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Following the meeting of the Working Party on Technical Harmonisation (SMEI Omnibus) on 15 September 2023, delegations will find in Annex a Presidency compromise proposal for the SMEI Omnibus Directive.

Changes compared to the previous version of the proposal (doc 12783/23) are marked in **highlighted, bold and underlined** for the new text and in ~~highlighted-strikethrough~~ for deletions.

2022/0280 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, ~~2013/29/EU~~, 2014/28/EU, 2014/29/EU, 2014/30/EU, ~~2014/31/EU, 2014/32/EU~~, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single 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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

¹ OJ C , , p. .

² OJ C , , p. .

Acting in accordance with the ordinary legislative procedure³,

Whereas:

- (1) [*insert reference to SMEI Regulation*] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.
- (2) The framework established by [*insert reference to SMEI Regulation*] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.
- (3) [*insert reference to SMEI Regulation*] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.
- (4) [*insert reference to SMEI Regulation*] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [*insert reference to SMEI Regulation*] applies to both goods and services.
- (5) In order to complement, ensure consistency and further enhance the effectiveness of such measures, it is appropriate to ensure that crisis-relevant goods referred to in [*insert reference to SMEI Regulation*] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.

³ Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.

- (6) A number of EU sectoral 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/EC⁴, 2006/42/EC⁵, 2010/35/EU⁶, ~~2013/29/EU⁷~~, 2014/28/EU⁸, 2014/29/EU⁹, 2014/30/EU¹⁰, ~~2014/31/EU¹¹~~, ~~2014/32/EU¹²~~, 2014/33/EU¹³, 2014/34/EU¹⁴, 2014/35/EU¹⁵, 2014/53/EU¹⁶ and 2014/68/EU¹⁷ of the European Parliament

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- ⁴ 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).
- ⁵ 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).
- ⁶ 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).
- ⁷ ~~Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (OJ L 178, 28.6.2013, p. 27).—~~
- ⁸ Directive 2014/28/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 and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1).
- ⁹ 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).
- ¹⁰ 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).
- ¹¹ ~~Directive 2014/31/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 non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).~~
- ¹² ~~Directive 2014/32/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 measuring instruments (OJ L 96, 29.3.2014, p. 149).—~~
- ¹³ 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).
- ¹⁴ 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).
- ¹⁵ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).
- ¹⁶ 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).

and of the Council. 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 768/2008/EC EC of the European Parliament and of the Council¹⁸.

- (7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral EU harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Directives, aimed at responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Directives.
- (8) Experience from the past crises that have affected the Single Market has shown that the procedures laid down in the sectoral legal acts are not designed to cater 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 as a complement to the measures adopted under *[insert reference to SMEI Regulation]*.
- (9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. **In the context of such prioritisation, any potential additional costs charged by the conformity assessment body to the manufacturer should be proportionate to the direct costs incurred by the conformity assessment bodies in order to put in place the said prioritisation. The notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.**

¹⁷ 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).

¹⁸ 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).

- (10) To that end, emergency procedures should be laid down in Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, ~~2013/29/EU~~, 2014/28/EU, 2014/29/EU, 2014/30/EU, ~~2014/31/EU~~, ~~2014/32/EU~~, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and, 2014/68/EU. Those procedures should be available only following the activation of the Single Market emergency and only when a specific good covered by those Directives is designated as crisis-relevant mode in accordance with [*insert reference to SMEI Regulation*].
- (11) Furthermore, in cases where, **for example**, the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products 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 EU sectoral legislation.
- (12) As regards products falling within the scope of those Directives that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Directives, in those cases where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they ~~comply~~ **ensure conformity** with the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may 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.

(12a) Since the essential safety requirements harmonised by the existing Directives remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Directives, this amending Directive continues to improve the conditions for the functioning of the internal market. Therefore, this amending 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 would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also 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, unless the requirements set in the authorisation do not ensure conformity with the essential requirements laid down in these 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 health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Directive aims to avoid any circumvention or undermining of the CE marking procedure and thereby to maintain consumer confidence in the safety of products bearing the CE marking in the Union market. Therefore, these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected.

- (12aa) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. All pre-existing authorisations adopted by Member States prior to the entry into force of the 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 are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in corrective or restrictive actions to be taken by the Commission by means of another implementing act.**
- (12b) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active Single Market emergency mode, as referred to in [the SMEI Regulation], should automatically expire on the date of expiry or deactivation of the Single Market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant goods on the market should occur 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 measures at their disposal in accordance with the provisions of those Directives and Regulation (EU) 2019/1020. 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.**

- (12c) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-relevant goods. The Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespective whether those measures have to be notified or not in [Safety Gate formerly known as RAPEX] due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between [Safety Gate formerly known as RAPEX] and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.**
- (13) Where a Single Market emergency entails 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 provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.
- (14) A number of sectoral EU harmonised frameworks provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.

- (15) With respect to Directives ~~2006/42/EC, Directives 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/53/EU and 2014/68/EU~~, the competent national authorities should be able to presume that products manufactured in accordance with ~~national or international~~, **European or national** standards within the meaning of Regulation (EU) No 1025/2012¹⁹ **identified by the Commission as suitable to reach conformity and** ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.
- (16) Furthermore, **if no such international or European standards are available**, with respect to Directives 2006/42/EC, ~~2013/29/EU~~, 2014/28/EU, 2014/29/EU, 2014/30/EU, ~~2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU~~, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may 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 Single Market emergency.
- ~~(17) With respect to Directives **2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU**, in exceptional and duly justified circumstances, notably in order to ensure the interoperability among products or systems, the Commission should be able to adopt by means of implementing acts common specifications laying down mandatory technical specifications, with which the manufacturers will be required to comply. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.~~

¹⁹ OJ L 316, 14.11.2012, p. 12.

- (18) 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 and including by enabling closer cooperation and mutual support among the market surveillance authorities.
- (18a) In accordance with the relevant provisions of the amended Directives, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Directives including the new provisions introduced by this amending Directive and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority.**
- (19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.
- (20) Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, ~~2013/29/EU~~, 2014/28/EU, 2014/29/EU, 2014/30/EU, ~~2014/31/EU~~, ~~2014/32/EU~~, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU should therefore be amended accordingly.²

HAVE ADOPTED THIS DIRECTIVE:

Article 1
Amendments to Directive 2000/14/EC

Directive 2000/14/EC is amended as follows:

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

“(g) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(h) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(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 only apply if Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 226 of [the SMEI Regulation] with respect to **equipment covered by** this Directive.
2. Member States shall ensure that measures taken to transpose in Articles 17b, 17 c and 17d apply exclusively to equipment, which has been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.

3. Member States shall ensure that measures taken to transpose in Articles 17b, 17c and 17d **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 17c(2), second subparagraph, and Article 17c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **corrective or restrictive actions** to be taken, ~~the~~ **procedures to be followed and the specific labelling and traceability requirements** with respect to equipment placed on the market in accordance with Article 17c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19a~~8~~(2).

Article 17b

Prioritisation of the conformity assessment of crisis-relevant equipment

1. This Article shall apply to equipment listed in the implementing act referred to in Article 17a(1), which is subject to conformity assessment procedures in accordance with Article 14, which require the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of equipment designated as crisis-relevant goods as a matter of priority-, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 17a.**
- ~~3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of equipment designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 17a.~~
4. The prioritisation of applications for conformity assessment of equipment pursuant to paragraph ~~3~~**2** shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for equipment designated as crisis-relevant goods in respect of which they have been notified.~~

Article 17c

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

1. By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, 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 requiring mandatory involvement of a notified body referred to in Article 14 have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable requirements concerning the noise emission in the environment of this Directive has been demonstrated in accordance with procedures referred to in that authorisation.

- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable requirements concerning the noise emission in the environment of this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the 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. 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 modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 18(2). 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).

When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of equipment subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the equipment concerned complies with all the applicable requirements concerning the noise emission in the environment of this Directive and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the equipment, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ 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, ~~including~~. **The authorisations shall at least set out the following:**
- (a) a description of the procedures, by means of which the compliance with the applicable requirements concerning the noise emission in the environment of this Directive 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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the equipment concerned;
 - (e) measures to be taken with respect to the equipment ~~concerned~~ **placed on the market** upon expiry of the ~~authorisation~~ **Single Market emergency** ~~in order to ensure that the equipment concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 17a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~

5. 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 benefit from free movement across the Union and shall not bear the CE marking~~ **and Article 6 shall not apply**. The market surveillance authorities are not required to recognise the validity of ~~authorisations issued by the competent national authorities of another Member State.~~
6. The market surveillance authorities of ~~the a~~ Member State, whose competent authority has ~~granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such equipment.
- They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**
7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of equipment in accordance with paragraph 1.~~
8. ~~The application of Articles 17a to 17d and the use of the authorisation procedure set out in paragraphs 1~~ **to 1c** ~~of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 17d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for equipment, designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for equipment, designated as crisis-relevant goods.’

(23) Article 18~~7~~ is **replaced by the following**~~amended as follows~~:

(a) ~~In paragraph 1, the following sentence is added after the first sentence:~~

‘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*. ~~‘The committee referred to in Article 18 shall:’;; ‘The committee referred to in Article 18 shall:’;~~

(b) ~~the following paragraph is added after paragraph 1:~~

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

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

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

Article 2

Amendments to 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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(o) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2006/42/EC, the following articles are inserted:

Application of emergency procedures

1. Member States shall ensure that measures taken to transpose Articles 21c to 21h of this directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **machinery covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 21c to 21h ~~are~~ apply exclusively to machinery, which has been designated as crisis-relevant goods in the ~~implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 21c to 21h **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 21d(2), second subparagraph, and Article 21d(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 to 21g. 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 crisis-relevant machinery

1. This Article shall apply to machinery designated as crisis-relevant goods, which is subject to conformity assessment procedures in accordance with Article 12, which require the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of machinery designated as crisis-relevant goods as a matter of priority-, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 21b.**
- ~~3. All pending applications for conformity assessment of machinery designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of machinery, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of machinery designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 21b.~~
4. The prioritisation of applications for conformity assessment of machinery pursuant to paragraph ~~3~~**2** shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for machinery designated as crisis-relevant goods in respect of which they have been notified.~~

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

1. By way of derogation from Article 12, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of specific machinery which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in Article 12 have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential health and safety requirements has been demonstrated in accordance with procedures referred to in that authorisation.

- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential health and safety requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the 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. 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 modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 22(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).

~~When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.~~

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of machinery subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the machinery concerned complies 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 ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the machinery, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ 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, ~~including~~ **The authorisations shall at least set out the following:**
- (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of this Directive was successfully demonstrated;
 - (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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the machinery concerned;
 - (e) measures to be taken with respect to the machinery ~~concerned~~ **placed on the market or put into service** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the machinery concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 21d(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3, also after the deactivation or expiry of the Single Market Emergency mode.~~
5. 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 leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 6 shall not apply.**

6. The market surveillance authorities of the a Member State, whose competent authority has granted an authorisation pursuant to paragraph 1 where an authorisation pursuant to paragraphs 1, 1a and 1c is valid, shall be entitled to take all corrective and restrictive measures actions at national level provided for under Regulation (EU) 2019/1020 and under this Directive with respect to such machinery.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of machinery in accordance with paragraph 1.~~
8. The application of Articles 21b to 21h and the use of the authorisation procedure set out in paragraphs 1 to 1c of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 12 on the territory of the Member State concerned.

Article 21e

~~Presumption of conformity based on national and international standards~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that the machinery which complies with of relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex I, complies with those essential health and safety requirements in either of the following cases:~~

- a) ~~where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~

- b) ~~where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012~~

Article 21f

~~Adoption of common specifications conferring a presumption~~ **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 essential health and safety requirements set out in Annex I, in either of the following cases:
 - (a) ~~where~~ no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ the severe disruptions in the functioning of the Single Market which led to the activation the Single Market emergency mode in accordance with Article ~~14~~**15**(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential health and safety requirements set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**
- (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential health and safety requirements set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;**
- (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.**

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following ~~a consultation of the sectoral experts and~~ in accordance with the examination procedure referred to in Article 22(3). They shall apply to ~~machinery placed on the market~~ until the last day of the period for which the Single Market emergency mode ~~has been activated in accordance with Article 15(4) of [the SMEI Regulation]~~ **remains active, unless amended or repealed in accordance with paragraph 5.**

- 2a. ~~In the early~~ **Before** ~~preparation~~ **ing** of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under ~~relevant sectoral Union legislation~~ **this Directive and shall duly consult all relevant stakeholders**. Based on that consultation, the Commission shall prepare the draft implementing act.
3. Without prejudice to Article 7, machinery which is in conformity with **the standards or common specifications adopted pursuant referred to in paragraph 21 of this Article, or parts thereof,** shall be presumed to be in conformity with the essential health and safety requirements set out in Annex I covered by those **standards or common specifications or parts thereof.** **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. 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 **which is** in compliance **conformity** with those **standards or common specifications** **and** which has been placed on the market **or put into service** shall be deemed compliant with ~~this Directive~~ **the essential health and safety requirements set out in Annex I** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements ~~which it aims to cover and which are~~ set out in Annex I, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation. ~~And the~~ The Commission shall assess that ~~information~~ **detailed explanation** and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

Article 21g

Adoption of mandatory common specifications

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex I for machinery listed in the implementing act referred to in Article 21b(1).~~
- ~~2. The implementing acts establishing mandatory common specifications referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the procedure referred to in Article 22(3). They shall apply to machinery placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

~~3. By way of derogation from Article 21b(3), first subparagraph, unless there is sufficient reason to believe that the machinery covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the machinery in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 21h

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for machinery, designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for machinery designated as crisis-relevant goods.’

(3) 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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(28) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) the following **chapter** ~~Chapter 5a~~ 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 only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] 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 apply exclusively to transportable pressure equipment, which has been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation].**

3. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.
4. However, ~~Article 33c(2), second subparagraph, and Article 33c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.
5. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 crisis-relevant transportable pressure equipment

1. This Article shall apply to transportable pressure equipment designated as crisis-relevant goods, which is subject to conformity assessment procedures in accordance with Article 12, which require the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of transportable pressure equipment designated as crisis-relevant goods as a matter of priority, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 33a.**

- ~~3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of transportable pressure equipment designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 33a.~~
4. The prioritisation of applications for conformity assessment of transportable pressure equipment pursuant to paragraph ~~23~~ shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for transportable pressure equipment designated as crisis-relevant goods in respect of which they have been notified.~~

Article 33c

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

1. By way of derogation from Article 12, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific transportable pressure equipment designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 12 have not been carried out by a notified body 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.**

1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive, the Commission shall without delay but not earlier than 5 days after receiving the information, adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the 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. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 38a(2).

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 modalities 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.

- 1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 38a(2). 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).**
- When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.**
- 1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.**
- Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.**
2. The manufacturer, the importer, the distributor and the user of a transportable pressure equipment subject to the authorisation procedure referred to in paragraph 1 of this Article shall declare on his 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 ~~national~~ competent **national** authority.
- ~~The manufacturer, the importer, the distributor and the user shall also deploy all reasonable measures to ensure that the transportable pressure equipment, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued~~s~~ by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the transportable pressure equipment may be placed on the market or put into service. **The authorisations shall at least set out the following**, including:
- (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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the transportable pressure equipment concerned;
 - (e) measures to be taken with respect to the transportable pressure equipment ~~concerned~~ **placed on the market** upon expiry of the **Single Market emergency** ~~authorisation in order to ensure that the transportable pressure equipment concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 33a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~

5. 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 leave the territory of the Member State that has granted the authorisation~~ **shall not bear the Pi marking and Article 16 shall not apply.**
6. The market surveillance authorities of ~~the a~~ Member State, ~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such transportable pressure equipment.
- They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**
- ~~7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a transportable pressure equipment in accordance with paragraph 1.~~
8. ~~The application of Articles 33a to 33d and the use of the authorisation procedure set out in paragraphs 1 to 1c of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 12 on the territory of the Member State concerned.

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, designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for transportable pressure equipment, designated as crisis-relevant goods.²

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

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

Article 4

Amendments to Directive 2013/29/EU

In Directive 2013/29/EU, the following Chapter 5a is inserted:

‘CHAPTER 5a

EMERGENCY PROCEDURES

Article 42a

Application of emergency procedures,

1. ~~Member States shall ensure that measures taken to transpose Articles 42b to 42g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.~~
2. ~~Member States shall ensure that measures taken to transpose Articles 42b to 42g apply exclusively to pyrotechnic articles, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.~~
3. ~~Member States shall ensure that measures taken to transpose Articles 42b to 42g apply during the Single Market emergency mode.~~
4. ~~The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to pyrotechnic articles placed on the market in accordance with Articles 42e to 42f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).~~

Article 42b

Prioritisation of the conformity assessment of crisis-relevant pyrotechnic articles

- ~~1. This Article shall apply to all pyrotechnic articles designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17 requiring the mandatory involvement of a notified body.~~
- ~~2. The notified bodies shall process all applications for conformity assessment of pyrotechnic articles designated as crisis-relevant goods as a matter of priority.~~
- ~~3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of pyrotechnic articles designated as crisis-relevant goods, irrespective of, whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 42a.~~
- ~~4. The prioritisation of applications for conformity assessment of pyrotechnic articles pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.~~
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for pyrotechnic articles designated as crisis-relevant goods in respect of which they have been notified.~~

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

- ~~1. By way of derogation from Article 17, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific pyrotechnic article which has been designated as crisis-relevant good and for which the conformity assessment procedures which require the mandatory involvement of a notified body referred to in Article 17 have not been carried out by a notified body but for which the compliance with all the applicable essential safety requirements has been demonstrated.~~
- ~~2. The manufacturer of a pyrotechnic article subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the pyrotechnic article concerned complies with all the applicable essential safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.~~
- ~~3. The manufacturer shall also deploy all reasonable measures to ensure that the pyrotechnic article, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~
- ~~4. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the pyrotechnic article may be placed on the market, including:~~
 - ~~(a) a description of the procedures, by means of which the compliance with the applicable essential safety requirements of Directive was successfully demonstrated;~~
 - ~~(b) specific requirements regarding the traceability of the pyrotechnic article concerned;~~

- ~~(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;~~
- ~~(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the pyrotechnic article concerned;~~
- ~~(e) measures to be taken with respect to the pyrotechnic article concerned upon expiry of the authorisation in order to ensure that the pyrotechnic article concerned is brought back in compliance with all the requirements of this Directive.~~

- ~~5. By way of derogation from Article 42a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~
- ~~6. By way of derogation from Articles 4 and 20, pyrotechnic articles, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not benefit from free movement across the Union and shall not bear the CE marking. The market surveillance authorities are not required to recognise the validity of authorisations issued by the competent national authorities of another Member State.~~
- ~~7. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such pyrotechnic articles.~~
- ~~8. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a pyrotechnic article in accordance with paragraph 1.~~

~~9. The application of Articles 42a to 42g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned.~~

~~Article 42d~~

~~**Presumption of conformity based on national and international standards**~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that pyrotechnic articles which comply with the relevant international standards or any national standards in force in the Member State of manufacture, if such standards ensuring the safety level required by the essential safety requirements set out in Annex I, complies with those essential safety requirements in either of the following cases:~~

- ~~(a) where no reference to harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
- ~~(b) where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

Adoption of common specifications conferring a presumption of conformity

1. ~~Where pyrotechnic articles, have been designated as crisis relevant goods, the Commission is empowered to adopt implementing acts for such pyrotechnic articles establishing common specifications to cover the essential safety requirements set out in Annex I in either of the following cases:~~
 - (a) ~~where no reference to harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
 - (b) ~~where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive and already 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 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to for pyrotechnic articles placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

- ~~3. Without prejudice to Article 16, pyrotechnic articles which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential safety requirements set out in Annex I covered by those common specifications or parts thereof.~~
- ~~4. By way of derogation from Article 42a(3), first subparagraph, unless there is sufficient reason to believe that the pyrotechnic articles covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the pyrotechnic articles in compliance with the said common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~
- ~~5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential safety requirements which it aims to cover and which are set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.~~

~~Article 42f~~

~~Adoption of mandatory common specifications~~

- ~~1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential safety requirements set out in Annex I for pyrotechnic articles, which have been designated as crisis-relevant goods.~~

- ~~2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they apply to pyrotechnic articles placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 42a(3), first subparagraph, unless there is sufficient reason to believe that the pyrotechnic articles covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the pyrotechnic articles in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 42g

~~Prioritisation of market surveillance activities and mutual assistance among authorities~~

- ~~1. Member States shall prioritise the market surveillance activities for pyrotechnic articles designated as crisis relevant goods.~~
- ~~2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for pyrotechnic articles designated as crisis relevant goods.²~~

Article 5

Amendments to Directive 2014/28/EU

Directive 2014/28/EU is amended as follows:

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

“(25) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(26) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/28/EU, the following ~~chapter~~Chapter 6a is inserted:

**‘CHAPTER 6a
EMERGENCY PROCEDURES**

Article 45a

Application of emergency procedures

1. Member States shall ensure that measures taken to transpose Articles 45b to 45g of this Directive shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **explosives covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 45b to 45g apply exclusively to explosives, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation].**

3. Member States shall ensure that measures taken to transpose Articles 45b to 45g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 45c(2), second subparagraph, and Article 45c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** be empowered to lay down by means of implementing acts ~~rules regarding the follow-up actions~~ **corrective or restrictive actions** to be taken, ~~the~~ **procedures to be followed and the specific labelling and traceability requirements** with respect to explosives placed on the market in accordance with Articles 45c to 45f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

Article 45b

Prioritisation of the conformity assessment of crisis-relevant explosives

1. This Article shall apply to explosives designated as crisis-relevant goods, which are subject to conformity assessment procedures, in accordance with Article 20 requiring the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of explosives designated as crisis-relevant goods as a matter of priority, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 45a.**
- ~~3. All pending applications for conformity assessment of such explosives designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of explosives designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 45a.~~

4. The prioritisation of applications for conformity assessment of explosives pursuant to paragraph 3~~2~~ shall not give rise to any **disproportionate** additional costs for the manufacturers, which have lodged those applications.
5. ~~The notified bodies shall deploy their best efforts to increase their testing capacities for explosives designated as crisis-relevant goods in respect of which they have been notified.~~

Article 45c

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

1. By way of derogation from Article 20, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific explosive which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in that Article 20 have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential safety requirements has been demonstrated **in accordance with procedures referred to in that authorisation.**
- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential safety requirements laid down in this Directive, the Commission shall without delay but not earlier than 5 days after receiving the information, adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the explosive 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. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 49(3) .**

The explosive 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 modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 49(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 49(4).

~~When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.~~

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of an explosive subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the explosive concerned complies with all the applicable essential safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the explosive, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued by a ~~national competent authority~~ pursuant to paragraph 1 shall set out the conditions and requirements under which the explosive may be placed on the market, including **The authorisations shall at least set out 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 explosive concerned;
- (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
- (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the explosive concerned;
- (e) measures to be taken with respect to the explosive concerned **placed on the market** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the explosive concerned is brought back in compliance with all the requirements of this Directive.~~

4. ~~By way of derogation from Article 45a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~
5. By way of derogation from Articles 3, **22** and 23, explosives, for which an authorisation has been granted in accordance with paragraph 1 of this Article, ~~shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 3 shall not apply.**
6. The market surveillance authorities of the **a** Member State, ~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such explosives.
- They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**
7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of an explosive in accordance with paragraph 1.~~
8. The ~~application of Articles 45a to 45g and the use of the authorisation procedure set out in paragraphs 1 to 1c of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 20 on the territory of the Member State concerned.

Presumption of conformity based on national and international standards

- (a) — ~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the explosives which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential safety requirements set out in Annex II, complies with those essential safety requirements in either of the following cases:~~
- (a) — ~~where no reference to harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
- (b) — ~~where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

~~Adoption of common specifications conferring a presumption~~ **Presumption of conformity based on standards and common specifications**

1. Where explosives, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts ~~for such explosives~~ **listing appropriate standards or** establishing common specifications **for such explosives** to cover the essential safety requirements set out in Annex II in either of the following cases:
- (a) ~~where~~ no reference to harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex II already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover essential safety requirements set out in Annex II, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**
- (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential safety requirements set out in Annex II; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;**

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following ~~a consultation of the sectoral experts and~~ in accordance with the examination procedure referred to in Article 49(3). They shall apply to the explosives placed on the market until the last day of the period for which the Single Market emergency mode remains applicable in accordance with ~~[the SMEI Regulation]~~ **active, unless amended or repealed in accordance with paragraph 5.**
- 2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under ~~relevant sectoral Union legislation~~ **this Directive and shall duly consult all relevant stakeholders.** Based on that consultation, the Commission shall prepare the draft implementing act.
3. Without prejudice to Article 19, explosives which are in conformity with **the standards or common specifications adopted pursuant referred to in paragraph 21 of this Article, or parts thereof,** shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those **standards or** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**

4. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the explosives 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 explosives **which are** in **conformity** ~~compliance~~ with these **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential safety requirement set out in Annex II** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*
5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential safety requirements ~~which it aims to cover and which are~~ set out in Annex II, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation, ~~and~~ **and** The Commission shall assess that **detailed explanation** ~~information~~ and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential safety requirements set out in Annex II for explosives which have been designated as crisis relevant goods.~~
- ~~2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 49(3) and they shall apply to explosives placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the explosives covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the explosives in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.~~

Article 45g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for explosives designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for explosives, designated as crisis-relevant goods.’

Article 6

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(19) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/29/EU, the following ~~chapter~~Chapter 5a 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 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to vessels covered by this Directive.
2. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply exclusively to vessels, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 38b to 38g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 38c(2), second subparagraph, and Article 38c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission shall may adopt be empowered to lay down by means of implementing acts rules regarding the follow-up actions 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 to 38f. 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 crisis-relevant vessels

1. This Article shall apply to vessels designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 13 requiring the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of vessels designated as crisis-relevant goods as a matter of priority-, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.
- ~~3. All pending applications for conformity assessment of vessels designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of vessels designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.~~
4. The prioritisation of applications for conformity assessment of vessels pursuant to paragraph ~~3~~2 shall not give rise to any disproportionate additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for vessels designated as crisis-relevant goods in respect of which they have been notified.~~

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

1. By way of derogation from Article 13, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific vessel which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 13 have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential safety requirements has been demonstrated in accordance with procedures referred to in that authorisation.

- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential safety requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the vessel 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. 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 modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 39(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).

~~When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.~~

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of a vessel subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the vessel concerned complies with all the applicable essential safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the vessel, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ pursuant to paragraph 1 shall set out the conditions and requirements under which the vessel may be placed on the market or put into service, ~~including~~ **The authorisations shall at least set out 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 Single Market emergency mode has been activated in accordance with Article 14 of [the SMEI Regulation];
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the vessel concerned;
 - (e) measures to be taken with respect to the vessel concerned placed on the market upon expiry of the authorisation Single Market emergency in order to ensure that the vessel concerned is brought back in compliance with all the requirements of this Directive.
4. ~~By way of derogation from Article 38a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~
5. 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 leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking and inscriptions~~ **and Article 5 shall not apply.**

6. The market surveillance authorities of the a Member State, whose competent authority has ~~granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such vessels.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a vessel in accordance with paragraph 1.~~
8. The ~~application of Articles 38a to 38g and the use of the authorisation procedure set out in paragraphs 1~~ **to 1c** ~~of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned..

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent consider vessels which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring a safety level required by the essential safety requirements set out in Annex I, complies with those essential safety requirements in either of the following cases:

- (a) — where no reference to harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
- (b) — where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

~~Adoption of common specifications conferring a presumption~~ **Presumption of conformity based on standards and common specifications**

1. Where vessels¹ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts ~~for such vessels~~ **listing appropriate standards or** establishing common specifications **for such vessels** to cover the essential safety requirements set out in Annex I, in either of the following cases:
- (a) ~~where~~ no reference to harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~the~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex I to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential safety requirements set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**

(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential safety requirements set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to vessels placed on the market until the last day of the period for which the Single Market emergency mode remains active in accordance with Article 15(4) of [the SMEI Regulation], **unless amended or repealed in accordance with paragraph 5.**

2a. ~~In the early~~ **Before** preparation of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under relevant sectoral Union legislation **this Directive and shall duly consult all relevant stakeholders.** ~~Based on that consultation, the Commission shall prepare the draft implementing act.~~

3. Without prejudice to Article 12, vessels which are in conformity with **the standards or common specifications adopted pursuant referred to in paragraph 21 of this Article, or parts thereof**, shall be presumed to be in conformity with the essential safety requirements set out in Annex I covered by those **standards or common specifications or parts thereof**. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated**.
4. 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 **which are in conformity** ~~compliance~~ with these **standards or common specifications** **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential safety requirements set out in Annex I** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. When a Member State considers that a **standard or common specification referred to in paragraph 1** does not entirely satisfy the essential safety requirements ~~which it aims to cover and which are~~ set out in Annex I, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation. ~~and~~ **The Commission shall assess that detailed explanation** information and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential safety requirements set out in Annex I for vessels, which have been designated as crisis-relevant goods.~~
- ~~2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3) and they shall apply to vessels placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the vessels covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the vessels in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for vessels, designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for vessels, designated as crisis-relevant goods.’

Article 7

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(27) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) the following **chapter** ~~Chapter 5a~~ is inserted:

**“CHAPTER 5a
EMERGENCY PROCEDURES**

Article 40a

Application of emergency procedures

1. Member States shall ensure that measures taken to transpose Articles 40b to 40g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **apparatus covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 40b to 40g apply exclusively to apparatus, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 40b to 40g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

4. The Commission shall may adopt be empowered to lay down by means of implementing acts rules regarding the follow-up actions 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 Articles 40c to 40f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(2a).

Article 40b

Prioritisation of the conformity assessment of crisis-relevant apparatus

1. This Article shall apply to apparatus designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring the mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of apparatus designated as crisis-relevant goods as a matter of priority-, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.
- ~~3. All pending applications for conformity assessment of apparatus designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for equipment, which has not been designated as crisis-relevant goods. This requirement is applies with respect to all applications for conformity assessment of apparatus designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.~~
4. The prioritisation of applications for conformity assessment of apparatus pursuant to paragraph ~~3~~2 shall not give rise to any disproportionate additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for apparatus designated as crisis-relevant goods in respect to which they have been notified.~~

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

1. ~~By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific apparatus which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 14 have not been carried out by a notified body but for which the compliance with all the applicable essential safety requirements has been demonstrated.~~
2. ~~The manufacturer of apparatus subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the apparatus concerned complies with all the applicable essential safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.~~

~~The manufacturer shall also deploy all reasonable measures to ensure that the apparatus, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~
3. ~~Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the apparatus may be placed on the market or put into service, including:~~
 - ~~(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) specific requirements regarding the traceability of the apparatus concerned;~~
 - ~~(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;~~

- (d) ~~any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the apparatus concerned;~~
- (e) ~~measures to be taken with respect to the apparatus concerned upon expiry of the authorisation in order to ensure that the apparatus concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 also after the deactivation or expiry of the Single Market Emergency mode.~~
5. ~~By way of derogation from Articles 5 and 17, apparatus, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.~~
6. ~~The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such apparatus.~~
7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of apparatus in accordance with paragraph 1.~~
8. ~~The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.~~

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that apparatus which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring a safety level required by the essential health and safety requirements set out in Annex I, complies with those essential health and safety requirements in either of the following cases:

- (a) — where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 or
- (b) — where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

~~Adoption of common specifications conferring a presumption~~ **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 ~~for such apparatus~~ **listing appropriate standards or** establishing common specifications **for such apparatus** to cover the essential ~~health and safety~~ requirements set out in Annex I, in either of the following cases:
- (a) ~~where~~ no reference to harmonised standards covering the relevant essential ~~safety~~ requirements set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode **in accordance with Article 14 of [the SMEI Regulation]**, significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential ~~health and safety~~ requirements set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**

(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential health and safety requirements set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(2a). They shall apply to apparatus placed on the market until the last day of the period for which the Single Market emergency mode remains active, **unless amended or repealed in accordance with paragraph 5.**

2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under relevant sectoral Union legislation **this Directive and shall duly consult all relevant stakeholders.** Based on that consultation, the Commission shall prepare the draft implementing act..

3. Without prejudice to Article 13, apparatus which is in conformity with **the standards or common specifications adopted pursuant referred to in paragraph 21 of this Article, or parts thereof**, shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those **standards or common specifications or parts thereof**. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. By way of derogation from Article 40a(3), first subparagraph, 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 **which are in conformity compliance** with these **standards or common specifications and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential safety requirements set out in Annex I** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. When a Member State considers that a **standard or common specification referred to in paragraph 1** does not entirely satisfy the essential ~~safety~~ requirements ~~which it aims to cover and which are~~ set out in Annex I, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation. ~~and~~ **The Commission shall assess that detailed explanation information** and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Article 40f~~

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex I for apparatus, which has been designated as crisis-relevant goods.~~
- ~~2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(2a). They shall apply to apparatus placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the apparatus covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the apparatus in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.~~

Article 40g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for apparatus, designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for apparatus, designated as crisis-relevant goods.’

3.~~(3)~~ in Article 41, the following paragraph ~~2a~~ is inserted:

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

Article 8

Amendments to Directive 2014/31/EU

In Directive 2014/31/EU, the following Chapter 5a is inserted:

“CHAPTER 5a

EMERGENCY PROCEDURES

Article 40a

**Application of emergency procedures,
and their deactivation**

1. ~~Member States shall ensure that measures taken to transpose Articles 40b to 40g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.~~
2. ~~Member States shall ensure that measures taken to transpose Articles 40b to 40g apply exclusively to instruments, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.~~
3. ~~Member States shall ensure that measures taken to transpose Articles 40b to 40g apply during the Single Market emergency mode.~~

~~However, Article 40c(2), second subparagraph, and Article 40c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.~~

4. ~~The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to instruments placed on the market in accordance with Articles 40e to 40f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(3).~~

Article 40b

Prioritisation of the conformity assessment of crisis-relevant instruments

- ~~1. This Article shall apply to instruments designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 13 requiring the mandatory involvement of a notified body.~~
- ~~2. The notified bodies shall process all applications for conformity assessment of instruments designated as crisis-relevant goods as a matter of priority.~~
- ~~3. All pending applications for conformity assessment of such instruments designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of instruments, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of instruments designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.~~
- ~~4. The prioritisation of applications for conformity assessment of instruments pursuant to paragraph 2 and 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.~~
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for instruments designated as crisis-relevant goods in respect to which they have been notified.~~

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

1. ~~By way of derogation from Article 13, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific instrument which has been designated as crisis relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 13 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.~~
2. ~~The manufacturer of an instrument subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the instrument concerned complies with all the applicable essential requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.~~

~~The manufacturer shall also deploy all reasonable measures to ensure that the instrument, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~
3. ~~Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the instrument may be placed on the market, including:~~
 - ~~(a) a description of the procedures, by means of which the compliance with the applicable essential requirements of this Directive was successfully demonstrated;~~
 - ~~(b) specific requirements regarding the traceability of the instrument concerned;~~

- (c) ~~an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;~~
- (d) ~~any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the instrument concerned;~~
- (e) ~~measures to be taken with respect to the instrument concerned upon expiry of the authorisation in order to ensure that the instrument concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~
5. ~~By way of derogation from Articles 5 and 16, instruments, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking, nor the supplementary metrology marking.~~
6. ~~The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such instruments.~~
7. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of an instrument in accordance with paragraph 1.~~

~~8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned.~~

Article 40d

Presumption of conformity based on national and international standards

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that instruments which comply with the relevant international standards any national standards in force in the Member State of manufacture, ensuring the safety level equivalent to that required by the essential requirements set out in Annex I, comply with those essential requirements in either of the following cases:~~

- ~~(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012 or~~
- ~~(b) where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

Adoption of common specifications conferring a presumption of conformity

- ~~1. Where instruments, have been designated as crisis relevant goods, the Commission is empowered to adopt implementing acts with respect to such instruments establishing common specifications to cover the essential requirements set out in Annex I in either of the following cases:~~
- ~~(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
 - ~~(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I of this Directive and already 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 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(3). They shall apply to instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

- ~~3. Without prejudice to Article 12, instruments which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof.~~
- ~~4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the instruments in compliance with the said common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~
- ~~5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.~~

~~Article 40f~~

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Annex I for instruments, which have been designated as crisis-relevant goods.~~

- ~~2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(3). They shall apply to for instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the instruments in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 40g

~~Prioritisation of market surveillance activities and mutual assistance among authorities~~

- ~~1. Member States shall prioritise the market surveillance activities for instruments, designated as crisis-relevant goods.~~
- ~~2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for instruments, designated as crisis-relevant goods.²~~

Article 9

Amendments to Directive 2014/32/EU

In Directive 2014/32/EU, the following Chapter 5a is inserted:

“CHAPTER 5a

EMERGENCY PROCEDURES

Article 45a

**Application of emergency procedures,
and their deactivation**

1. ~~Member States shall ensure that measures taken to transpose Articles 45b to 45g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.~~
2. ~~Member States shall ensure that measures taken to transpose Articles 45b to 45g apply exclusively to measuring instruments, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.~~
3. ~~Member States shall ensure that measures taken to transpose Articles 45b to 45g apply during the Single Market emergency mode.~~

~~However, Article 45c(2), second subparagraph, and Article 45c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.~~

4. ~~The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to measuring instruments placed on the market in accordance with Articles 45e to 45f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).~~

Article 45b

Prioritisation of the conformity assessment of crisis-relevant measuring instruments

1. ~~This Article shall apply to all measuring instruments designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17 requiring the mandatory involvement of a notified body.~~
2. ~~The notified bodies shall process all applications for conformity assessment of measuring instruments designated as crisis-relevant goods as a matter of priority.~~
3. ~~All pending applications for conformity assessment of such measuring instruments shall be processed as a matter of priority, ahead of any other applications for conformity assessment of measuring instruments, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of measuring instruments designated as crisis-relevantrelevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 45a.~~
4. ~~The prioritisation of applications for conformity assessment of measuring instruments pursuant to paragraph 2 and 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.~~
5. ~~The notified bodies shall deploy their best efforts to increase their testing capacities for measuring instruments designated as crisis-relevant goods in respect to which they have been notified.~~

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

1. ~~By way of derogation from Article 17, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into use within the territory of the Member State concerned, of a specific measuring instrument which has been designated as crisis relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body, referred to in Article 17 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.~~
2. ~~The manufacturer of a measuring instrument subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the measuring instrument concerned complies with all the applicable essential requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.~~

~~The manufacturer shall also deploy all reasonable measures to ensure that the measuring instrument, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~
3. ~~Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the measuring instrument may be placed on the market or put into use, including:~~
 - ~~(a) a description of the procedures, by means of which the compliance with the applicable essential requirements of this Directive was successfully demonstrated;~~
 - ~~(b) specific requirements regarding the traceability of the measuring instrument concerned;~~
 - ~~(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;~~

- (d) ~~any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the measuring instrument concerned;~~
- (e) ~~measures to be taken with respect to the measuring instrument concerned upon expiry of the authorisation in order to ensure that the measuring instrument concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Articles 7 and 20, measuring instruments, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking, nor the supplementary metrology marking.~~
5. ~~The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such measuring instruments.~~
6. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market and/or putting into use of a measuring instrument in accordance with paragraph 1.~~
7. ~~The application of Articles 45a to 45g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned.~~

Presumption of conformity based on national and international standards

~~Where either:~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into use, their competent authorities consider that the measuring instruments which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in the relevant instrument-specific Annexes, comply with those essential requirements in either of the following cases:~~

- ~~(a) — where no reference to harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
- ~~(b) — where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

Adoption of common specifications conferring a presumption of conformity

1. ~~Where measuring instruments have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such measuring instruments to cover the essential requirements set out in Annex I and in the relevant instrument-specific Annexes in either of the following cases:~~
 - (a) ~~where no reference to harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
 - (b) ~~the severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes to this Directive and already 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 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 46(3). They shall remain apply to measuring instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

- ~~3. Without prejudice to Article 14, measuring instruments which are in conformity with common specifications adopted pursuant to paragraph 2 shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those common specifications or parts thereof.~~
- ~~4. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the measuring instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the measuring instruments in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~
- ~~5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I and in the relevant instrument-specific Annexes, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.~~

~~Article 45f~~

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Annex I and in the instrument-specific Annexes for measuring instruments, which have been designated as crisis relevant goods.~~

- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 46(3). They shall apply to measuring instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the measuring instruments covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the measuring instruments in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 45g

~~Prioritisation of market surveillance activities and mutual assistance among authorities~~

- ~~1. Member States shall prioritise the market surveillance activities for measuring instruments, designated as crisis-relevant goods.~~
- ~~2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for measuring instruments, designated as crisis-relevant goods.²~~

Article 10

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(23) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/33/EU, the following ~~chapter~~Chapter Va 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 41g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] 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 41g apply exclusively to lifts and safety components for lifts, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation].**

3. Member States shall ensure that measures taken to transpose Articles 41b to 41g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 41c(3), second subparagraph, and Article 41c(6)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 ~~or put into service~~ in accordance with Articles 41c to 41f. 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 crisis-relevant lifts and safety components for lifts

1. This Article shall apply to all lifts and safety components for lifts designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Articles 15 and 16 requiring mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of lifts and safety components for lifts designated as crisis-relevant goods as a matter of priority, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.**

3. ~~All pending applications for conformity assessment of such lifts and safety components for lifts shall be processed as a matter of priority, ahead of any other applications for conformity assessment of lifts and safety components for lifts which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of lifts and safety components for lifts designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.~~
4. The prioritisation of applications for conformity assessment of lifts and safety components for lifts pursuant to paragraph 3~~2~~ shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
5. ~~The notified bodies shall deploy their best efforts to increase their testing capacities for lifts and safety components for lifts designated as crisis-relevant goods in respect to which they have been notified.~~

Article 41c

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

1. By way of derogation from Article 15, any competent national authority may authorise, on a duly justified request, ~~the making available~~ the placing on the market ~~or putting into service~~ within the territory of the Member State concerned, of a specific safety component for lifts which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential health and safety requirements has been demonstrated **in accordance with procedures referred to in that authorisation.**

2. By way of derogation from Article 16, any competent national authority may authorise, on a duly justified request, the placing on the market ~~or putting into service~~ within the territory of the Member State concerned, of a specific lift which has been designated as crisis-relevant good and for which the third-party conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential health and safety requirements has been demonstrated **in accordance with the procedures referred to in that authorisation.**

2a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraphs 1 or 2. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential health and safety requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 2 to the territory of the Union and set the conditions under which the lifts or the safety components 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. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).

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 modalities 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.

2b. The implementing acts referred to in paragraph 2a shall be adopted in accordance with the examination procedure referred to in Article 42(3). On duly justified imperative grounds of urgency, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4). When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraphs 1 or 2.

2c. As long as the implementing act referred to in paragraph 2a is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act. Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

3. The manufacturer of a lift or a safety component for lifts subject to the authorisation procedures referred to in paragraphs 1 or 2 shall declare on his sole responsibility that the lift or the safety component for lifts concerned complies 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 ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the lift or the safety component for lifts, which has been granted an authorisation pursuant to paragraphs 1 or 2 does not leave the territory of the Member State, which has granted the authorisation.~~

4. Any authorisation issued by a national competent authority pursuant to paragraphs 1 or 2 shall set out the conditions and requirements under which the lift or a the safety component for lifts may be placed on the market, ~~made available or put into service respectively;~~ including **The authorisations shall at least set out the following:**
- (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of 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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the lift or safety component for lifts concerned;
 - (e) measures to be taken with respect to the lift or safety component for lifts ~~concerned~~ **placed on the market** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the lift or safety component for lifts concerned is brought back in compliance with all the requirements of this Directive.~~
5. ~~By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 4 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~

6. 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 paragraphs 1 or 2 ~~of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 3 shall not apply.**
7. The market surveillance authorities of ~~the~~ **a** Member State, ~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 2, 2a and 2c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such lifts or safety components for lifts.
- They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**
8. ~~Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market, making available or putting into service respectively of a lift or a safety component for lifts in accordance with paragraphs 1 or 2.~~
9. ~~The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraphs 1 to 2c of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 15 or 16 on the territory of the Member State concerned.

Article 41d

~~Presumption of conformity based on national and international standards~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, making available or putting into service respectively, their competent authorities consider that the lifts and safety components of lifts which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex I, comply with those essential health and safety requirements in either of the following cases:~~

- ~~(a) — where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
- ~~(b) — where the severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.~~

Article 41e

~~Adoption of common specifications conferring a presumption~~ **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 essential health and safety requirements set out in Annex I in either of the following cases:

- (a) ~~where~~ no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
- (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential health and safety requirements set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**
- (c) **if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential health and safety requirements set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;**

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following ~~a consultation of the sectoral experts and~~ in accordance with the examination procedure referred to in Article 42(3). They shall apply to lifts and safety components for lifts placed ~~on the market~~ until the last day of the period for which the Single Market emergency mode remains active, **unless amended or repealed in accordance with paragraph 5.**
- 2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under ~~relevant sectoral Union legislation~~ **this Directive and shall duly consult all relevant stakeholders.** ~~Based on that consultation, the Commission shall prepare the draft implementing act..~~
3. Without prejudice to Article 14, lifts and safety components for lifts which are in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred to in** paragraph ~~21~~ **1** of this Article, **or parts thereof,** shall be presumed to be in conformity with the essential health and safety requirements set out in Annex I covered by those **standards or** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**

4. 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 **which are in conformity** ~~compliance~~ with these **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential health and safety requirements set out in Annex I** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements ~~which it aims to cover and which are~~ set out in Annex I, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation, ~~and~~ **the** Commission shall assess that **detailed explanation** ~~information~~ and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Article 41f~~

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex I for lifts and safety components for lifts, which have been designated as crisis relevant goods.~~

- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3) and they shall apply to lifts and safety components for lifts placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. 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 mandatory 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 in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 41g

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 designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for lifts and safety components for lifts designated as crisis-relevant goods.’

Article 11

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(28) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/34/EU, the following ~~chapter~~Chapter 5a 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 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **products covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply exclusively to products, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 38b to 38g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 38c(2), second subparagraph, and Article 38c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 in accordance with Articles 38c to 38f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 39(3).

Prioritisation of the conformity assessment of crisis-relevant products

1. This Article shall apply to all products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 13 requiring mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of products designated as crisis-relevant goods as a matter of priority-, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.**
- ~~3. All pending applications for conformity assessment of such equipment products be processed as a matter of priority, ahead of any other applications for conformity assessment of products, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of products designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.~~
4. The prioritisation of applications for conformity assessment of products pursuant to paragraph ~~3~~**2** shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for products designated as crisis-relevant goods in respect to which they have been notified.~~

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

1. By way of derogation from Article 13, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific product which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body, referred to in that Article have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential health and safety requirements has been demonstrated in accordance with procedures referred to in that authorisation.
- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential health and safety requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the product 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. 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 as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 39(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).

~~When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.~~

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of a product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the product concerned complies 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 ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the product, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ pursuant to paragraph 1 shall set out the conditions and requirements under which the product may be placed on the market or put into service, ~~including~~ **The authorisations shall at least set out the following:**
- (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of 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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the product concerned;
 - (e) measures to be taken with respect to the product ~~concerned~~ **placed on the market** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the product concerned is brought back in compliance with all the requirements of this Directive.~~
4. ~~By way of derogation from Article 38a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~

5. 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 leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 5 shall not apply.**
6. The market surveillance authorities of ~~the a~~ Member State, ~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such products.
- They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**
- ~~7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a product in accordance with paragraph 1.~~
8. ~~The application of Articles 38a to 38g and the use of the authorisation procedure set out in paragraphs 1~~ **to 1c** ~~of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned.

Presumption of conformity based on national and international standards

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that the products which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex II comply with those essential health and safety requirements in either of the following cases:~~

- ~~(a) — where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Directive is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;~~

~~where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

~~Adoption of common specifications conferring a presumption~~ **Presumption of conformity based on standards and common specifications**

1. Where products¹ 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 essential health and safety requirements set out in Annex II in either of the following cases:
 - (a) ~~where~~ no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential health and safety requirements set out in Annex II, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**

(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential health and safety requirements set out in Annex II; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to products placed on the market until the last day of the period for which the Single Market emergency mode remains active, **unless amended or repealed in accordance with paragraph 5.**

2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under relevant sectoral Union legislation **this Directive and shall duly consult all relevant stakeholders.** Based on that consultation, the Commission shall prepare the draft implementing act..

3. Without prejudice to Article 12, products which are in conformity with **the standards or common specifications adopted pursuant referred to in paragraph 21 of this Article, or parts thereof**, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those **standards or common specifications or parts thereof**. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. 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 **which are in conformity** ~~compliance~~ with these **standards or common specifications** **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential health and safety requirements set out in Annex II** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. When a Member State considers that a **standard or common specification** referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements ~~which it aims to cover and which are~~ set out in Annex II, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation, ~~and~~ **The Commission shall assess that detailed explanation** information and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex II for products, which have been designated as crisis relevant goods.~~
- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the products in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.~~

Article 38g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for products designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for products designated as crisis-relevant goods.’

Article 12

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(16) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/35/EU, the following ~~chapter~~Chapter 4a is inserted:

‘CHAPTER 4a
EMERGENCY PROCEDURES

Article 22a

Application of emergency procedures

1. Member States shall ensure that measures taken to transpose Articles 22b to 22c and 22d of this Directive ~~only~~ apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **electrical equipment covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 22b, 22c and 22d apply exclusively to electrical equipment, which has been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 22b, 22c and 22d **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.
4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 Articles 22b and 22c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

~~Adoption of common specifications conferring a presumption~~ **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 and set out in Annex I in either of the following cases:
 - (a) ~~where~~ no reference to harmonised standards covering the safety objective set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the safety objectives referred to in Article 3 and set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the safety objectives referred to in Article 3 and set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**

(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the safety objectives referred to in Article 3 and set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 23(2). They shall apply to electrical equipment placed on the market until the last day of the period for which the Single Market emergency mode remains active, **unless amended or repealed in accordance with paragraph 5.**

2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft** **implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under relevant sectoral Union legislation **this Directive and shall duly consult all relevant stakeholders.** Based on that consultation, the Commission shall prepare the draft implementing act..

3. Without prejudice to Articles 12, 13 and 14, electrical equipment which is in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred to in** paragraph ~~21 of 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 covered by those **standards or** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that the 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 **which is in conformity** ~~compliance~~ with these **standards or** common specifications **and** which has been placed on the market shall be deemed compliant with ~~this Directive~~ **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 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. 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 ~~with~~ **by submitting** a detailed explanation, ~~and~~ **The Commission shall assess that** **detailed explanation** ~~information~~ and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

Article 22e

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the safety objectives referred to in Article 3 and set out in Annex I for electrical equipment, which has been designated as crisis relevant goods.~~
- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article, shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 23(2). They shall apply to electrical equipment placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that the electrical equipment covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the electrical equipment in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.~~

Article 22d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for electrical equipment designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for electrical equipment designated as crisis-relevant goods.’

Article 13

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];

(28) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/53/EU, the following ~~chapter~~Chapter 5a 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 43g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **radio equipment covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply exclusively to radio equipment, which has been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.
3. Member States shall ensure that measures taken to transpose Articles 43b to 43g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 43c(2), second subparagraph, and Article 43c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** ~~be empowered to lay down by means of implementing acts rules regarding the follow-up actions~~ **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 to 43f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Prioritisation of the conformity assessment of crisis-relevant radio equipment

1. This Article shall apply to all radio equipment designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17 requiring mandatory involvement of a notified body.
2. The notified bodies shall process all applications for conformity assessment of radio equipment designated as crisis-relevant goods as a matter of priority-, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.**
- ~~3. All pending applications for conformity assessment of such radio equipment shall be processed as a matter of priority, ahead of any other applications for conformity assessment of radio equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of radio equipment designated as crisis-relevant good, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.~~
4. The prioritisation of applications for conformity assessment of radio equipment pursuant to paragraph ~~3~~**2** shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
- ~~5. The notified bodies shall deploy their best efforts to increase their testing capacities for radio equipment designated as crisis-relevant goods in respect to which they have been notified.~~

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

1. By way of derogation from Article 17, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of specific radio equipment which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring mandatory involvement of a notified body, referred to in that Article have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential requirements has been demonstrated in accordance with procedures referred to in that authorisation.

- 1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the essential requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the 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. 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 modalities 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.

1b. The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 45(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).

When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of radio equipment subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the radio equipment concerned complies with all the applicable essential requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer, the importer and the distributor shall also deploy all reasonable measures to ensure that the radio equipment, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which has granted the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ pursuant to paragraph 1 shall set out the conditions and requirements under which the radio equipment may be placed on the market, ~~including~~ **The authorisations shall at least set out the following:**
- (a) a description of the procedures, by means of which the compliance with the applicable essential requirements of this Directive was successfully demonstrated;
 - (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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
 - (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the radio equipment concerned;
 - (e) measures to be taken with respect to the radio equipment ~~concerned~~ **placed on the market** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the radio equipment concerned is brought back in compliance with all the requirements of this Directive.~~
4. 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 leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 9 shall not apply.**

5. The market surveillance authorities of the a Member State, whose competent authority has ~~granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such radio equipment.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

- ~~6. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of radio equipment in accordance with paragraph 1.~~
7. The ~~application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraphs 1~~ **to 1c** of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned.

Article 43d

~~Presumption of conformity based on national and international standards~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the radio equipment which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Article 3, complies with those essential requirements in either of the following cases:~~

- ~~(a) where no reference to harmonised standards covering the relevant essential requirements set out in Article 3 of this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~

~~(b) severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Article 3 of this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

Article 43e

~~Adoption of common specifications conferring a presumption~~ **Presumption of conformity based on standards and common specifications**

1. Where radio equipment² 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 essential requirements set out in Article 3 in either of the following cases:
 - (a) ~~where~~ no reference to harmonised standards covering the relevant essential requirements set out in Article 3 has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article ~~14~~¹⁵(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Article 3 of this Article and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Article 3, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**
- (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Article 3; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;**
- (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.**

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following ~~a consultation of the sectoral experts and~~ in accordance with the examination procedure referred to in Article 45(3). They shall apply to radio equipment placed on the market until the last day of the period for which the Single Market emergency remains active, **unless amended or repealed in accordance with paragraph 5.**

- 2a. ~~In the early~~ **Before** ~~preparation~~**ing** of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under ~~relevant sectoral Union legislation~~ **this Directive and shall duly consult all relevant stakeholders**. Based on that consultation, the Commission shall prepare the draft implementing act..
3. Without prejudice to Article 16, radio equipment which is in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred to in** paragraph ~~21~~ **21** of this Article, **or parts thereof,** shall be presumed to be in conformity with the essential requirements set out in Article 3 covered by those **standards or** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. 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 **which is** in **conformity** ~~compliance~~ with those **standards or** common specifications **and** which has been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential requirements set out in Article 3** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*

5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential requirements ~~which it aims to cover and which are~~ set out in Article 3, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation, ~~and the Commission shall assess that~~ **detailed explanation** ~~information~~ and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Article 43f~~

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Article 3 for radio equipment, which has been designated as crisis-relevant goods.~~
- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3) and they shall apply to radio equipment placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

- ~~3. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the radio equipment covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the radio equipment in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Article 43g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for radio equipment designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for radio equipment designated as crisis-relevant goods.’

Article 145

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’ within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];**

(34) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].”;

(2) In Directive 2014/68/EU, the following **chapter**Chapter 5a 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 43g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **pressure equipment and assemblies covered by** this Directive.
2. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply exclusively to pressure equipment and assemblies, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~ **pursuant to Article 14 of [the SMEI Regulation]**.

3. Member States shall ensure that measures taken to transpose Articles 43b to 43g **shall** apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 43c(2), second subparagraph, and Article 17 43c(5)~~ shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission ~~shall~~ **may adopt** be empowered to lay down by means of implementing acts ~~rules regarding the follow-up actions~~ **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 in accordance with Articles 43c to 43f. 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 crisis-relevant pressure equipment and assemblies

1. This Article shall apply to pressure equipment or assemblies designated as crisis-relevant goods, which are subject to conformity assessment procedures, which require the mandatory involvement of a notified body, in accordance with Article 14.
2. The notified bodies shall process all applications for conformity assessment of pressure equipment and assemblies designated as crisis-relevant goods as a matter of priority, **irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.**

3. ~~All pending applications for conformity assessment of such in accordance with Article 14 shall be processed as a matter of priority, ahead of any other applications for conformity assessment of pressure equipment or assemblies, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of pressure equipment and assemblies designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.~~
4. The prioritisation of applications for conformity assessment of pressure equipment and assemblies pursuant to paragraph 32 shall not give rise to any **disproportionate** additional costs for the manufacturers, who have lodged those applications.
5. ~~The notified bodies shall deploy their best efforts to increase their testing capacities for pressure equipment and assemblies designated as crisis-relevant goods in respect of which they have been notified.~~

Article 43c

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

1. By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of specific pressure equipment or assembly designated as crisis-relevant good and for which the conformity assessment procedures referred to in that Article have not been carried out ~~by a notified body~~ but for which the compliance with all the applicable essential safety requirements has been demonstrated **in accordance with procedures referred to in that authorisation.**

1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure conformity with the applicable essential safety requirements laid down in this Directive, the Commission shall without delay ~~but not earlier than 5 days after receiving the information,~~ adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the pressure equipment or assemblies 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. 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 it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities 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.

1b. ~~The implementing acts referred to in paragraph 1a shall be adopted in accordance with the examination procedure referred to in Article 44(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).~~

~~When preparing the draft implementing act referred to in this paragraph, the Commission shall consult the national market surveillance authorities with respect to the technical assessment, which served as the basis for the authorisation in paragraph 1.~~

1c. As long as the an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.

Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

2. The manufacturer of pressure equipment or assembly subject to the authorisation procedure referred to in paragraph 1 of this Article shall declare on his sole responsibility that the pressure equipment or assembly concerned complies with all the applicable essential safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the pressure equipment or assembly, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, issued the authorisation.~~

3. Any authorisation issued ~~by a national competent authority~~ 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 put into service, ~~including~~ **The authorisations shall at least set out the following:**

- (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of 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 Single Market emergency mode has been activated **in accordance with Article 14 of [the SMEI Regulation]**;
- (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the pressure equipment or assembly concerned;
- (e) measures to be taken with respect to the pressure equipment or assembly ~~concerned~~ **placed on the market** upon expiry of the authorisation **Single Market emergency** ~~in order to ensure that the pressure equipment or assembly concerned is brought back in compliance with all the requirements of this Directive.~~

~~4. By way of derogation from Article 43a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~

5. 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 leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking~~ **and Article 5 shall not apply.**

6. The market surveillance authorities of the **a** Member State, ~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**, shall be entitled to take all corrective and restrictive measures **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Directive with respect to such pressure equipment or assemblies.

They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.

- ~~7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a pressure equipment or assembly in accordance with paragraph 1.~~
8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraphs 1 **to 1c** of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 43d

~~Presumption of conformity based on national and international standards~~

~~Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the pressure equipment or assemblies which comply with relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential safety requirements set out in Annex II, comply with those essential safety requirements in either of the following cases:~~

- ~~(a) where no reference to harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~
- ~~(b) where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

~~Adoption of common specifications conferring a presumption~~ **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 ~~for such pressure equipment and assemblies~~ **listing appropriate standards or** establishing common specifications **for such pressure equipment and assemblies** to cover the essential safety requirements set out in Annex II in either of the following cases:
 - (a) ~~where~~ no reference to harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
 - (b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 145(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

1a. The implementing acts referred to in paragraph 1 may :

- (a) **publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**
- (b) **if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential safety requirements set out in Annex I, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**

(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential safety requirements set out in Annex I; establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;

(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.

2. The implementing acts referred to in paragraph 1 ~~of this Directive~~ shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to the pressure equipment and assemblies placed on the market until the last day of the period for which the Single Market emergency mode remains active, **unless amended or repealed in accordance with paragraph 5.**

2a. ~~In the early~~ **Before** preparation ~~ing~~ of the draft implementing act **referred to in paragraph 1** ~~establishing the common specification,~~ **the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1,** the Commission shall ~~gather~~ **take into account** the views of relevant bodies or expert groups established under relevant sectoral Union legislation **this Directive and shall duly consult all relevant stakeholders.** ~~Based on that consultation, the Commission shall prepare the draft implementing act..~~

3. Without prejudice to Article 12, pressure equipment or assemblies which are in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred to in** paragraph ~~21 of this Article~~, **or parts thereof**, shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those **standards or** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**
4. 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 **which are in conformity** ~~compliance~~ with these **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential safety requirements set out in Annex I** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.
5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential safety requirements ~~which it aims to cover and which are~~ set out in Annex I, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation. ~~and~~ **The Commission shall assess that detailed explanation** information and, if appropriate, amend or ~~withdraw~~ **repeal** the implementing act **listing the standard or** establishing the common specification in question.

~~Adoption of mandatory common specifications~~

- ~~1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential safety requirements set out in Annex II, for pressure equipment or assemblies, which have been designated as crisis relevant goods.~~
- ~~2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to pressure equipment and assemblies placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~
- ~~3. 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 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 in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].~~

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for pressure equipment and assemblies designated as crisis-relevant goods. **The Commission shall facilitate coordination of these 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 deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, 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 reinforcement of the testing capacity for pressure equipment and assemblies designated as crisis-relevant goods.’

Article 15

Transposition

1. **By ... [OP: Please insert the date identical to that of the entry into application of the SMEI Regulation]** Member States shall adopt and publish, by ~~[OP: please insert date 6 months after entry into force of this Directive]~~ at the latest, the laws, regulations and administrative provisions **the measures** necessary to comply with this Directive. They shall **immediately inform** ~~forthwith communicate to~~ the Commission **thereof** ~~the text of those provisions.~~

~~2.~~ They shall apply those ~~measures~~provisions from [...] **[OP: please insert the date of the entry into application of the SMEI Regulation + 1 day]** ~~please add date 6 months after the date of entry into force of this Directive].~~

When Member States adopt those ~~measures~~provisions, they shall contain a reference to this Directive or **shall** be accompanied by such a reference on the occasion of their official publication. **The methods of making** ~~Member States shall determine how such reference is to be made~~ **shall be laid down by Member States.**

~~23.~~ **As soon as this Directive has entered into force,** Member States shall **ensure that** ~~communicate to 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** ~~the text of the main provisions of national law which they adopt in the field covered by this Directive.~~

Article 16

Entry into force

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

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President
