



Council of the
European Union

196667/EU XXVII. GP
Eingelangt am 18/09/24

Brussels, 18 September 2024
(OR. en)

13040/24

Interinstitutional File:
2022/0279(COD)

CODEC 1753
MI 770
COMPET 869
CONSUM 273
IND 421
PE 201

INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (first reading) - Outcome of the European Parliament's first reading and Corrigendum procedure (Strasbourg, 24 April 2024 and Strasbourg, 17 September 2024)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint Declaration on practical arrangements for the co-decision procedure¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this legislative file at first reading.

This file was expected² to undergo the Corrigendum procedure³ in the European Parliament after adoption by the outgoing Parliament of its position at first reading.

¹ OJ C 145, 30.6.2007, p.5.

² 10078/24.

³ Rule 251, EP Rules of Procedure.

II. VOTES

At its sitting of 24 April 2024, the European Parliament adopted amendment 165 (without legal linguistic revision) to the Commission proposal and a legislative resolution, constituting the European Parliament's position at first reading. It reflects what had been provisionally agreed between the Institutions.

After finalisation of the adopted text by the legal linguists, the European Parliament approved on 17 September 2024 a corrigendum to the position adopted at first reading.

With this corrigendum, the Council should be able to approve the position of the European Parliament as set out in the Annex⁴ hereto, thus bringing to a close the first reading for both Institutions.

The act would then be adopted in the wording which corresponds to the European Parliament's position.

⁴ The text of the corrigendum is set out in the Annex. It is presented in the form of a consolidated text, where changes to the Commission's proposal are highlighted in bold and italics. The symbol "■" indicates deleted text.

P9_TA(2024)0321

Amending certain Regulations as regards the establishment of the Single Market Emergency Instrument

European Parliament legislative resolution of 24 April 2024 on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (COM(2022)0461 – C9-0314/2022 – 2022/0279(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2022)0461),
- having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0314/2022),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 14 December 2022¹,
- having regard to the opinion of the Committee of the Regions of 8 February 2023²,
- having regard to the provisional agreement approved by the responsible committee under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 16 February 2024 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

¹ OJ C 100, 16.3.2023, p. 95.

² OJ C 157, 3.5.2023, p. 82.

- having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection (A9-0244/2023),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Position of the European Parliament adopted at first reading on 24 April 2024 with a view to the adoption of Regulation (EU) 2024/... of the European Parliament and of the Council amending Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 and (EU) 2023/1230 as regards emergency procedures for the conformity assessment, *presumption of conformity*, adoption of common specifications and market surveillance due to an internal market emergency

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee⁷,

Having regard to the opinion of the Committee of the Regions⁸,

Acting in accordance with the ordinary legislative procedure⁹,

⁷ OJ C 100, 16.3.2023, p. 95.

⁸ OJ C 157, 3.5.2023, p. 82.

⁹ Position of the European Parliament of 24 April 2024 [(OJ ...)/(not yet published in the Official Journal)] and Decision of the Council of

Whereas:

- (1) **Regulation (EU) 2024/... of the European Parliament and of the Council**¹⁰⁺ lays down rules aiming to ensure, during a crisis, the normal functioning of the *internal* market, including the free movement of goods, services and persons, and the availability of crisis-relevant goods and services and of goods and services of *critical* importance to citizens, businesses and public authorities. *That* Regulation applies to both goods and services.
- (2) **Regulation (EU) 2024/...**⁺⁺ lays down measures which are to be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact of a crisis on the functioning of the *internal* market.
- (3) **Regulation (EU) 2024/...**⁺⁺ lays down a multi-layered mechanism consisting of contingency planning *and of internal* market *vigilance and* emergency *modes*.
- (4) In order to complement, ensure consistency and further enhance the effectiveness of the framework established by **Regulation (EU) 2024/...**⁺⁺, it is appropriate to ensure that crisis-relevant goods referred to in that Regulation can be swiftly placed on the *internal* market in order to contribute to addressing and mitigating disruptions to that market.

¹⁰ **Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).**

⁺ **OJ: please insert in the text the number of the Regulation contained in document PE-CONS No 46/24 (2022/0278(COD)), and the number, date and OJ and ELI reference of the same Regulation in the footnote.**

⁺⁺ **OJ: please insert in the text the number of the Regulation contained in document PE-CONS No 46/24 (2022/0278(COD)).**

- (5) A number of sectorial Union legal acts lay down harmonised rules regarding the design, manufacture, placing on the market and, as applicable, conformity assessment of certain products. Such legal acts include Regulations (EU) No 305/2011¹¹, (EU) 2016/424¹², (EU) 2016/425¹³, (EU) 2016/426¹⁴ and (EU) 2023/1230¹⁵ of the European Parliament and of the Council (the ‘amended Regulations’). Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2023/1230 are based on the principles of the new approach to technical harmonisation. Moreover, those Regulations are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council¹⁶. *Given the specificity of construction products and the particular focus of the system for their assessment, the procedures for the conformity assessment provided for in Decision No 768/2008/EC, and the modules set out therein, are not appropriate. Therefore, Regulation (EU) No 305/2011 lays down specific methods for the assessment and verification of constancy of performance in relation to the essential characteristics of construction products.*

¹¹ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

¹² 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).

¹³ 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).

¹⁴ 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).

¹⁵ Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1).

¹⁶ 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).

- (6) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectorial **Union** harmonisation legislation, provide for procedures designed to apply during a crisis. Therefore it is appropriate to introduce targeted adjustments to the amended Regulations, to allow a response to the impact of crises affecting products that have been designated as crisis-relevant goods in accordance with Regulation (EU) 2024/...⁺⁺ and covered by the amended Regulations.
- (7) Experience from previous crises that have affected the **internal** market has shown that the procedures laid down in the sectorial Union legal acts are not designed to cater to the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures in order to complement the measures adopted under **Regulation (EU) 2024/...**⁺⁺.
- (8) *Non-harmonised products can also be designated as crisis-relevant goods. Therefore, some of the relevant mechanisms under this Regulation, in particular the presumption of conformity with the general safety requirement based on national requirements, or on national or international standards, could provide an additional way to demonstrate the presumption of safety of non-harmonised crisis-relevant goods during a crisis. This would facilitate the placing on the market of those goods during a crisis.*

- (9) In order to overcome the potential effects of disruptions to the functioning of the *internal* market in the event of a crisis and in order to ensure that during an internal market emergency mode crisis-relevant goods can be placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications for such goods over any pending applications concerning products which have not been designated as crisis-relevant goods. *In the context of such prioritisation, the conformity assessment body should not be allowed to charge additional disproportionate costs to the manufacturer. All additional costs charged by a conformity assessment body to the manufacturer should be strictly proportionate to the actual additional efforts deployed by the conformity assessment body to implement the prioritisation and should be charged only during the internal market emergency mode. The transfer of certain additional and proportionate costs by the conformity assessment bodies to the manufacturers should remain exceptional and reflect a fair distribution of the costs among all the stakeholders involved in the efforts to contain the disruptions to the functioning of the internal market. The costs associated with a conformity assessment should not become a barrier to the entry on the market of prospective new manufacturers, in particular small and medium-sized enterprises, and should not restrict the emergence of innovative products. Furthermore, conformity assessment bodies notified under the amended Regulations should be encouraged to increase their testing capacities for products designated as crisis-relevant goods in respect of which they have been notified.*

- (10) Emergency procedures should be laid down in Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, *(EU) 2023/988 of the European Parliament and of the Council*¹⁷ and *Regulation (EU) 2023/1230*. Those procedures should become applicable only following the activation of the *internal* market emergency mode and only when a specific good covered by those Regulations is designated as *a* crisis-relevant *good* in accordance with *Regulation (EU) 2024/...*⁺⁺ and the Commission has adopted an implementing act activating those procedures in accordance with that Regulation.
- (11) Furthermore, in cases where, *for example*, the disruptions to the functioning of the internal market could affect the conformity assessment bodies or in cases where the testing capacities for products designated as crisis-relevant goods would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products which have not undergone the usual conformity assessment procedures required by the respective sectorial *Union harmonisation* legislation.

¹⁷ *Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).*

- (12) As regards products falling within the scope of the *amended* Regulations that have been designated as crisis-relevant goods, in the context of an ongoing *internal* market emergency the national competent authorities should be able to derogate from the obligation to carry out the conformity assessment procedures laid down in the amended Regulations, ■ where the involvement of a notified body is mandatory. In such cases those authorities should be able to issue authorisations for placing on the market, and, as applicable, for putting into service, those products, provided that *conformity with all* the applicable essential safety requirements is ensured. It should be possible to demonstrate compliance with those requirements by various means, which could include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures ■ which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.

- (13) *Given that the essential safety requirements harmonised by the amended Regulations will remain applicable and that it should be possible for a national competent authority to issue the authorisation for placing products on the market without the CE marking exceptionally, temporarily and in addition to the conformity assessment procedures laid down in those Regulations, this Regulation continues to improve the conditions for the functioning of the internal market. This Regulation takes into account both the context constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that this Regulation makes to them. Those amendments would allow national authorities to recognise authorisations issued in other Member States and require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union, by means of implementing acts, provided that the requirements set out in the authorisation ensure conformity with the essential requirements laid down in those amended Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting the health, life and safety of persons. By not providing for an automatic mutual recognition of each national authorisation that derogates from conformity assessment procedures in times of crisis, this Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby aims to maintain consumer confidence in the safety of products in the Union market bearing the CE marking.*

Therefore, those new derogating rules, insofar as they prohibit affixing the CE marking to products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in CE marking, which can only be affixed where all the harmonised substantive and procedural rules have been respected. By providing an additional, parallel avenue for exceptionally placing crisis-relevant goods on the market in the context of an internal market emergency, the derogating rules enable new manufacturers to swiftly place their products on the market without waiting for the finalisation of the normal conformity assessment procedures. Such an accelerated and exceptional placing on the market would contribute to the swift increase in the supply of crisis-relevant goods, and at the same time facilitate manufacturers as it would allow them to place initial batches or series of products on the market before the completion of the conformity assessment procedures. Once the conformity assessment procedures have been successfully completed, subsequent batches or series of products should be fully compliant with the relevant applicable rules and thus benefit from free movement. The co-existence, during an internal market emergency, of an exceptional, derogating set of rules alongside the ordinarily applicable rules makes it possible to transition to the ordinarily applicable rules, enabling the manufacturers to continue placing their products on the market after the expiry or deactivation of the internal market emergency mode.

- (14) *Where the Commission has extended the validity of an authorisation issued by a Member State to the territory of the whole Union by means of an implementing act, the conditions for the placing on the market of the goods concerned set out therein should apply only to those goods placed on the market after the date of entry into force of that implementing act. That implementing act could provide that the benefit of the free movement is also granted to goods already placed on the market on the basis of pre-existing authorisations. All pre-existing authorisations issued by Member States prior to the entry into force of a Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry into force of the Commission implementing act concerning the same goods, and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act should not need to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in the need for corrective or restrictive actions to be taken by the Commission by means of another implementing act.*

- (15) *The validity of all authorisations, issued during an active internal market emergency mode in accordance with the emergency procedures established by this Regulation, for the placing on the market of products designated as crisis-relevant goods, should automatically expire on the date of expiry or deactivation of the internal market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once an authorisation has expired, crisis-relevant goods should no longer be placed on the market on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that the goods covered by such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive actions at their disposal in accordance with the amended Regulations and Regulation (EU) 2019/1020 of the European Parliament and of the Council¹⁸. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in accordance with the relevant sectorial emergency procedures.*

¹⁸ *Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).*

- (16) *In order to ensure the timely sharing of information and to allow all Member States to react, the Commission and the other Member States should be informed immediately of any decisions taken at national level to authorise crisis-relevant goods. The Information and Communication System for Market Surveillance (ICSMS) provided for in Regulation (EU) 2019/1020 already provides the necessary functions to allow quick notification of administrative decisions and therefore Member States should be able to use it for that purpose. Moreover, information on all corrective or restrictive actions should also be shared. Pursuant to Regulation (EU) 2019/1020 , such information is to be accessible in the ICSMS irrespective of whether those actions have to be notified in the Safety Gate due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between the Safety Gate and the ICSMS, which will be maintained by the Commission in accordance with Regulation (EU) 2019/1020.*

- (17) *All authorisations for the placing on the market of crisis-relevant goods issued by Member States should contain at least certain information supporting the assessment that the goods concerned are compliant with the applicable essential requirements and should contain certain elements ensuring traceability. The elements concerning traceability should include specific requirements regarding the labelling, accompanying documents or any additional means of ensuring the identification of the goods concerned and allowing them to be traced along the supply chain. In order to ensure uniform and coherent implementation of the traceability requirements across the Union, Commission implementing acts extending the validity of authorisations issued by a Member State should also specify the common traceability requirements. Those requirements should include the specific arrangements regarding the indication that the product concerned is a ‘crisis-relevant good’. The Commission should be empowered to adopt via implementing acts, on expiry or deactivation of the internal market emergency mode, any necessary adjustments to the traceability requirements for crisis-relevant goods that have already been placed on the market on the basis of an authorisation issued by a Member State.*

- (18) Where *an internal* market emergency causes an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to establish a mechanism for the provision of technical references which manufacturers should be able to use to design and produce crisis-relevant goods that comply with the applicable essential health and safety requirements.
- (19) A number of sectorial Union harmonised acts provide for the possibility for a manufacturer to benefit from a presumption of conformity if its product complies with a harmonised standard. *In addition, the Union general product safety framework established by Regulation (EU) 2023/988 establishes, under certain conditions, a mechanism of presumption of conformity with the general safety requirement where a product complies with relevant European standards, the references of which have been published in the Official Journal of the European Union.* However, in cases where such standards do not exist or compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative *crisis-response* mechanisms.

- (20) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2023/1230, the competent national authorities should be able to presume that products manufactured in accordance with *European standards, relevant applicable national standards of the Member States, or relevant applicable international standards developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and* ensuring an equivalent level of protection to that offered by the harmonised standards, comply with the relevant *and applicable* essential requirements. *Products placed on the market on the basis of the presumption of conformity established via the emergency mechanism established by this Regulation should not be withdrawn automatically when the implementing act listing the European or the relevant applicable national or international standards ceases to apply. In cases where there are concerns regarding the compliance of a harmonised product that has been designated as a crisis-relevant good and placed on the market during an internal market emergency mode on the basis of a presumption of conformity established via such implementing act, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After such implementing act ceases to apply, compliance with the European or the relevant applicable national or international standards should no longer provide a presumption of conformity with the relevant and applicable essential requirements.*

- (21) *With respect to Regulation (EU) 2023/988, the competent national authorities should be able to presume that products manufactured in accordance with European or national standards of the Member States, or with relevant international standards developed by a recognised international standardisation body comply with the general safety requirement. Products placed on the market on the basis of the presumption of conformity established via the emergency mechanism established by this Regulation should not be withdrawn automatically when the implementing act listing the European or the relevant applicable national or international standards ceases to apply. Where there is evidence that the product that has been designated as a crisis-relevant good and placed on the market during an internal market emergency mode on the basis of the presumption of conformity established via such implementing act, is dangerous, the market surveillance authorities should be allowed to take all appropriate measures under Regulation (EU) 2023/988. After such implementing act ceases to apply a demonstration of compliance with the European or the relevant applicable international or national standards should no longer provide a presumption of conformity with the general safety requirement.*

- (22) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 *and* (EU) 2023/1230, the Commission should have the possibility to adopt, by means of implementing acts, common specifications, on which the manufacturers should be able to rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the *internal* market emergency mode. *Products placed on the market on the basis of the presumption of conformity established by demonstrating compliance with those common specifications should not be withdrawn automatically when the implementing act laying down such common specifications ceases to apply. In cases where there are concerns regarding the compliance of a product designated as a crisis-relevant good and placed on the market during an internal market emergency mode, on the basis of the presumption of conformity established by demonstrating compliance with common specifications, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the implementing act laying down the common specifications ceases to apply, a demonstration of compliance with those common specifications should no longer provide a presumption of conformity with the relevant and applicable essential requirements.*

- (23) In order to ensure that the level of safety provided by the harmonised **and non-harmonised** products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant, including by enabling closer cooperation and mutual support among the market surveillance authorities.
- (24) *In accordance with the relevant provisions of the amended Regulations, Member States should lay down rules on penalties applicable to infringements of the provisions of those Regulations, including of the new provisions introduced by this Regulation, by economic operators and conformity assessment bodies. Member States should also ensure that those rules are enforced by the competent national authorities, including the respective notifying authorities.*
- (25) In accordance with its established practice, the Commission should systematically consult the relevant stakeholders in the context of the early stages of preparation of all draft implementing acts laying down common specifications.
- (26) Regulations (EU) **No 305/2011**, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) **2023/988 and (EU) 2023/1230** should therefore be amended accordingly.
- (27) In order for this Regulation to apply from the same date as **Regulation (EU) 2024/...**⁺⁺ **■**, its application should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1
Amendments to Regulation (EU) No 305/2011

■ Regulation (EU) No 305/2011 is amended as follows:

(1) *in Article 2, the following points are added:*

‘(29) “*crisis-relevant goods*” means *crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/... of the European Parliament and of the Council*^{*,+};

(30) “*internal market emergency mode*” means *internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...^{+,}.*

* *Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).*[?];

(2) the following chapter is inserted:

‘CHAPTER VIA

■ EMERGENCY PROCEDURES

Article 38a

Application of emergency procedures

1. Articles 38b to 38d *of this Regulation* shall apply only if the Commission has adopted an implementing act pursuant to Article ■ 28 of *Regulation (EU) 2024/...*^{+,} with respect to construction products covered by this Regulation.
2. Articles 38b to 38d of this Regulation shall apply only to construction products which have been designated as crisis-relevant goods *pursuant to Article 18(4) of Regulation (EU) 2024/...*^{+,}.

3. Articles 38b to 38d of this Regulation shall apply *only* during the *internal* market emergency mode *that has been activated in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺.
4. The Commission *may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements* with respect to construction products placed on the market in accordance with Articles 38b *and* 38c. *Those* implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a).

Article 38b

Prioritisation of the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods

1. This Article applies to construction products listed in the implementing act referred to in Article 38a(1) that are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance in accordance with Article 28(1).
2. The notified bodies shall *make best efforts to* process as a matter of priority requests for third party tasks related to the assessment and verification of constancy of performance of construction products referred to in paragraph 1, *irrespective of whether those requests have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.*
- 1
3. The prioritisation of requests for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph 2 shall not result in *additional disproportionate* costs for the *manufacturers who* have lodged those requests.

4. The notified bodies shall ***make reasonable*** efforts to increase their respective assessment and verification capacities regarding construction products referred to in paragraph 1 in respect of which they have been notified.

■

Article 38c

Assessment and declaration of performance based on standards and common specifications

1. Where construction products ■ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, ***listing appropriate standards or*** establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in the following cases:
 - (a) where a reference to harmonised standards covering the relevant methods and the criteria for assessing the performance of those products in relation to their essential characteristics has not been published in the ***Official Journal of the European Union*** in accordance with ***Regulation (EU) No 1025/2012 of the European Parliament and of the Council**** and no such reference is expected to be published 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/...*⁺⁺, significantly restrict the possibilities of manufacturers to make use of the harmonised standards ■ that provide the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics, 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*.

2. *The implementing acts referred to in paragraph 1 shall set out the most appropriate alternative technical solution for the purposes of providing assessment and declaration of performance in accordance with paragraph 5. To that end, the 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, common specifications may be established by those implementing acts.*
3. The implementing acts referred to in paragraph 1 ■ of this Article shall be adopted ■ in accordance with the examination procedure referred to in Article 64(2a) *and* shall apply ■ until the last day of the period during which the *internal* market emergency mode is activated, *unless such implementing acts are amended or repealed in accordance with paragraph 7 of this Article.*

4. *Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article have been fulfilled. When preparing that draft implementing act, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.*
5. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the *standards or* common specifications *referred to in* paragraph 1 of this Article, *or parts thereof*, may be used for assessing and declaring the performance of construction products covered by those *standards or* common specifications in relation to their essential characteristics. *From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible to draw up declarations of performance based on the standards or the common specifications referred to in the implementing act referred to in paragraph 1 of this Article.*

6. By way of derogation from Article 38a(3), *unless there is sufficient reason to believe that construction products covered by the standards or common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons or fail to achieve the declared performance, the declarations of performance of construction products which have been placed on the market in compliance with those standards or common specifications shall remain valid 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* common specification as referred to in paragraph 1 is incorrect in terms of methods and criteria for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof *by submitting* a detailed explanation. The Commission shall assess that *detailed explanation and, if* appropriate, amend or *repeal* the implementing *act listing the standard or* establishing the common specification in question.

■

1. Member States shall prioritise the market surveillance activities for construction products listed in the implementing act referred to in Article 38a(1) of this Regulation. *The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020 of the European Parliament and of the Council**.*
2. The market surveillance authorities of the Member States shall *ensure that* best efforts *are made* to provide assistance to other market surveillance authorities during *an internal* market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support, such as the reinforcement of the testing capacity for construction products listed in the implementing act referred to in Article 38a(1).

* 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).

** *Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).*’;

(3) in Article 64, the following paragraph is inserted:

‘2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council* shall apply.

* ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).***’

Article 2
Amendments to Regulation (EU) 2016/424

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

(1) *in Article 3, the following points are added*:

‘(28) “*crisis-relevant goods*” means crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/... of the European Parliament and of the Council^{*,+};

(29) “*internal market emergency mode*” means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...⁺⁺.

* *Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI:...).*’;

(2) *the following chapter is inserted*:

‘**CHAPTER VA**

EMERGENCY PROCEDURES

Article 43a

Application of emergency procedures

1. Articles 43b to 43e *of this Regulation* shall apply only if the Commission has adopted an implementing act pursuant to Article ■ 28 of *Regulation (EU) 2024/...*⁺⁺ with respect to subsystems and safety components covered by this Regulation.
2. Articles 43b to 43e of this Regulation shall apply only to subsystems and safety components ■ which have been designated as crisis-relevant goods *pursuant to Article 18(4) of Regulation (EU) 2024/...*⁺⁺.

3. Articles 43b to 43e of this Regulation shall apply *only* during the *internal* market emergency mode *that has been activated in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺.

However, ■ Article 43c(7) of this Regulation shall apply during the *internal* market emergency mode and after its expiry or deactivation.

4. The Commission *may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements* with respect to subsystems and safety components placed on the market or incorporated into a cableway installation in accordance with Articles 43c and *43d*. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 43b

Prioritisation of the conformity assessment of subsystems and safety components designated as crisis-relevant goods

1. This Article applies to subsystems and safety components listed in the implementing act referred to in Article 43a(1) that are subject to the conformity assessment procedures referred to in Article 18 that require the mandatory involvement of a notified body.
2. The notified bodies shall *make best efforts to* process as a matter of priority all applications for a conformity assessment of subsystems and safety components referred to in paragraph 1 of this Article, *irrespective of whether those applications have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.*
3. The prioritisation of applications for a conformity assessment of subsystems and safety components pursuant to paragraph 2 shall not result in *additional disproportionate* costs for the manufacturers who have lodged those applications.
4. The notified bodies shall *make reasonable* efforts to increase their testing capacities for subsystems and safety components referred to in paragraph 1 in respect of which they have been notified.

1. By way of derogation from Article 18, **a Member State** may authorise, on a duly justified request *from an economic operator*, the placing on the market or the incorporation into a cableway installation within the territory of that Member State, of a specific subsystem or safety component listed in the implementing act referred to in Article 43a(1) and for which the conformity assessment procedures referred to in Article 18 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable essential requirements laid down in Annex II has been demonstrated *in accordance with procedures referred to in that authorisation*.
2. *The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1 of this Article. Provided that the requirements set out in the authorisation ensure conformity with the applicable essential requirements laid down in Annex II, the Commission shall adopt, without delay, an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the whole Union and shall set out the conditions under which the specific subsystem or safety component may be placed on the market or incorporated into a cableway installation. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).*

The subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the content and presentation of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

- 3. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).*
- 4. As long as an implementing act as referred to in paragraph 2 or 3 is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of that Member State, and on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of such an implementing act. Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.*

5. Manufacturers of subsystems or safety components subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the █ competent *national* authority.
- █
6. Any authorisation issued █ pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation. *Such authorisations shall set out at least the following:*
- (a) a description of the procedures, by means of which compliance with the applicable essential requirements set out in Annex II to this Regulation was successfully demonstrated;
 - (b) *any* specific requirements regarding the traceability of the subsystem or safety component concerned;
 - (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the *internal* market emergency mode has been activated *in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺;

- (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the subsystem or safety component concerned;
- (e) measures to be taken ■ upon expiry or deactivation of the *internal market emergency mode with respect to* the subsystem or safety component concerned that has been *placed on the market or incorporated into a cableway installation*.

■

- 7. By way of derogation from Articles 7, **20 and 21**, subsystems or safety components for which an authorisation has been granted in accordance with paragraph 1 ■ of this Article shall not *bear the CE marking and Article 7* shall not *apply*.
- 8. The market surveillance authorities of *a* Member State, *where* an authorisation pursuant to *paragraphs 1, 2 and 4 of this Article is valid* shall be entitled, with respect to such subsystems or safety components, to take all corrective and restrictive *actions* at national level provided for *under Regulation (EU) 2019/1020 of the European Parliament and of the Council** and under this Regulation. *They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.*

■

9. ■ The use of the authorisation procedure set out in *paragraphs 1 to 4 of this Article shall* not affect the application on the territory of the Member State concerned of the relevant conformity assessment procedures laid down in Article 18.

■

Article 43d

Presumption of conformity based on standards and common specifications

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 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; 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/...*⁺⁺, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover 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.

2. *The implementing acts referred to in paragraph 1 shall set out the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 5. 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, common specifications may be established by those implementing acts.*
3. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 44(3) and shall apply until the last day of the period during which the *internal* market emergency mode is activated, *unless such implementing acts are amended or repealed in accordance with paragraph 7 of this Article.*

4. *Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article have been fulfilled. When preparing that draft implementing act, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.*
5. Without prejudice to Article 17, subsystems and safety components that are in conformity with *the standards or 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*, 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 common specifications referred to in 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* common 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* 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 2 **■** 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* 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 common specification in question.
-

Article 43e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for subsystems and safety components listed in the implementing act referred to in Article 43a(1) of this Regulation. *The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.*
2. The market surveillance authorities of the Member States shall **ensure that** best efforts **are made** to provide assistance to other market surveillance authorities during **an internal** market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support, such as the reinforcement of the testing capacity for subsystems and safety components listed in the implementing act referred to in Article 43a(1).

* *Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).*

Article 3
Amendments to Regulation (EU) 2016/425

■ Regulation (EU) 2016/425 *is amended as follows:*

(1) *in Article 3, the following points are added:*

‘(19) “crisis-relevant goods” means crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/... of the European Parliament and of the Council^{+};*

(20) “internal market emergency mode” means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...⁺⁺.

^{*} *Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).’;*

(2) *the following chapter is inserted:*

‘CHAPTER VIA
EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures

1. Articles 41b to 41e *of this Regulation* shall apply only if the Commission has adopted an implementing act pursuant to Article 28 of *Regulation (EU) 2024/...*⁺⁺ with respect to PPE covered by this Regulation.
2. Articles 41b to 41e of this Regulation shall apply only to PPE which has been designated as crisis-relevant goods *pursuant to Article 18(4) of Regulation (EU) 2024/...*⁺⁺.
3. Articles 41b to 41e of this Regulation shall apply *only* during the *internal* market emergency mode *that has been activated in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺.

However, Article 41d(7) of this Regulation shall apply during the *internal* market emergency mode and after its expiry or deactivation.

4. The Commission *may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements* with respect to PPE placed on the market in accordance with Articles 41c and 41d. *Those* implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 41b

Prioritisation of the conformity assessment of PPE designated as crisis-relevant goods

1. This Article applies to PPE listed in the implementing act referred to in Article 41a(1) that *is* subject to the conformity assessment procedures referred to in Article 19 that require the mandatory involvement of a notified body.
2. The notified bodies shall *make best efforts to* process as a matter of priority all applications for a conformity assessment of PPE referred to in paragraph 1 of this Article, *irrespective of whether those applications have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.*
3. The prioritisation of applications for a conformity assessment of PPE pursuant to paragraph 2 shall not result in *additional disproportionate* costs for the manufacturers who have lodged those applications.
4. The notified bodies shall *make reasonable* efforts to increase their testing capacities for PPE referred to in paragraph 1 in respect *of* which they have been notified.

Article 41c

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body

1. By way of derogation from Article 19, **a Member State** may authorise, on a duly justified request *from an economic operator*, the placing on the market within the territory of that Member State, of specific PPE listed in the implementing act referred to in Article 41a(1) and for which the conformity assessment procedures referred to in Article 19 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable essential health and safety requirements laid down in Annex II has been demonstrated *in accordance with procedures referred to in that authorisation*.
2. *The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1 of this Article. Provided that the requirements set out in the authorisation ensure conformity with the applicable essential health and safety requirements laid down in Annex II, the Commission shall adopt, without delay, an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the whole Union and shall set out the conditions under which the specific PPE may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).*

The PPE subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the content and presentation of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

- 3. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).*
- 4. As long as an implementing act as referred to in paragraph 2 or 3 is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of that Member State, and on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of such an implementing act. Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.*

5. Manufacturers of PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the █ competent *national* authority.

█

6. Any authorisation issued █ pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market. *Such authorisations shall set out at least the following:*

- (a) a description of the procedures by means of which compliance with the applicable essential health and safety requirements set out in Annex II to this Regulation was successfully demonstrated;
- (b) *any* specific requirements regarding the traceability of the PPE concerned;
- (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the *internal* market emergency mode has been activated *in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺;
- (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the PPE concerned;
- (e) measures to be taken █ upon expiry or deactivation of the *internal market emergency mode with respect to* the PPE concerned that has been *placed on the market*.

█

7. By way of derogation from Articles 7, **16** and 17, PPE for which an authorisation has been granted in accordance with paragraph 1 **■** of this Article shall not *bear the CE marking and Article 7* shall not *apply*.
8. The market surveillance authorities of *a* Member State *where* an authorisation pursuant to *paragraphs 1, 2 and 4 of this Article is valid* shall be entitled, with respect to such PPE, to take all corrective and restrictive *actions* at national level provided for *under Regulation (EU) 2019/1020 of the European Parliament and of the Council** and under this Regulation. *They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.*
-
9. **■** The use of the authorisation procedure set out in *paragraphs 1 to 4 of this Article shall* not affect the application on the territory of the Member State concerned of the relevant conformity assessment procedures laid down in Article 19.

Presumption of conformity based on standards and common specifications

1. Where PPE ***has*** been designated as crisis-relevant ***goods***, the Commission is empowered to adopt implementing acts, ***listing appropriate standards or*** establishing 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 published 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/...***⁺⁺, 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.

2. *The implementing acts referred to in paragraph 1 shall set out the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 5. 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, common specifications may be established by those implementing acts.*
3. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 44(3) and shall apply until the last day of the period during which the *internal* market emergency mode is activated, *unless such implementing acts are amended or repealed in accordance with paragraph 7 of this Article.*
4. *Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article have been fulfilled. When preparing that draft implementing act, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.*

5. Without prejudice to Article 14, PPE that *is* in conformity with *the standards or* 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 II that are covered by those *standards*, 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 common specifications referred to in 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* 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* 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** 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 common specification in question.



Article 41e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for PPE listed in the implementing act referred to in Article 41a(1) of this Regulation. **The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.**
2. The market surveillance authorities of the Member States shall **ensure that** best efforts **are made** to provide assistance to other market surveillance authorities during **an internal** market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support, such as the reinforcement of the testing capacity for **PPE** listed in the implementing act referred to in Article 41a(1).

* **Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).**'.

Article 4
Amendments to Regulation (EU) 2016/426

■ Regulation (EU) 2016/426 *is amended as follows:*

(1) *in Article 2, the following points are added:*

‘(32) “*crisis-relevant goods*” means *crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/...of the European Parliament and of the Council*^{*,+};

(33) “*internal market emergency mode*” means *internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...*⁺⁺.

* *Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).*[?];

(2) *the following chapter is inserted:*

‘CHAPTER VA

EMERGENCY PROCEDURES

Article 40a

Application of emergency procedures

1. Articles 40b to 40e *of this Regulation* shall apply only if the Commission has adopted an implementing act pursuant to Article 28 of *Regulation (EU) 2024/...*⁺⁺ with respect to appliances and fittings covered by this Regulation.
2. Articles 40b to 40e of this Regulation shall apply only to appliances and fittings which *have* been designated as crisis-relevant goods *pursuant to Article 18(4) of Regulation (EU) 2024/...*⁺⁺.
3. Articles 40b to 40e of this Regulation shall apply *only* during the *internal* market emergency mode that has been *activated in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺.

However, Article 40c(7) of this Regulation shall apply during the *internal* market emergency mode and after its expiry or deactivation.

4. The Commission *may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements* with respect to appliances and fittings placed on the market or used for the manufacturer's own purposes in accordance with Articles 40c and **40d**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

Article 40b

Prioritisation of the conformity assessment of appliances and fittings designated as crisis-relevant goods

1. This Article applies to all appliances and fittings listed in the implementing act referred to in Article 40a(1) that are subject to the conformity assessment procedures referred to in Article 14 that require the mandatory involvement of a notified body.
2. The notified bodies shall *make best efforts to* process as a matter of priority all applications for a conformity assessment of appliances and fittings referred to in paragraph 1 of this Article, *irrespective of whether those applications have been lodged before or after the activation of the emergency procedures pursuant to Article 40a*.

■

3. The prioritisation of applications for a conformity assessment of appliances and fittings pursuant to paragraph 2 shall not result in *additional disproportionate* costs for the manufacturers who have lodged those applications.
4. The notified bodies shall *make reasonable* efforts to increase their testing capacities for appliances and fittings referred to in paragraph 1 in respect *of* which they have been notified.

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified **body**

1. By way of derogation from Article 14, **a Member State** may authorise, on a duly justified request **from an economic operator**, the placing on the market or use for the manufacturer's own purposes within the territory of that Member State, of a specific appliance or fitting listed in the implementing act referred to in Article 40a(1) and for which the conformity assessment procedures referred to in Article 14 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable essential requirements laid down in **Annex I** has been demonstrated **in accordance with procedures referred to in that authorisation**.
2. **The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1 of this Article. Provided that the requirements set out in the authorisation ensure conformity with the applicable essential requirements laid down in Annex I, the Commission shall adopt, without delay, an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the whole Union and shall set out the conditions under which the specific appliance or fitting may be placed on the market or used for the manufacturer's own purposes. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).**

The appliance or fitting subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market or used for the manufacturer's own purposes as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the content and presentation of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

3. *On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).*
4. *As long as an implementing act as referred to in paragraph 2 or 3 is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of that Member State, and on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of such an implementing act. Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.*
5. Manufacturers of appliances or fittings subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the appliance or *the* fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the █ competent *national* authority.

█

6. Any authorisation issued ■ pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market or used for the manufacturer's own purposes. *Such authorisations shall set out at least the following:*
- (a) a description of the procedures, by means of which compliance with the applicable essential requirements set out in Annex I to this Regulation was successfully demonstrated;
 - (b) *any* specific requirements regarding the traceability of the *appliance or fitting* concerned;
 - (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the *internal* market emergency mode has been activated *in accordance with Article 18 of Regulation (EU) 2024/...*⁺⁺;
 - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the *appliance or fitting* concerned;
 - (e) measures to be taken ■ upon expiry or deactivation of the *internal market emergency mode with respect to* the appliance or fitting concerned that has been *placed on the market or used for the manufacturer's own purposes*.

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7. By way of derogation from Articles 6, **16** and 17, appliances or fittings for which an authorisation has been granted in accordance with paragraph 1 ■ of this Article shall not *bear the CE marking and Article 6* shall not *apply*.
8. The market surveillance authorities of *a* Member State, *where* an authorisation pursuant to *paragraphs 1, 2 and 4 of this Article is valid* shall be entitled, with respect to such appliances or fittings, to take all corrective and restrictive *actions* at national level provided for *under Regulation (EU) 2019/1020 of the European Parliament and of the Council** and under this Regulation. *They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.*
-
9. ■ The use of the authorisation procedure set out in *paragraphs 1 to 4 of this Article shall* not affect the application on the territory of the Member State concerned of the relevant conformity assessment procedures laid down in Article 14.

Article 40d

Presumption of conformity based on standards and common specifications

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 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; 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/...***⁺⁺, 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.

2. *The implementing acts referred to in paragraph 1 shall set out the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 5. 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, common specifications may be established by those implementing acts.*
3. The implementing acts referred to in paragraph 1 ■ of this Article shall be adopted ■ in accordance with the examination procedure referred to in Article 42(3) **and** shall apply ■ until the last day of the period during which the *internal* market emergency mode is activated, **unless such implementing acts are amended or repealed in accordance with paragraph 7** of this Article ■ .
4. *Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article have been fulfilled. When preparing that draft implementing act, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.*

5. Without prejudice to Article 13, appliances or fittings that are in conformity with *the standards or* 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*, 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 common specifications referred to in 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* 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* 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** 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 common specification in question.

■

Article 40e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. **■** Member States shall prioritise the market surveillance activities for **appliances** and fittings listed in the implementing act referred to in Article 40a(1) of this Regulation. ***The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.***
2. The market surveillance authorities of the Member States shall **ensure that** best efforts **are made** to provide assistance to other market surveillance authorities during **an internal** market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support, such as the reinforcement of the testing capacity for appliances and fittings listed in the implementing act referred to in Article 40a(1).

* ***Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).***

Article 5

Amendments to Regulation (EU) 2023/988

Regulation (EU) 2023/988 is amended as follows:

(1) *in Article 2(1), third subparagraph, point (b) is replaced by the following:*

‘(b) Chapter IIa, Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.’;

(2) *in Article 3, the following points are added:*

‘(29) “crisis-relevant goods” means crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/... of the European Parliament and of the Council^{+};*

(30) “internal market emergency mode” means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...⁺⁺.

^{*} *Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).’;*

(3) *the following chapter is inserted:*

‘CHAPTER IIA

EMERGENCY PROCEDURES

Article 8a

Application of emergency procedures

- 1. Articles 8b and 8c of this Regulation shall apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...⁺⁺ with respect to products covered by this Regulation.***
- 2. Articles 8b and 8c of this Regulation shall apply only to products covered by this Regulation which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...⁺⁺.***
- 3. Articles 8b and 8c of this Regulation shall apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...⁺⁺.***

Article 8b

Presumption of conformity with the general safety requirement in the context of an internal market emergency

- 1. In addition to the presumption of conformity laid down in Article 7 of this Regulation, where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 18 of Regulation (EU) 2024/...⁺⁺, significantly restrict the possibilities for manufacturers to make use of relevant European standards the references of which have already been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the presumption of conformity with the general safety requirement laid down in Article 5 may also be established for the purpose of placing products on the market if the product conforms to national requirements as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which the product is made available on the market, provided that such law is in compliance with Union law.*

2. *In addition to the cases where the presumption of conformity with the general safety requirement laid down in Article 5 of this Regulation applies under paragraph 1 of this Article and Article 7(1) of this Regulation, Member States shall take all appropriate measures to ensure that, for the purpose of placing or making available of products on the market, their competent authorities consider that products which comply with relevant European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012, with relevant international standards developed by a recognised international standardisation body as defined in Article 2(9) of Regulation (EU) No 1025/2012, or with relevant national standards developed by a national standardisation body as defined in Article 2(10) of Regulation (EU) No 1025/2012, are presumed to meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those standards are concerned, unless such standards are not adequate in view of the other elements of Articles 6 and 8 of this Regulation.*
3. *Article 7(3) applies to the presumption of conformity established in accordance with this Article.*



Article 8c

Prioritisation of market surveillance activities and mutual assistance among authorities

1. *Member States shall prioritise market surveillance activities for products covered by this Regulation that are listed in the implementing act referred to in Article 8a(1).*
2. *The market surveillance authorities of the Member States shall ensure that best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency mode.’*

Article 6
Amendments to Regulation (EU) 2023/1230

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

(1) in Article 3, the following points are added:

‘(37) “crisis-relevant goods” means crisis-relevant goods as defined in Article 3, point (6), of Regulation (EU) 2024/... of the European Parliament and of the Council^{*+};

(38) “internal market emergency mode” means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...⁺⁺.

^{*} **Regulation (EU) 2024/... of the European Parliament and of the Council of ... establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, ..., ELI: ...).’;**

(2) *the following chapter is inserted:*

**‘CHAPTER IVA
EMERGENCY PROCEDURES**

Article 25a

Application of emergency procedures

- 1. Articles 25b to 25e of this Regulation shall apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...⁺⁺ with respect to machinery and related products covered by this Regulation.***
- 2. Articles 25b to 25e of this Regulation shall apply only to machinery and related products which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...⁺⁺.***
- 3. Articles 25b to 25e of this Regulation shall apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...⁺⁺.***

However, Article 25c(7) of this Regulation shall apply during the internal market emergency mode and after its expiry or deactivation.

4. *The Commission may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements with respect to machinery and related products placed on the market or put into service in accordance with Articles 25c and 25d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).*

Article 25b

Prioritisation of the conformity assessment of machinery and related products designated as crisis-relevant goods

1. *This Article applies to all types of machinery and related products listed in the implementing act referred to in Article 25a(1) that are subject to the conformity assessment procedures referred to in Article 25 that require the mandatory involvement of a notified body.*
2. *The notified bodies shall make best efforts to process as a matter of priority all applications for a conformity assessment of machinery and related products referred to in paragraph 1 of this Article, irrespective of whether those applications have been lodged before or after the activation of the emergency procedures pursuant to Article 25a.*

3. *The prioritisation of applications for a conformity assessment of machinery and related products pursuant to paragraph 2 shall not result in additional disproportionate additional costs for the manufacturers, who have lodged those applications.*
4. *The notified bodies shall make reasonable efforts to increase their testing capacities for machinery and related products referred to in paragraph 1 in respect of which they have been notified.*

Article 25c

Derogation from conformity assessment procedures requiring the mandatory involvement of a notified body

1. *By way of derogation from Article 25, a Member State may authorise, on a duly justified request from an economic operator, the placing on the market or putting into service within the territory of that Member State, of specific machinery or related products listed in the implementing act referred to in Article 25a(1) and for which the conformity assessment procedures referred to in Article 25 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable essential health and safety requirements set out in Annex III has been demonstrated in accordance with procedures referred to in that authorisation.*

2. *The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1 of this Article. Provided that the requirements set out in the authorisation ensure conformity with the applicable essential health and safety requirements laid down in Annex III, the Commission shall adopt, without delay, an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the whole Union and shall set out the conditions under which the specific machinery or related products may be placed on the market or put into service. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).*

The machinery or related products subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market or put into service as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the content and presentation of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

3. *On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 48(4).*
4. *As long as an implementing act as referred to in paragraph 2 or 3 is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of that Member State, and on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of such an implementing act.*

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.
5. *Manufacturers of machinery or of related products subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the machinery or the related products concerned comply with all the applicable essential health and safety requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.*

6. *Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery or the related products may be placed on the market or put into service. Such authorisations shall set out at least the following:*
- (a) a description of the procedures by means of which compliance with the applicable essential health and safety requirements set out in Annex III to this Regulation was successfully demonstrated;*
 - (b) any specific requirements regarding the traceability of the machinery and the related products concerned;*
 - (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the internal market emergency mode has been activated in accordance with Article 18 of Regulation (EU) 2024/...⁺⁺;*
 - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the machinery and the related products concerned;*
 - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the machinery or the related products concerned that have been placed on the market or put into service.*
7. *By way of derogation from Articles 4, 23 and 24, machinery or related products for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the CE marking and Article 4 shall not apply.*

8. *The market surveillance authorities of a Member State where an authorisation pursuant to paragraphs 1, 2 and 4 of this Article is valid shall be entitled, with respect to such machinery and related products, to take all corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation. They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.*
9. *The use of the authorisation procedure set out in paragraphs 1 to 4 of this Article shall not affect the application on the territory of the Member State concerned of the relevant conformity assessment procedures laid down in Article 25.*

Article 25d

Presumption of conformity based on standards and common specifications

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 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; 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/...⁺⁺, 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.*
2. *The implementing acts referred to in paragraph 1 shall set out the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 5. 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, common specifications may be established by those implementing acts.*
3. *The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 48(3) and shall apply until the last day of the period during which the internal market emergency mode is activated, unless such implementing acts are amended or repealed in accordance with paragraph 7 of this Article.*

4. *Before preparing the draft implementing act referred to in paragraph 1 of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 of this Article have been fulfilled. When preparing that draft implementing act, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.*
5. *Without prejudice to Article 20, machinery and related products that are in conformity with the standards or 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, 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 common specifications referred to in 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 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 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 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 common specification in question.*

Article 25e

Prioritisation of market surveillance activities and mutual assistance among authorities

- 1. The Member States shall prioritise the market surveillance activities for machinery and related products listed in the implementing act referred to in Article 25a(1) of this Regulation. The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.*
- 2. The market surveillance authorities of the Member States shall ensure that best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support, such as the reinforcement of the testing capacity for machinery and the related products listed in the implementing act referred to in Article 25a(1).’*

Article 7

Entry into force

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

It shall apply from ... [*date of application of the Regulation contained in document PE-CONS No 46/24 (2022/0278(COD))*].

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

Done at ...,

For the European Parliament
The President

For the Council
The President
