

### **EUROPEAN UNION**

### THE EUROPEAN PARLIAMENT

THE COUNCIL

Brussels, 18 September 2024

(OR. en)

2022/0280(COD) PE-CONS 48/24

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### LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency

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# DIRECTIVE (EU) 2024/... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU 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 Articles 91 and 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure<sup>3</sup>,

OJ C 100, 16.3.2023, p. 95.

OJ C 157, 3.5.2023, p. 82.

Position of the European Parliament of 24 April 2024 (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<sup>4+</sup> 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/...<sup>++</sup> 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.

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 46/24 (2022/0278(COD)) and insert the number, date and OJ reference and ELI reference of that Regulation in the footnote.

OJ: please insert in the text the number of the Regulation contained in document PE-CONS 46/24(2022/0278(COD)).

- (3) Regulation (EU) 2024/...<sup>++</sup> 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/...<sup>++</sup>, 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.

(5) A number of sectorial Union legal acts lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of certain products. Such legal acts include Directives 2000/14/EC<sup>5</sup>, 2006/42/EC<sup>6</sup>, 2010/35/EU<sup>7</sup>, 2014/29/EU<sup>8</sup>, 2014/30/EU<sup>9</sup>, 2014/33/EU<sup>10</sup>, 2014/34/EU<sup>11</sup>, 2014/35/EU<sup>12</sup>, 2014/53/EU<sup>13</sup> and 2014/68/EU<sup>14</sup> of the European Parliament and of the Council (the 'amended Directives'). Moreover, most of those legal acts are based on the principles of the new approach to technical harmonisation and are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council<sup>15</sup>.

Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1).

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).

Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309).

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).

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).

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- (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 Directives, 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/...<sup>++</sup> and which are covered by the amended Directives.
- (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/...<sup>++</sup>.

In order to overcome the potential effects of disruptions to the functioning of the internal market in the event of a crisis and to ensure that during an internal market emergency mode harmonised 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, the conformity assessment bodies notified under the amended Directives should be encouraged to increase their testing capacities for products designated as crisis-relevant goods in respect of which they have been notified.

(8)

- (9) Emergency procedures should be laid down in Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU. Those procedures should become applicable only following the activation of the internal market emergency mode and only when a specific good covered by those Directives is designated as a crisis-relevant good in accordance with Regulation (EU) 2024/...<sup>++</sup> and the Commission has adopted an implementing act activating those procedures in accordance with that Regulation.
- (10) 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.

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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 Directives, 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.

Given that the essential safety requirements harmonised by the amended Directives will (12)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 Directives, this Directive continues to improve the conditions for the functioning of the internal market. This Directive takes into account both the context constituted by the fully harmonised rules stemming from the existing Directives and the complementary rules stemming from amendments that this Directive 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 Directives. 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 Directive 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 would 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.

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(13)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.

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The validity of all authorisations, issued during an active internal market emergency mode (14)in accordance with the emergency procedures established by this Directive, 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 Directives and Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>16</sup>. 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.

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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).

(15) 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.

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- All authorisations for the placing on the market of crisis-relevant goods issued by Member (16)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.
- (17) 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.

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(18) 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. 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.

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(19)With respect to Directives 2006/42/EC, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU, 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 applicable essential requirements. Products placed on the market on the basis of the presumption of conformity established via the emergency mechanism established by this Directive 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.

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(20)Furthermore, with respect to Directives 2006/42/EC, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU, 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.

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- (21) In order to ensure that the level of safety provided by the 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.
- In accordance with the relevant provisions of the amended Directives, Member States should lay down rules on penalties applicable to infringements of national provisions adopted pursuant to those Directives, including pursuant to the new provisions introduced by this Directive, 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.
- (23) In accordance with its established practice, the Commission should systematically consult the relevant sectorial stakeholders in the context of the early stages of preparation of all draft implementing acts laying down common specifications.
- (24) Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

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# Article 1 Amendments to Directive 2000/14/EC

Directive 2000/14/EC is amended as follows:

- (1) in Article 3, the following points are added:
  - '(g) "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\*+;
  - (h) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

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<sup>\*</sup> 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 articles are inserted:

'Article 17a

Application of emergency procedures

- 1 Member States shall ensure that measures taken to transpose Articles 17b, 17c and 17d of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/... ++ with respect to equipment covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 17b, 17c and 17d of this Directive apply only to equipment referred to in Article 2(1) of this Directive which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 17b, 17c and 17d of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 17c(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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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 equipment referred to in Article 2(1) and placed on the market or put into service in accordance with Article 17c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 18(2).

### Article 17b

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

- 1. This Article applies to equipment listed in the implementing act referred to in Article 17a(1) that is 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 equipment 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 17a.
- 3. The prioritisation of applications for a conformity assessment of equipment pursuant to paragraph 2 shall not result in additional disproportionate costs for the manufacturers who have lodged those applications.

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4. The notified bodies shall make reasonable efforts to increase their testing capacities for equipment referred to in paragraph 1 in respect of which they have been notified.

Article 17c

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 putting into service within the territory of that Member State, of specific equipment referred to in Article 12 and listed in the implementing act referred to in Article 17a(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 requirements laid down in this Directive concerning noise emission in the environment has been demonstrated in accordance with procedures referred to in that authorisation.

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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 requirements laid down in this Directive concerning noise emission in the environment, 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 equipment 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 18(2).

The equipment 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.

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- 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 18(3).
- 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 equipment subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the equipment concerned complies with all the applicable requirements set out in this Directive concerning noise emission in the environment and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.

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- 6. Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the equipment 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 requirements of this Directive concerning noise emission in the environment was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the equipment 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the equipment concerned;
  - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the equipment concerned that has been placed on the market or put into service.

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- 7. By way of derogation from Articles 6 and 11, equipment 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 equipment, 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 Directive. 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 17d

Prioritisation of market surveillance activities and mutual assistance among authorities

 Member States shall prioritise the market surveillance activities for equipment listed in the implementing act referred to in Article 17a(1) of this Directive. The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.

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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 equipment listed in the implementing act referred to in Article 17a(1).

(3) Article 18 is replaced by the following:

'Article 18

Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council\*.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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<sup>\*</sup> 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. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

# Article 2 Amendments to Directive 2006/42/EC

Directive 2006/42/EC is amended as follows:

- (1) in Article 2, second paragraph, the following points are added:
  - '(n) "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\*+;
  - (o) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...\*+.

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COMPET.1 EN

<sup>\*</sup> 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).'.

<sup>\*</sup> 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 articles are inserted:

'Article 21b

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 21c to 21f of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to machinery covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 21c to 21f of this Directive apply only to machinery which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 21c to 21f of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 21d(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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COMPET.1 EN

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 placed on the market or put into service in accordance with Articles 21d and 21e. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(3).

#### Article 21c

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

- 1. This Article applies to machinery listed in the implementing act referred to in Article 21b(1) that is subject to the conformity assessment procedures referred to in Article 12 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 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 21b.
- 3. The prioritisation of applications for a conformity assessment of machinery 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 machinery referred to in paragraph 1 in respect of which they have been notified.

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COMPET.1 EN

### Article 21d

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

1. By way of derogation from Article 12, 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 listed in the implementing act referred to in Article 21b(1) and for which the conformity assessment procedures referred to in Article 12 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 this Directive has been demonstrated in accordance with procedures referred to in that authorisation.

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COMPET.1 EN

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 the conformity with the applicable essential health and safety requirements set out 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 machinery 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 22(3).

The machinery subject to the extension of validity referred to in the first subparagraph shall bear the information that it is 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.

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COMPET.1 EN

- 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 22(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 subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the machinery concerned complies with all the applicable essential health and safety 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 machinery may be placed on the market or put into service. Such authorisations shall set out at least the following:
  - a description of the procedures, by means of which compliance with the applicable essential health and safety requirements set out in Annex I to this Directive was successfully demonstrated;

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- (b) any specific requirements regarding the traceability of the machinery 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/...<sup>++</sup>;
- (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the machinery concerned;
- (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the machinery concerned that has been placed on the market or put into service.
- 7. By way of derogation from Articles 6 and 16, machinery 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 machinery, 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 Directive. They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

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COMPET.1 EN

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 12.

## Article 21e

Presumption of conformity based on standards and common specifications

- 1. Where machinery has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such machinery to cover the relevant essential health and safety requirements set out in Annex I to this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive 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

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COMPET.1 EN

- (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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the relevant essential health and safety requirements set out in Annex I to this Directive 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 22(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.

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COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.
- 5. Without prejudice to Article 7, machinery 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 relevant essential health and safety 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.

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- 6. By way of derogation from Article 21b(3), first subparagraph, unless there is sufficient reason to believe that the machinery 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 machinery that is in conformity with those standards or common specifications and which has been placed on the market or put into service shall be deemed to be in conformity with the relevant essential health and safety 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 relevant essential health and safety 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.

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## Article 21f

Prioritisation of market surveillance activities and mutual assistance among authorities

- 1. Member States shall prioritise the market surveillance activities for machinery listed in the implementing act referred to in Article 21b(1) of this Directive. 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 listed in the implementing act referred to in Article 21b(1).

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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).

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).';

- in Article 22, the following paragraph is added:
  - '4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.'.

# Article 3 Amendments to Directive 2010/35/EU

Directive 2010/35/EU is amended as follows:

- (1) in Article 2, the following points are added:
  - '(27) "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\*+;
  - (28) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...\*+.

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COMPET.1 EN

<sup>\*</sup> 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 5a

## **Emergency procedures**

Article 33a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to transportable pressure equipment covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d of this Directive apply only to transportable pressure equipment which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 33c(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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COMPET.1 EN

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 transportable pressure equipment placed on the market in accordance with Article 33c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38a(2).

## Article 33b

Prioritisation of the conformity assessment of transportable pressure equipment designated as crisis-relevant goods

- 1. This Article applies to transportable pressure equipment listed in the implementing act referred to in Article 33a(1) that is subject to the conformity assessment procedures referred to in Article 12 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 transportable pressure equipment 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 33a.
- 3. The prioritisation of applications for a conformity assessment of transportable pressure equipment pursuant to paragraph 2 shall not result in additional disproportionate costs for the manufacturers who have lodged those applications.

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COMPET.1 FN

4. The notified bodies shall make reasonable efforts to increase their testing capacities for transportable pressure equipment referred to in paragraph 1 in respect of which they have been notified.

# Article 33c

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

1. By way of derogation from Article 12, 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 transportable pressure equipment listed in the implementing act referred to in Article 33a(1) and for which the conformity assessment procedures referred to in Article 12 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive has been demonstrated in accordance with procedures referred to in that authorisation.

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COMPET.1 EN

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 requirements set out in the Annexes to Directive 2008/68/EC and in this Directive, 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 transportable pressure equipment 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 38a(2) of this Directive.

The transportable pressure equipment 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 endusers, as determined by the Member State concerned.

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COMPET.1 EN

- 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 38a(3).
- 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 and importers of transportable pressure equipment subject to the authorisation procedure referred to in paragraph 1 of this Article shall declare on their sole responsibility that the transportable pressure equipment concerned complies with all the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.

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COMPET.1 EN

- 6. Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the transportable pressure equipment 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 the compliance with the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the transportable pressure equipment 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the transportable pressure equipment concerned;
  - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the transportable pressure equipment concerned that has been placed on the market.

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COMPET.1 EN

- 7. By way of derogation from Articles 14 and 16, transportable pressure equipment for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the Pi marking and Article 16 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 transportable pressure equipment, 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 Directive. 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 33d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for transportable pressure equipment listed in the implementing act referred to in Article 33a(1) of this Directive. The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.

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COMPET.1 EN

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 transportable pressure equipment listed in the implementing act referred to in Article 33a(1).

(3) the following article is inserted:

'Article 38a

Committee procedure

1. The Commission shall be assisted by the committee on the transport of dangerous goods established by Article 9 of Directive 2008/68/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council\*.

PE-CONS 48/24 GG/RC/cc 48
COMPET.1 EN

<sup>\*</sup> 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).';

- 2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- Where reference is made to this paragraph, Article 8 of Regulation 3. (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

# Article 4 Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

- (1) in Article 2, the following points are added:
  - '(18) "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\*+;

PE-CONS 48/24 GG/RC/cc

COMPET.1 EN

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).'.

(19) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

(2) the following chapter is inserted:

# 'Chapter 5a

## **Emergency procedures**

Article 38a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to vessels covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only to vessels which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.

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COMPET.1 EN

<sup>\*</sup> 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. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 38c(7) of this Directive 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 vessels placed on the market in accordance with Articles 38c and 38d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 39(3).

#### Article 38b

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

- 1. This Article applies to vessels listed in the implementing act referred to in Article 38a(1) that are subject to the conformity assessment procedures referred to in Article 13 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 vessels 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 38a.

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COMPET.1 EN

- 3. The prioritisation of applications for a conformity assessment of vessels 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 vessels referred to in paragraph 1 in respect of which they have been notified.

Article 38c

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

1. By way of derogation from Article 13, 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 vessels listed in the implementing act referred to in Article 38a(1) and for which the conformity assessment procedures referred to in Article 13 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the applicable essential safety requirements of this Directive has been demonstrated in accordance with procedures referred to in that authorisation.

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COMPET.1 EN

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 safety requirements of this Directive, 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 vessel 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 39(3).

The vessel 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.

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COMPET.1 EN

- 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 39(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 vessels subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the vessels concerned comply with all the applicable essential safety requirements of this Directive and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.

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COMPET.1 EN

- 6. Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the vessel 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 the compliance with the applicable essential safety requirements of this Directive was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the vessel 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the vessel concerned;
  - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the vessel concerned that has been placed on the market.
- 7. By way of derogation from Articles 5, 15 and 16, vessels for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the CE marking and the inscriptions provided for in point 1 of Annex III and Article 5 shall not apply.

PE-CONS 48/24 GG/RC/cc 55
COMPET.1 EN

- 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 vessels, 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 Directive. 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 13.

## Article 38d

*Presumption of conformity based on standards and common specifications* 

- 1. Where vessels have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such vessels to cover the essential safety requirements of this Directive in either of the following cases:
  - (a) where a reference to harmonised standards covering the essential safety requirements of this Directive 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

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COMPET.1 EN

- (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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the essential safety requirements of this Directive 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 39(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.

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COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.
- 5. Without prejudice to Article 12, vessels 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 essential safety requirements of this Directive 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.

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COMPET.1 EN

- 6. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the vessels 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 vessels 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 essential safety requirements of this Directive 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 essential safety requirements of this Directive, 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 38e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for vessels listed in the implementing act referred to in Article 38a(1) of this Directive. The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.

PE-CONS 48/24 GG/RC/cc 59
COMPET.1 FN

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 vessels listed in the implementing act referred to in Article 38a(1).

# Article 5 Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

- **(1)** in Article 3(1), the following points are added:
  - '(26) "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\*+;

PE-CONS 48/24 GG/RC/cc 60 COMPET.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).'.

(27) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

the following chapter is inserted: (2)

# 'Chapter 5a

# **Emergency procedures**

Article 40a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 40b and 40c of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to apparatus covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 40b and 40c of this Directive apply only to apparatus which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...++.

PE-CONS 48/24 GG/RC/cc 61 COMPET.1

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. Member States shall ensure that measures taken to transpose Articles 40b and 40c of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
- 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 apparatus placed on the market in accordance with Article 40b. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2a).

## Article 40b

Presumption of conformity based on standards and common specifications

- 1. Where apparatus has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such apparatus to cover the essential requirements set out in Annex I to this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the essential requirements set out in Annex I to this Directive 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

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COMPET.1 EN

- (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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the essential requirements set out in Annex I to this Directive 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 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 41(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.

PE-CONS 48/24 GG/RC/cc 63

COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.
- or common specifications referred to in paragraph 1 of this Article, or parts thereof, shall be presumed to be in conformity with the 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.

PE-CONS 48/24 GG/RC/cc 64

COMPET.1 EN

- 6. By way of derogation from Article 40a(3), unless there is sufficient reason to believe that the apparatus 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 apparatus 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 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 referred to in paragraph 1 does not entirely satisfy the 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 40c

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for apparatus listed in the implementing act referred to in Article 40a(1) of this Directive. 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\*.

PE-CONS 48/24 GG/RC/cc 65
COMPET.1 EN

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 apparatus listed in the implementing act referred to in Article 40a(1).

- (3) in Article 41, the following paragraph is inserted:
  - '2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.'.

PE-CONS 48/24 GG/RC/cc 66 COMPET.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 6 Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

- (1) in Article 2, the following points are added:
  - '(22) "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\*+;
  - (23) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

PE-CONS 48/24 GG/RC/cc 67
COMPET.1 EN

<sup>\*</sup> 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 41a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 41b to 41e of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to lifts and safety components for lifts covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 41b to 41e of this Directive apply only to lifts and safety components for lifts which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 41b to 41e of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 41c(8) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

PE-CONS 48/24 GG/RC/cc 68

COMPET.1 EN

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 lifts and safety components for lifts 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 42(3).

## Article 41b

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

- 1. This Article applies to all lifts and safety components for lifts listed in the implementing act referred to in Article 41a(1) that are subject to the conformity assessment procedures referred to in Articles 15 and 16 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 lifts and safety components for lifts 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.

PE-CONS 48/24 GG/RC/cc 69
COMPET.1 EN

- 3. The prioritisation of applications for a conformity assessment of lifts and safety components for lifts pursuant to paragraph 2 shall not result in additional disproportionate costs for the installers and manufacturers who have lodged those applications.
- 4. The notified bodies shall make reasonable efforts to increase their testing capacities for lifts and safety components for lifts 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 15, 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 a specific safety component for lifts listed in the implementing act referred to in Article 41a(1) and for which the conformity assessment procedures referred to in Article 15 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 this Directive has been demonstrated in accordance with procedures referred to in that authorisation.

PE-CONS 48/24 GG/RC/cc 70
COMPET.1 EN

- 2 By way of derogation from Article 16, 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 a specific lift listed in the implementing act referred to in Article 41a(1) and for which the conformity assessment procedures referred to in Article 16 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 this Directive has been demonstrated in accordance with procedures referred to in that authorisation.
- 3. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1 or 2 of this Article. Provided that the requirements set out in the authorisation ensure conformity with the applicable essential health and safety requirements set out 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 or 2 of this Article to the territory of the whole Union and shall set out the conditions under which the specific lift or safety component for lifts 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 or 2 of this Article. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).

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The lifts or the safety components for lifts subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market as "crisis-relevant goods". 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.

- 4. 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).
- 5. As long as an implementing act as referred to in paragraph 3 or 4 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.

PE-CONS 48/24 GG/RC/cc 72
COMPET.1 EN

- 6. Installers of lifts or manufacturers of safety components for lifts subject to the authorisation procedure referred to in paragraph 1 or 2 shall declare on their sole responsibility that the lifts or safety components for lifts concerned comply with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.
- 7. Any authorisation issued pursuant to paragraph 1 or 2 shall set out the conditions and requirements under which the lift or safety component for lifts 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 the compliance with the applicable essential health and safety requirements set out in Annex I to this Directive was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the lift or safety component for lifts 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the lifts or safety components for lifts concerned;

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COMPET.1 EN

- (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the lifts or safety components for lifts concerned that have been placed on the market.
- 8. By way of derogation from Articles 3, 18 and 19, lifts or safety components for lifts for which an authorisation has been granted in accordance with paragraph 1 or 2 of this Article shall not bear the CE marking and Article 3 shall not apply.
- 9. The market surveillance authorities of a Member State where an authorisation pursuant to paragraphs 1, 2, 3 and 5 of this Article is valid shall be entitled, with respect to such lifts or safety components for lifts, 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 Directive. They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.
- 10. The use of the authorisation procedure set out in paragraphs 1 to 5 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 Articles 15 and 16.

PE-CONS 48/24 GG/RC/cc 74
COMPET.1 EN

#### Article 41d

Presumption of conformity based on standards and common specifications

- 1. Where lifts and safety components for lifts have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such lifts and safety components for lifts to cover the applicable essential health and safety requirements set out in Annex I to this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the applicable essential health and safety requirements set out in Annex I to this Directive 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/...<sup>++</sup>, significantly restrict the possibilities of installers or manufacturers to make use of the harmonised standards that cover the applicable essential health and safety requirements set out in Annex I to this Directive 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.

PE-CONS 48/24 GG/RC/cc 75
COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.

PE-CONS 48/24 GG/RC/cc 76
COMPET.1 EN

- 5. Without prejudice to Article 14, lifts and safety components for lifts 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 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 installers and 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 lifts and safety components for lifts 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 lifts and safety components for lifts 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 health and safety 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.

PE-CONS 48/24 GG/RC/cc 77
COMPET.1 FN

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 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 41e

Prioritisation of market surveillance activities and mutual assistance among authorities

- 1. Member States shall prioritise the market surveillance activities for lifts and safety components for lifts listed in the implementing act referred to in Article 41a(1) of this Directive. 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 lifts and safety components for lifts listed in the implementing act referred to in Article 41a(1).

PE-CONS 48/24 GG/RC/cc 78
COMPET.1 EN

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 7 Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

- **(1)** in Article 2, the following points are added:
  - '(27) "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\*+;
  - (28) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

PE-CONS 48/24 GG/RC/cc COMPET.1

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 5a

## **Emergency procedures**

Article 38a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to products covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only to products which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 38b to 38e of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 38c(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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COMPET.1 EN

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 products placed on the market or used for the manufacturer's own purposes in accordance with Articles 38c and 38d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 39(3).

#### Article 38b

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

- 1. This Article applies to all products listed in the implementing act referred to in Article 38a(1) that are subject to the conformity assessment procedures referred to in Article 13 that require 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 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 38a.
- 3. The prioritisation of applications for a conformity assessment of products pursuant to paragraph 2 shall not result in additional disproportionate costs for the manufacturers who have lodged those applications.

PE-CONS 48/24 GG/RC/cc 81
COMPET.1

4. The notified bodies shall make reasonable efforts to increase their testing capacities for products referred to in paragraph 1 in respect of which they have been notified.

Article 38c

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

1. By way of derogation from Article 13, 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 product which has been listed in the implementing act referred to in Article 38a(1) and for which the conformity assessment procedures referred to in Article 13 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 II has been demonstrated in accordance with procedures referred to in that authorisation.

PE-CONS 48/24 GG/RC/cc 82

COMPET.1 EN

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 set out 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 product 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 39(3).

The product 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.

PE-CONS 48/24 GG/RC/cc 83
COMPET.1 EN

- 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 39(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 products subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the product 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 product may be placed on the market or used for the manufacturer's own purposes. Such authorisations shall set out at least the following:
  - 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 Directive was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the product 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the product concerned;
  - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the products concerned that have been placed on the market or used for the manufacturer's own purposes.
- 7. By way of derogation from Articles 5, 15 and 16, products for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the CE marking and Article 5 shall not apply.

PE-CONS 48/24 GG/RC/cc 85
COMPET.1 EN

- 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 products, 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 Directive. 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 13.

Article 38d

Presumption of conformity based on standards and common specifications

- 1. Where 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 products to cover the applicable essential health and safety requirements set out in Annex II to this Directive 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 Directive 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

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COMPET.1 EN

- (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/...<sup>++</sup>, 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 Directive 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 39(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.

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COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.
- 5. Without prejudice to Article 17, 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 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.

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EN

- 6. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the 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 products 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 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 38e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for products listed in the implementing act referred to in Article 38a(1) of this Directive. The Commission shall facilitate coordination of such prioritisation efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.

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COMPET.1 **FN** 

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 products listed in the implementing act referred to in Article 38a(1).

# Article 8 Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

- (1) in Article 2, the following points are added:
  - '(15) "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\*+;
  - (16) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...\*+.

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COMPET.1 EN

<sup>\*</sup> 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).'

- 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 4a

# **Emergency procedures**

Article 22a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 22b and 22c of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to electrical equipment covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 22b and 22c of this Directive apply only to electrical equipment which has been designated as crisisrelevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...++.
- 3. Member States shall ensure that measures taken to transpose Articles 22b and 22c of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...++.

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COMPET.1 EN 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 electrical equipment placed on the market in accordance with Article 22c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

#### Article 22b

Presumption of conformity based on standards and common specifications

- 1. Where electrical equipment has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such electrical equipment to cover the safety objectives referred to in Article 3 of this Directive and set out in Annex I to this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the safety objectives referred to in Article 3 of this Directive and set out in Annex I to this Directive 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

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COMPET.1 EN

- (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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the safety objectives referred to in Article 3 of this Directive and set out in Annex I to this Directive 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 23(2) 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.

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COMPET.1 EN

- 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 Directive and shall duly consult all relevant stakeholders.
- 5. Without prejudice to Articles 12, 13 and 14, electrical equipment that is in conformity with the standards or common specifications referred to in paragraph 1 this Article, or parts thereof, shall be presumed to be in conformity with the safety objectives referred to in Article 3 and 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.

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EN

- 6. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that electrical equipment 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 electrical equipment 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 safety objectives referred to in Article 3 and 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 referred to in paragraph 1 does not entirely satisfy the safety objectives referred to in Article 3 and 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.

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EN

#### Article 22c

Prioritisation of market surveillance activities and mutual assistance among authorities

- 1. Member States shall prioritise the market surveillance activities for electrical equipment listed in the implementing act referred to in Article 22a(1) of this Directive. 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 electrical equipment listed in the implementing act referred to in Article 22a(1).

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COMPET.1 EN

<sup>\*</sup> 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 9 Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

- (1) in Article 2(1), the following points are added:
  - '(27) "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\*+;
  - (28) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

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EN

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. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to radio equipment covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only to radio equipment which has been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 43c(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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COMPET.1 EN

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 radio equipment placed on the market in accordance with Articles 43c and 43d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

#### Article 43b

Prioritisation of the conformity assessment of radio equipment designated as crisisrelevant goods

- 1. This Article applies to radio equipment listed in the implementing act referred to in Article 43a(1) that is subject to the conformity assessment procedures referred to in Article 17 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 radio equipment 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 radio equipment pursuant to paragraph 2 shall not result in additional disproportionate costs for the manufacturers who have lodged those applications.

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COMPET.1

4. The notified bodies shall make reasonable efforts to increase their testing capacities for radio equipment referred to in paragraph 1 in respect of which they have been notified.

## Article 43c

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

1. By way of derogation from Article 17, 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 radio equipment listed in the implementing act referred to in Article 43a(1) and for which the conformity assessment procedures referred to in Article 17 that require the mandatory involvement of a notified body have not been carried out but for which the compliance with all the relevant essential requirements set out in Article 3 has been demonstrated in accordance with procedures referred to in that authorisation.

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COMPET.1 EN

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 relevant essential requirements set out in Article 3, 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 radio equipment 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 45(3).

The radio equipment 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.

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COMPET.1 FN

- 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 45(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 radio equipment subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the radio equipment concerned complies with all the relevant essential requirements set out in Article 3 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 radio equipment may be placed on the market. Such authorisations shall set out at least the following:
  - a description of the procedures, by means of which compliance with the relevant essential requirements set out in Article 3 of this Directive was successfully demonstrated;

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COMPET.1 EN

- (b) any specific requirements regarding the traceability of the radio equipment 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 Regulation (EU) 2024/...<sup>++</sup>;
- (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the radio equipment concerned;
- (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the radio equipment concerned that has been placed on the market.
- 7. By way of derogation from Articles 9, 19 and 20, radio equipment for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the CE marking and Article 9 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 radio equipment, 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 Directive. They shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

PE-CONS 48/24 GG/RC/cc 103
COMPET.1

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 17.

#### Article 43d

Presumption of conformity based on standards and common specifications

- 1. Where radio equipment has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such radio equipment to cover the relevant essential requirements set out in Article 3 of this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the relevant essential requirements set out in Article 3 of this Directive 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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the relevant essential requirements set out in Article 3 of this Directive 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.

PE-CONS 48/24 GG/RC/cc 104
COMPET.1 EN

- 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 45(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 Directive and shall duly consult all relevant stakeholders.

PE-CONS 48/24 GG/RC/cc 105
COMPET.1 EN

- 5. Without prejudice to Article 16, radio equipment 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 relevant essential requirements set out in Article 3 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 radio equipment 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 radio equipment 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 relevant essential requirements set out in Article 3 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.

PE-CONS 48/24 GG/RC/cc 106
COMPET.1 EN

7. When a Member State considers that a standard or common specification as referred to in paragraph 1 of this Article does not entirely satisfy the relevant essential requirements set out in Article 3, 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 radio equipment listed in the implementing act referred to in Article 43a(1) of this Directive. 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 radio equipment listed in the implementing act referred to in Article 43a(1).

PE-CONS 48/24 GG/RC/cc 107
COMPET.1 EN

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 10 Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

- (1) in Article 2, the following points are added:
  - '(33) "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\*+;
  - (34) "internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3), of Regulation (EU) 2024/...<sup>++</sup>.

PE-CONS 48/24 GG/RC/cc 108 COMPET.1 EN

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 5a

### **Emergency procedures**

Article 43a

Application of emergency procedures

- 1. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only if the Commission has adopted an implementing act pursuant to Article 28 of Regulation (EU) 2024/...<sup>++</sup> with respect to pressure equipment and assemblies covered by this Directive.
- 2. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only to pressure equipment and assemblies which have been designated as crisis-relevant goods pursuant to Article 18(4) of Regulation (EU) 2024/...<sup>++</sup>.
- 3. Member States shall ensure that measures taken to transpose Articles 43b to 43e of this Directive apply only during the internal market emergency mode that has been activated in accordance with Article 18 of Regulation (EU) 2024/...<sup>++</sup>.
  - However, Article 43c(7) of this Directive shall apply during the internal market emergency mode and after its expiry or deactivation.

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COMPET.1 EN

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 pressure equipment and assemblies placed on the market or used for the manufacturer's own purposes 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 pressure equipment and assemblies designated as crisis-relevant goods

- 1. This Article applies to pressure equipment or assemblies listed in the implementing act referred to in Article 43a(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 pressure equipment and assemblies 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.

PE-CONS 48/24 GG/RC/cc 110
COMPET.1 EN

- 3. The prioritisation of applications for conformity assessment of pressure equipment and assemblies 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 pressure equipment and assemblies referred to in paragraph 1 in respect of which they have been notified.

#### Article 43c

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 specific pressure equipment or assembly listed in the implementing act referred to in Article 43a(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 safety requirements set out in Annex I has been demonstrated in accordance with procedures referred to in that authorisation.

PE-CONS 48/24 GG/RC/cc 111
COMPET.1 EN

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 safety requirements set out 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 pressure equipment or assemblies 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 44(3).

The pressure equipment or assemblies subject to the extension of validity referred to in the first subparagraph shall bear the information that they are 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.

PE-CONS 48/24 GG/RC/cc 112
COMPET.1 EN

- 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 pressure equipment or assemblies subject to the authorisation procedure referred to in paragraph 1 shall declare on their sole responsibility that the pressure equipment or assembly concerned complies with all the applicable essential safety 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.

PE-CONS 48/24 GG/RC/cc 113
COMPET.1

- 6. Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the pressure equipment or assembly 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 safety requirements set out in Annex I to this Directive was successfully demonstrated;
  - (b) any specific requirements regarding the traceability of the pressure equipment or assembly 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/...<sup>++</sup>;
  - (d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the pressure equipment or assembly concerned;
  - (e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the pressure equipment or assembly concerned that has been placed on the market or used for the manufacturer's own purposes.

PE-CONS 48/24 GG/RC/cc 114
COMPET.1 EN

- 7. By way of derogation from Articles 5, 18 and 19, pressure equipment or assemblies for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not bear the CE marking and Article 5 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 pressure equipment or assemblies, 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 Directive. 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.

PE-CONS 48/24 GG/RC/cc 115
COMPET.1 EN

#### Article 43d

Presumption of conformity based on standards and common specifications

- 1. Where pressure equipment and assemblies have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts listing appropriate standards or establishing common specifications for such pressure equipment and assemblies to cover the applicable essential safety requirements set out in Annex I to this Directive in the following cases:
  - (a) where a reference to harmonised standards covering the applicable essential safety requirements set out in Annex I to this Directive 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/...<sup>++</sup>, significantly restrict the possibilities of manufacturers to make use of the harmonised standards that cover the applicable essential safety requirements set out in Annex I to this Directive 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.

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- 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 Directive and shall duly consult all relevant stakeholders.

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COMPET.1 EN

- 5. Without prejudice to Article 12, pressure equipment or assemblies 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 safety 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 43a(3), first subparagraph, unless there is sufficient reason to believe that the pressure equipment and assemblies 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 pressure equipment and assemblies 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 safety 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.

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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 safety 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 43e

Prioritisation of market surveillance activities and mutual assistance among authorities

- 1. Member States shall prioritise the market surveillance activities for pressure equipment and assemblies listed in the implementing act referred to in Article 43a(1) of this Directive. 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 pressure equipment and assemblies listed in the implementing act referred to in Article 43a(1).

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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 11

# **Transposition**

- 1. By ... [date of application of the Regulation contained in document PE-CONS 46/24 (2022/0278(COD)] Member States shall adopt and publish the measures necessary to comply with this Directive. They shall immediately inform the Commission thereof.
- 2. They shall apply those measures from ... [date of application of the Regulation contained in document PE-CONS 46/24 (2022/0278(COD) + 1 day].
  - When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.
- 3. As soon as this Directive has entered into force, Member States shall ensure that the Commission is informed, in sufficient time for it to submit its comments, of any draft laws, regulations or administrative provisions which they intend to adopt in the field covered by this Directive.

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COMPET.1 EN

# Article 12 Entry into force

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

	Article 13
	Addressees
This Directive is addressed to th	e Member States.
Done at,	
For the European Parliament	For the Counci
The President	The President