (Justifications): New point (a0) is added amending paragraph 2, point (c) to avoid contradictions with Article 38(1).

Commission proposal	Drafting suggestions and Justifications
(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:	BG (Drafting suggestions): (8) ~~in~~ Article 42~~(6), the second sentence is replaced by the following~~ is amended as follows: (a) in paragraph 2, point (c) is replaced by the following: '(c) the battery is accompanied by the documents required pursuant to Articles 6 to 10 and Articles 12, 13 and 14, **and that** the instructions and safety information **for stationary battery energy storage systems are available in accordance with Article 38(1)** in a language or languages which can be easily understood by end-users, as determined by the Member State in which the battery is to be made available on the market or put into service; and'; (b) in paragraph 6, the second sentence is replaced by the following: BG (Justifications):

Commission proposal	Drafting suggestions and Justifications
	New point (a) is added amending paragraph 2, point (c) to avoid contradictions with Article 38(1).
'That information and the documentation shall be provided in electronic form.';	BG (Drafting suggestions): 'That information and the documentation shall be provided in electronic form.'; (8a) in Article 80, paragraph 3 is replaced by the following: '3. Where the national measure is considered justified and the non-compliance of the battery is attributed to shortcomings in the harmonised standards referred to in Article 15 of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 **or in Article 16(4) of this Regulation respectively**.'; BG (Justifications): New point (8a) is added in relation to the proposed amendments in Article 16.
(9) Annexes VIII, IX and XIII are amended in accordance with Annex V to this Regulation.	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
Article 7	DE (Drafting suggestions): (7) in Article 79 (1), point (a) (i) is replaced by the following: DE (Justifications): As it is foreseeable that the transitional period provided for in Art. 79 of Regulation (EU) 2024/1781 (ESPR) will not be sufficient to adopt all the legal acts referred to in Art. 79 (1), point (a) (i), Germany proposes a one-off extension of the deadline until 31 December 2028. A corresponding addition must therefore be included in Article 7 of the Omnibus.
Amendments to Regulation (EU) 2024/1781	DE (Drafting suggestions): (i) until 31 December ~~2026~~ **2028**, as regards photovoltaic panels, space and combination heaters, water heaters, solid fuel local space heaters, air conditioners including air-to-air heat pumps and comfort fans, solid fuel boilers, air heating and cooling products, ventilation units, vacuum cleaners, cooking appliances, water pumps, industrial fans, circulators, external power supplies, computers, servers and data storage products, power transformers, professional refrigeration equipment and imaging equipment;
Regulation (EU) 2024/1781 is amended as follows:	
(1) in Article 2, the following point (46a) is inserted:	

Commission proposal	Drafting suggestions and Justifications
'(46a) 'digital contact' means any up-to-date and accessible online communication channel through which economic operators can be reached or engaged without the need to register or to download an application;';	
(2) in Article 24(2), the second sentence is replaced by the following:	
'Such information and documentation shall be provided, in electronic form, within 30 days of receipt of the request.';	
(3) in Article 27(10), the second sentence is replaced by the following:	BG (Drafting suggestions): (3) in Article 27(10), first subparagraph, 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:	BG (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	(5) in Article 29(8), first subparagraph, the second sentence is replaced by the following:
'That information and documentation shall be provided, in electronic form, as soon as possible and in any event within 15 days of receipt of a request by that authority.';	
(6) in Article 30(5), first subparagraph, the second sentence is replaced by the following:	
'That information and documentation shall be provided, in electronic form, within 15 days of receipt of a request by that authority.';	
(7) in 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	DE (Justifications): Article 8 introduces a transitional provision that obliges member states for 24 months after coming into force of the omnibus not to impede the making available of products that were placed on the market in conformity with the regulations changed by the omnibus.
Transitional provision	DE (Justifications): We wonder whether this provision is only applicable to impeding the making available of products in cases stemming from the newly introduced changes. For example, the changes to Regulation (EU) 2024/1781 (ESPR) make it mandatory for economic actors to provide information in digital form. Would the effect of article 8 be that any

Commission proposal	Drafting suggestions and Justifications
	product in conformity with the regulations when placed on the market could be made available regardless of problems found or would it only affect cases where e.g. the dealer has not provided information in the digital form when the unchanged regulation would permit paper-only provision of said information? The latter case would only mean that the newly introduced provisions cannot be applied prematurely.
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*.	CZ (Drafting suggestions): ***It shall apply from ... [24 months after the date of entry into force of this Regulation].***
Article 5 and Annex IV shall apply from 20 January 2027.	
The following provisions shall apply from [OP: *please insert 24 months after entry into force of this amending Regulation*]:	CZ (Drafting suggestions): The following provisions shall apply from [OP: *please insert ~~24~~**8** months after entry into force of this amending Regulation*]:

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
(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.	
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:	

Commission proposal	Drafting suggestions and Justifications
'(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:	BG (Drafting suggestions): (b) in point 4, points 4.2, ~~and~~ 4.3 and 4.4 are replaced by the following:
'4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements 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;';	BE (Drafting suggestions): + add to 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 BE (Justifications): Needs to be completed BG

Commission proposal	Drafting suggestions and Justifications
	(Drafting suggestions): 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; 4.4. 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;'; BG (Justifications): Point 4.4 must be amended to take account of common specifications.
(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:	

Commission proposal	Drafting suggestions and Justifications
'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';	
(b) in point 3.3., first subparagraph, the second sentence is replaced by the following:	BG (Drafting suggestions): deleted
'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.';	BE (Drafting suggestions): But add to point 5.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. BG (Drafting suggestions): deleted BG (Justifications): This point must be deleted. Presumption of conformity for the quality system of the manufacturer must be based only on harmonised standards – see general comments.
(3) Annex V is amended as follows:	
(a) in point 3.1., point (a) is replaced by the following:	

Commission proposal	Drafting suggestions and Justifications
'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';	
(b) point 4.1 is replaced by the following:	
'4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.	
In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';	
(c) point 5.2. is replaced by the following:	
'5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';	BE (Drafting suggestions): Also change 6.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. BE (Justifications): Allow digital EU Declaration of Conformity
(4) Annex VI is amended as follows:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
(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.';	BE (Drafting suggestions): Also change 4.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or the safety component for which it has been drawn up BE (Justifications): Allow digital EU Declaration of Conformity
(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:	

Commission proposal	Drafting suggestions and Justifications
'(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;';	
(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:	BG (Drafting suggestions): deleted
'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.';	BG (Drafting suggestions): deleted BG (Justifications): This point must be deleted. Presumption of conformity for the quality system of the manufacturer must be based only on harmonised standards – see general comments.
(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.';	BE (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	+ Add to 5.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market BE (Justifications): Allow digital EU Declaration of Conformity
(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, or 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;';	BE (Drafting suggestions): '(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~~, or 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;' BE (Justifications): Not necessary, a standard is only harmonised if it published in the OJEU BG (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
	'(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*, ~~or~~ 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;';
(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:	

Commission proposal	Drafting suggestions and Justifications
(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:	BG (Drafting suggestions): (b) in the first subparagraph, points ~~(k) and (l)~~ (i) to (k) are deleted; ~~replaced by the following:~~ BG (Justifications): Points (i) to (k) of Annex II repeat part of the content of the EU declaration of conformity. In order to decrease administrative burden this overlapping must be avoided.
'(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;	BG (Drafting suggestions): deleted
(l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed.';	BG (Drafting suggestions): (b1) in the first subparagraph, point (l) is replaced by the following: '(l) the internet address or machine-readable code through which the EU declaration of conformity can be accessed.'; (b2) the second subparagraph is deleted;

Commission proposal	Drafting suggestions and Justifications
	BG (Justifications): The second subparagraph is no longer adequate. It reads: "The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer **if the EU declaration of conformity accompanies the PPE**."
(2) in Annex III, points (f) and (g) are replaced by the following:	
'(f) the references of the harmonised standards referred to in Article 14 or 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;	BG (Drafting suggestions): '(f) the references of the harmonised standards referred to in Article 14 ~~or~~ and the common specifications referred to in Article 14a that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts which have been applied;
(g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;';	
(3) Annex V is amended as follows:	
(a) in point 3., point (a) is replaced by the following:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE **Updated: 27/06/2025 16:11**

Commission proposal	Drafting suggestions and Justifications
‘(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;’;	

Commission proposal	Drafting suggestions and Justifications
(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;';	BE (Drafting suggestions): + Add to Annex VI point 3.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. BE (Justifications): Allow digital EU Declaration of Conformity
(4) Annex VII is amended as follows:	
(a) in point 3., point (a) is replaced by the following:	

Commission proposal	Drafting suggestions and Justifications
'(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.';	BE (Drafting suggestions): + Add to point 6.2: The manufacturer shall draw up a ~~written~~ digital EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. BE (Justifications): Allow digital EU Declaration of Conformity
(5) Annex VIII is amended as follows:	
(a) in point 3.1., point (a) is replaced by the following:	
'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';	
(b) in point 3.3., the second subparagraph is replaced by the following:	BG (Drafting suggestions): deleted
'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding	BE (Drafting suggestions):

Commission proposal	Drafting suggestions and Justifications
specifications of the relevant harmonised standard or common specification.’;	add to point 5.2: The manufacturer shall draw up a ~~written~~ **digital** EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market BG (Drafting suggestions): deleted BG (Justifications): This point must be deleted. Presumption of conformity for the quality system of the manufacturer must be based only on harmonised standards – see general comments.
(6) Annex IX is amended as follows:	
(a) point 2 is replaced by the following:	
‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;	
(b) point 6 is replaced by the following:	
‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’.	BE (Drafting suggestions): 6. References to the relevant harmonised standards or common specifications used, including the date of the standard or specification, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
ANNEX III	
Annexes III and V to Regulation (EU) 2016/426 are amended as follows:	BG (Drafting suggestions): Annexes I, III and V to Regulation (EU) 2016/426 are amended as follows: (0) Annex I is amended as follows: (a) point 1.5 is replaced by the following: '1.5. The manufacturer of the appliance shall include in the instructions: (a) instructions for installation intended for the installer; (b) instructions for use and servicing, intended for the user.'; (b) in point 1.6.2, the third subparagraph is replaced by the following: 'The manufacturer of the appliance shall include in the instructions all necessary information for adjustment, operation and maintenance of the fittings as part of the finished appliance, as appropriate.'; (c) point 1.6.3 is replaced by the following: '1.6.3. **All appliances shall bear appropriate warning notices, which shall also appear on the packaging.** The warning notices on the appliance and its packaging shall clearly state the type of gas to be used, the gas supply pressure, the appliance category and any restrictions on use, in particular the restriction whereby the appliance shall be installed only in areas where there is sufficient ventilation so as to ensure that the risks presented by it are minimised.';

Commission proposal	Drafting suggestions and Justifications
	(d) point 1.7 is replaced by the following: '1.7. The instructions for incorporation of the fitting into an appliance or its assembly in order to constitute an appliance and for its adjustment, operation and maintenance shall be provided as part of the EU declaration of conformity.'; BG (Justifications): Point 1.5 of Annex I must be modified as it is no longer adequate. It reads: 1.5. All appliances shall: (a) **be accompanied** by instructions for installation intended for the installer; (b) **be accompanied** by instructions for use and servicing, intended for the user; (c) bear appropriate warning notices, which shall also appear on the packaging. Point (c) is moved to point 1.6.3. In the third subparagraph of point 1.6.2 the text "accompanying the appliance" is deleted. Point 1.7 is modified to take into account that the EU declaration of conformity does not accompany the fitting.
(1) Annex III is amended as follows:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

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Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
(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 or 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;';	BG (Drafting suggestions): '(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* ~~or~~ 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.';	

Commission proposal	Drafting suggestions and Justifications
(b) in point 1.4., points 1.4.3. and 1.4.4. are replaced by the following:	BG (Drafting suggestions): (b) in point 1.4., points 1.4.2, 1.4.3. and 1.4.4. are replaced by the following: '1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards **or common specifications**, as well as the elements which have been designed in accordance with other relevant technical specifications; BG (Justifications): Common specification must be added also in point 1.4.2.
'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:	

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'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.';	BG (Drafting suggestions): 'An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation.'; (d1) in point 2.4.2, the second subparagraph is deleted; BG (Justifications): New point (d1) is added – the following text must be deleted **in all conformity assessment modules**: "A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of

Commission proposal	Drafting suggestions and Justifications
	conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”
(e) in point 3.3.1., point (a) is replaced by the following:	
‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;	
(f) in point 3.3.3., the second subparagraph is replaced by the following:	BG (Drafting suggestions): deleted
‘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.’;	BG (Drafting suggestions): Deleted (f1) in point 3.5.2, the second subparagraph is deleted; BG (Justifications): Point (f) must be deleted. Presumption of conformity for the quality system of the manufacturer must be based only on harmonised standards – see general comments. New point (f1) is added – the following text must be deleted **in all conformity assessment modules**: “A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of

Commission proposal	Drafting suggestions and Justifications
	conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”
(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:	BG (Drafting suggestions): deleted
‘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.’;	BG (Drafting suggestions): Deleted (h1) in point 4.5.2, the second subparagraph is deleted; BG (Justifications): Point (h) must be deleted. Presumption of conformity for the quality system of the manufacturer must be based only on harmonised standards – see general comments. New point (h1) is added – the following text must be deleted **in all conformity assessment modules**: “A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of

Commission proposal	Drafting suggestions and Justifications
	conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”
(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.’;	BG (Drafting suggestions): ‘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

Commission proposal	Drafting suggestions and Justifications
	notified body concerned shall decide on the appropriate tests to be carried out.'; (j1) in point 5.6.2, the second subparagraph is deleted; BG (Justifications): New point (j1) is added – the following text must be deleted **in all conformity assessment modules**: "A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment."
(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, or 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.';	BG (Drafting suggestions): '(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, ~~or~~ 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

Commission proposal	Drafting suggestions and Justifications
	standards or common specifications, the technical documentation shall specify the parts which have been applied.’;
(l) in point 6.4., the first subparagraph is replaced by the following:	
‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the appliances or fittings with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’;	BG (Drafting suggestions): ‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the 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.’; (l1) in point 6.5.2, the second subparagraph is deleted; BG (Justifications): New point (l1) is added – the following text must be deleted **in all conformity assessment modules**: “A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.”

Commission proposal	Drafting suggestions and Justifications
(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:	

Commission proposal	Drafting suggestions and Justifications
'(c) the EU declaration of conformity, or the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);';	BG (Drafting suggestions): '(c) ~~the EU declaration of conformity, or~~ the internet address or machine readable code, through which the EU declaration of conformity can be accessed, in accordance with Article 10(8);'; BG (Justifications): There is no need to repeat the content of the EU declaration of conformity in the instructions, the data for access to it is enough.
(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:	

REGULATION - Omnibus IV (part digitalisation and common specifications) – ST 9318/25 + ADD1

Deadline: ***23/06/2025***

From: BE, BG, CZ, DE, EL, FR, LT, HU, NL, AT, SI, SK, FI, SE

Updated: 27/06/2025 16:11

Commission proposal	Drafting suggestions and Justifications
'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;';	BE (Drafting suggestions): + add point 5.2: The manufacturer shall draw up a ~~written~~ EU declaration of conformity for each machinery or related product model and keep it at

Commission proposal	Drafting suggestions and Justifications
	the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market or put into service.
(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;'.	BE (Drafting suggestions): + add point 5.2: The manufacturer shall draw up a ~~written~~ EU declaration of conformity and keep it at the disposal of the national authorities for at least 10 years after the machinery or related product has been placed on the market or put into service
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:';	

Commission proposal	Drafting suggestions and Justifications
(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).'	BG (Drafting suggestions): '(t) ~~'~~clear, understandable and readable instructions ~~for use~~ and safety information in a format that makes it possible to print, download and save them on an electronic device so that the user can access them at all times, in particular during a breakdown of the battery (only for stationary battery energy storage systems).' BG (Justifications): See Article 38(1). FI (Drafting suggestions): 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).' FI (Justifications): Why only for stationary battery energy storage systems? From battery user point of view instructions and safety information available from battery passport could be useful for them. Battery passport requirement

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	applies to LMT-, industrial- (2 kWh or more) and electric vehicle batteries.