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From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	13714/23
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Subject:	Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency 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 regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency - Mandate for negotiations with the European Parliament

Delegations will find attached the text of the mandate for negotiations with the European Parliament as endorsed by the Coreper at its meeting on 11 October 2023.

ANNEX I

2022/0279 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009 and~~ (EU) No 305/2011 and (EU) 2023/1230 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 Article 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

Whereas:

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1 OJ C, , p. .

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

(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 to further enhance the effectiveness of such measures, it is appropriate to ensure that 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.

(6) A number of Union 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 Regulations (EU) 2016/424[3], (EU) 2016/425[4], (EU) 2016/426[5],~~ (EU) 2019/1009[6] and~~ (EU) No 305/2011[7] **and (EU) No 2023/1230[8]** of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 ~~and (EU) 2019/1009~~ **and (EU) No 2023/1230** are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council[9].

(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral **U**nion~~U~~ harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.

(8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for 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*].

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3 OJ L 81, 31.3.2016, p. 1.
4 OJ L 81, 31.3.2016, p. 51.
5 OJ L 81, 31.3.2016, p. 99.
6 ~~OJ L 170, 25.6.2019, p. 1.~~
7 OJ L 88, 4.4.2011, p. 5.
8 OJ L 165, 29.6.2023, p 1.
9 OJ L 218, 13.8.2008, p. 82.

(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.**

(10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009 and~~ (EU) No 305/2011 **and (EU) 2023/1230**. Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [*insert reference to SMEI Regulation*].

(11) Furthermore, in cases**, for example,** where 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 Regulations 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 Regulations, 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 the conformity** with all 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 Regulations 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 Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that 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 the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting 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 Regulation 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 Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230 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 irrespectively 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 Union harmonisation legislation 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 Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 ~~and, (EU) 2019/1009,~~ **and (EU) 2023/1230** 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 1025/2012[10] **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 Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426~~, (EU) 2019/1009~~**,** ~~and~~ (EU) No 305/2011 **and (EU) 2023/1230**, 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 Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, 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.~~

(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.

[10] OJ L 316, 14.11.2012, p. 12.

(18a) In accordance with the relevant provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation 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) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, ~~(EU) 2019/1009 and~~ (EU) No 305/2011 **and (EU) 2023/1230** should therefore be amended accordingly~~,~~**.**

(21) In order for this Regulation to apply from the same date as [*SMEI Regulation*], its application should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2016/424

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

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

"(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation]";

(29) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].";

(2) T~~t~~he following Chapter V~~I~~a is inserted **after Chapter V**:

‘CHAPTER V~~I~~a

EMERGENCY PROCEDURES

Article 43a

Application of emergency procedures

1. Articles 43b to 43g 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 **subsystems and safety components covered by** this Regulation.

2. Articles 43b to 43g ~~shall~~ apply exclusively to subsystems and safety components, which have been designated as crisis-relevant goods **pursuant to Article 14 of [the SMEI Regulation]**~~in the implementing act referred to in paragraph 1 of this Article~~.

3. Articles 43b to 43g, except as regards ~~provisions concerning~~ the power~~s~~ of the Commission **in Article 43e(5)**, 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 **may adopt**~~shall be empowered to lay down by means of~~ implementing acts ~~rules~~ regarding the **corrective or restrictive actions**~~follow-up actions~~ to be taken**, the procedures to be followed and the specific labelling and traceability requirements** with respect to subsystems and safety components placed on the market in accordance with Articles 43c to 43~~f~~**e**. 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 subsystems and safety components

1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components 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 subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of subsystems and safety components 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 subsystems and safety components 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 subsystems and safety components 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 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within the territory of the Member State concerned, of a specific subsystem or safety component 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 18 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 the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay 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 specific subsystem or safety component 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 44(3).

The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the 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. 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).

1c. As long as 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 subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the subsystem or safety component, 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 subsystem or safety component may be placed on the market or incorporated into a cableway installation**.**~~, including~~ **The authorisations shall at least set out the following**:

(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;

(b) **any** specific requirements regarding the traceability of the subsystem or safety component concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated 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 subsystem or safety component concerned;

(e) measures to be taken with respect to the subsystem or safety component ~~concerned~~ **placed on the market** upon expiry of the ~~authorisation~~ **Single Market emergency** ~~in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation~~.

~~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 3also after the deactivation or expiry of the Single Market Emergency mode.~~

5. By way of derogation from Articles 7**, 20** and 2~~0~~**1**, subsystems or safety components, 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 7 shall not apply**.

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

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 subsystems or safety components in accordance with paragraph 1.~~

8. The ~~application of Articles 43a to 43g and the~~ use of the authorisation procedure set out in paragraph 1 **to 1c** ~~of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 18 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 subsystems and safety components, 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 Annex II, 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 II is published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;~~

~~Where~~

~~(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 Annex II to this Regulation 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 subsystems and safety components~~,~~ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts ~~establishing~~**, listing appropriate standards or establishing** common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:

   (a) ~~where~~ no reference to harmonised standards covering the relevant essential requirements set out in Annex II 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 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 II ~~to this Regulation~~ 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 Annex II [to this Regulation], 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 Annex II [to this Regulation], 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 44(3) and they shall apply ~~to subsystems or safety components 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** prepara~~tion~~**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 **take into account** ~~gather~~ the views of relevant bodies or expert groups established under **this Regulation** ~~relevant sectoral Union legislation~~ **and shall duly consult all relevant stakeholders**. ~~Based on that consultation, the Commission shall prepare the draft implementing act.~~

3. Without prejudice to Article 17, subsystems and safety components which are in conformity with **the standards or** common specifications ~~adopted pursuant to paragraph 2 of this Article~~ **referred to in paragraph 1, or parts thereof,** shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those **standards,** 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 subsystems or safety components covered by the **standards or** common specifications referred to in paragraph 1 ~~of this Article~~ present a risk to the health or safety of persons, the subsystems or safety components **which are** in **conformity** ~~compliance~~ with the ~~said~~ **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with **the essential requirements set out in Annex II** ~~this Regulation~~ 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 Annex II, it shall inform the Commission thereof ~~with~~ **by submitting** a detailed explanation**. T**~~and t~~he 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 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 Annex II for subsystems or safety components, 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 subsystems or safety components 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 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation 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 subsystems and safety components 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 subsystems and safety components designated as crisis-relevant goods.

Article 2

Amendments to Regulation (EU) 2016/425

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

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

"(19) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation]";

(20) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].";

(2) ~~, t~~**T**he following Chapter VIa is inserted **after Chapter VI**:

'CHAPTER VIa

EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures

1. Articles 41b to 41g 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 **PPE covered by** this Regulation.

2. Articles 41b to 41g ~~shall~~ apply exclusively to PPE, which has been designated as **a** crisis-relevant good~~s~~ **pursuant to Article 14 of [the SMEI Regulation]**~~in the implementing act referred to in paragraph 1~~.

3. Articles 41b to 41g, except as regards ~~provisions concerning~~ the power~~s~~ of the Commission **in Article 41e(5)**, shall apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

However, ~~Article 41c(2), second subparagraph, and~~ Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

4. The Commission **may adopt** ~~shall 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 PPE placed on the market in accordance with Articles 41c to 41~~f~~**e**. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 41b

Prioritisation of the conformity assessment of crisis-relevant PPE

1. This Article shall apply to PPE designated as **a** crisis-relevant good~~s~~, which **is**~~are~~ subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of PPE designated as **a** crisis-relevant good~~s~~ 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 PPE shall be processed as a matter of priority, ahead of any other applications for conformity assessment of PPE, which has not been designated as crisis-relevant goods. This requirement applie with respect to all applications for conformity assessment of PPE designated as crisis-relevant good, 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 PPE 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 PPE designated as crisis-relevant goods in respect to which they have been notified.~~

Article 41c

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

1. By way of derogation from Article 19, 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 PPE which has been designated as **a** crisis-relevant good for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out 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 the conformity with the applicable essential health and safety requirements laid down in Annex II to this Regulation, the Commission shall without delay 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 specific PPE may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).

The specific PPE subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the 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. 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).

1c. As long as 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 PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE 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 **competent** national ~~competent~~ authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the PPE, 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 PPE 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 health and safety requirements was successfully demonstrated;

(b) **any** specific requirements regarding the traceability of the PPE concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the 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 PPE concerned;

(e) measures to be taken with respect to the PPE ~~concerned~~ **placed on the market** upon expiry of the **Single Market emergency**~~authorisation in order to ensure that the PPE concerned is brought back in compliance with all the requirements of this Regulation~~.

~~4. 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 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~

5. By way of derogation from Articles 7**, 16** and 17, PPE, for which an authorisation has been granted in accordance with paragraph 1 ~~of this Article, shall not leave the territory of the Member State which has issued the authorisation and~~ shall not bear the CE marking **and Article 7 shall not apply**.

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

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 PPE in accordance with paragraph 1.~~

8. The ~~application of Articles 41a to 41g and the~~ use of the authorisation procedure set out in paragraph**s** 1 **to 1c** ~~of this Article~~ does not affect the application of the relevant conformity assessment procedures laid down in Article 19 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, their competent authorities consider that the PPE, 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 health and safety requirements set out in Annex II, 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 II 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 II to this Regulation 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 PPE~~,~~ ha~~ves~~ been designated as **a** crisis-relevant good~~s~~, the Commission is empowered to adopt implementing acts**,** ~~establishing~~ **listing appropriate standards or establishing** common specifications for such PPE to cover the **applicable** 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~~**applicable** essential health and safety requirements set out in Annex II 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 led to the activation Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the ~~relevant~~ **applicable** essential health and safety requirements set out in Annex II to this Regulation 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 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 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 44(3). They shall remain applicable ~~to PPE 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** prepara~~tion~~**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 group~~s~~ established **under this Regulation and shall duly consult all relevant stakeholders.**~~under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.~~

3. Without prejudice to Article 14, PPE which ~~are~~**is** in conformity with **the standards or** common specifications **referred to in**~~adopted pursuant to~~ paragraph **1**~~2 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,** 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 PPE covered by the **standards or** common specifications referred to in paragraph 1 of this Article present**s** a risk to the health or safety of persons, the PPE **which is** in ~~compliance~~ **conformity** with those **standards or** common specifications **and** which has been placed on the market shall be deemed compliant with **the essential requirements set out in Annex II** ~~this Regulation~~ 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** a common specification referred to in paragraph 1 does not entirely satisfy the **applicable** essential health and safety requirements ~~which it aims to cover and which are~~ set out in Annex II, it shall inform the Commission thereof **by submitting** ~~with~~ a detailed explanation and 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 41f*~~

~~**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 health and safety requirements set out in Annex II for PPE, 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 44(3). They shall apply to PPE 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 PPE 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 PPE in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation 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 PPE designated as **a** crisis-relevant good~~s~~. **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 PPE designated as **a** crisis-relevant good~~s~~.'

Article 3

Amendments to Regulation (EU) 2016/426

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

(1) In Article 2 the following points is are added:

"(32) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation]";

(33) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].";

(2) ~~,~~ ~~t~~**T**he following Chapter V~~I~~a is inserted after Chapter V~~I~~:

‘CHAPTER V~~I~~a

EMERGENCY PROCEDURES

Article 40a

Application of emergency procedures

1. Articles 40b to 40g 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 **appliances and fittings covered by** this Regulation.

2. Articles 40b to 40g ~~shall~~ apply exclusively to appliances and fittings, which has been designated as crisis-relevant goods **pursuant to Article 14 of [the SMEI Regulation]** ~~in the implementing act referred to in paragraph 1 of this Article~~.

3. Articles 40b to 40g, except as regards ~~provisions concerning~~ the power~~s~~ of the Commission **in Article 40e(5)**, shall apply **only** during the Single Market emergency mode ~~remains active~~ **activated in accordance with Article 14 of [the SMEI Regulation]**.

   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 **may adopt**~~shall be empowered to lay down by means of~~ implementing acts ~~rules~~ regarding the **corrective or restrictive actions** ~~follow-up actions~~ to be taken**, the procedures to be followed and the specific labelling and traceability requirements** with respect to appliances and fittings placed on the market in accordance with Articles 40c to 40~~f~~**e**. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

Article 40b

Prioritisation of the conformity assessment of crisis-relevant appliances and fittings

1. This Article shall apply to all appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of appliances and fittings 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 appliances and fittings designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for appliances and fittings, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of appliances and fittings 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 appliances and fittings 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 appliances and fittings designated as crisis-relevant goods in respect to which they have been notified.~~

Article 40c

Derogation from 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 appliance or fitting 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 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 the conformity with the essential requirements laid down in Annex I to this Regulation, the Commission shall without delay 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 specific appliance or fitting 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 specific appliance or fitting subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market 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. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).

1c. As long as 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 appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the appliance or the fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.

~~The manufacturer shall also deploy all reasonable measures to ensure that the appliance or fitting, 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 appliance or fitting may be placed on the market**.**~~, including~~ **The authorisation shall at least set out the following**:

(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;

(b) **any** specific requirements regarding the traceability of the **appliance or fitting** ~~subsystem or safety component~~ concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated **in accordance with Article 14 [the SMEI Regulation].**

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the **appliance or fitting**~~subsystem or safety component~~ concerned;

(e) measures to be taken with respect to the appliance or fitting ~~concerned~~ **placed on the market** upon expiry of the ~~authorisation~~ **Single Market emergency**~~in order to ensure that the appliance or fitting concerned is brought back in compliance with all the requirements of this Regulation~~.

~~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 6**, 16** and 17, appliances or fittings, 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, **where an authorisation pursuant to paragraphs 1, 1a and 1c is valid**~~whose competent authority has granted an authorisation pursuant to paragraph 1~~ shall be entitled to take all corrective and restrictive ~~measures~~ **actions** at national level provided for under **Regulation (EU) 2019/1020 and under** this Regulation with respect to such appliances or fittings.

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 appliances or fittings in accordance with paragraph 1.~~

8. The ~~application of Articles 40a to 40g and the~~ use of the authorisation procedure set out in paragraph**s** 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 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 or putting into service, their competent authorities consider that appliances and fittings, 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 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 safety requirements set out in Annex I 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 health and safety requirements set out in Annex I to this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.~~

Article 40e

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

1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts**,** ~~establishing~~ **listing appropriate standards or establishing** common specifications for such appliances or fittings 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 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 led to the activation of the Single Market emergency mode in accordance with Article 1**4**~~5~~(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 in this Regulation 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 Annex I to this Regulation, 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 Annex I to this Regulation, 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 appliances and fittings placed on the market no longer than~~ 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** prepara~~tion~~**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 **take into account** ~~gather~~ the views of relevant bodies or expert groups established under **the Regulation**~~relevant sectoral Union legislation~~. ~~Based on that consultation, the Commission shall prepare the draft implementing act.~~

3. Without prejudice to Article 13, appliances or fittings which are in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred** to **in** paragraph ~~2~~**1** ~~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,** 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 date 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 appliances or fittings covered by the **standards or** common specifications referred to in paragraph 1 ~~of this Article~~ present a risk to the health or safety of persons, the appliances or fittings **which are** in **conformity** ~~compliance~~ with those **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with **the essential requirements set out in Annex I to** this Regulation 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 Annex I, it shall inform the Commission thereof **by submitting** ~~with~~ a detailed explanation**.** ~~and the~~ **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 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 appliances or fittings, 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 appliances or fittings placed on the market at the latest until the last day of the period for which the Single Market emergency 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 appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation 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. The Member States shall prioritise the market surveillance activities for appliances and fittings 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 appliances and fittings designated as crisis-relevant goods.

~~*Article 4*~~

~~**Amendments to Regulation (EU) 2019/1009**~~

~~In Regulation (EU) 2019/1009, the following Chapter Va is inserted:~~

~~**CHAPTER Va**~~

~~**EMERGENCY PROCEDURES**~~

~~*Article 41a*~~

~~**Applicationof emergency procedures**~~

~~1. Articles 41b to 41g 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 this Regulation.~~

~~2. Articles 41b to 41g shall apply exclusively to fertilising products, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.~~

~~3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.~~

~~However, Article 41c(2), second subparagraph, and Article 41c(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 fertilising products placed on the market in accordance with Articles 41c to 41f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).~~

~~*Article 41b*~~

~~**Prioritisation of the conformity assessment of crisis-relevant fertilising products**~~

~~1. This Article shall apply to fertilising products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 15 requiring mandatory involvement of a notified body.~~

~~2. The notified bodies shall process all applications for conformity assessment of fertilising products designated as crisis-relevant goods as a matter of priority.~~

3. All pending applications for conformity assessment of fertilising products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of fertilising products, which have not been designated as crisis-relevant goods. This requirement is applicable with respect to all applications for conformity assessment of fertilising 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 41a.

4. The prioritisation of applications for conformity assessment of fertilising products 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 fertilising products designated as crisis-relevant goods in respect of which they have been notified.

Article 41c

Derogation from 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 placing on the market within the territory of the Member State concerned, of a specific fertilising product 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 15 have not been carried out by a notified body but for which the compliance with the requirements set out in Annexes I and II has been demonstrated.

2. The manufacturer of a fertilising product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the fertilising product concerned complies with the requirements set out in Annexes I and II 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 fertilising 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 fertilising products may be placed on the market, including:~~

~~(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;~~

~~(b) specific requirements regarding the traceability of the fertilising 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;~~

~~(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the fertilising product;~~

~~(e) measures to be taken with respect to the fertilising product concerned upon expiry of the authorisation in order to ensure that the fertilising product concerned is brought back in compliance with all the requirements of this Regulation.~~

~~4. 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 3of this Article also after the deactivation or expiry of the Single Market Emergency mode.~~

~~5. By way of derogation from Articles 3 and 18, fertilising 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.~~

~~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 Regulation with respect to such fertilising products.~~

~~7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of fertilising products in accordance with paragraph 1.~~

~~8. The application of Articles 41a to 41g 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 15 on the territory of the Member State concerned.~~

~~*Article 41d*~~

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

~~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 requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012, the Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force in the Member State of manufacture, ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III.~~

Article 41e

Adoption of common specifications conferring a presumption of conformity

1. Where EU fertilising products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) where severe disruptions in the functioning of the Single Market, which led to the activation of [were taken into consideration when] the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation 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 45(3). They shall apply to EU fertilising products placed on the market until the last day of the period for which the Single Market emergency mode remains active in accordance with [the SMEI Regulation]. 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. Without prejudice to Article 13, EU fertilising products which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the requirements set out in Annex I, II or III [or tests referred to in Article 13(2)] covered by those common specifications or parts thereof.

4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation 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 requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed explanationand the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.

Article 41f

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications for EU fertilising products to cover the requirements set out in Annexes I and II 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 45(3) and they shall apply to EU fertilising 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 41a(3), first subparagraph, unless there is sufficient reason to believe that the EU fertilising 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 fertilising products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation 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 fertilising products 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 fertilising products designated as crisis-relevant goods.'7~~

Article 5

Amendments to Regulation (EU) No 305/2011

~~In~~ Regulation (EU) 305/2011 is amended as follows:

(1) In Article 2 the following points is are added:

"(29) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation]";

(30) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].";

(2) The following Chapter VIIIa is inserted **after Chapter VIII**:

‘‘**CHAPTER VIIIa**

EMERGENCY PROCEDURES

Article 59a

Application of emergency procedures

1. Articles 59b to 59f 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 **construction products covered by** this Regulation.

2. Articles 59b to 59f ~~shall~~ apply exclusively to construction products, which have been designated as crisis-relevant goods **pursuant to Article 14 of [the SMEI Regulation]**~~in the implementing act referred to in paragraph 1 of this Article~~.

3. Articles 59b to 59f, except as regards ~~provisions concerning~~ the power~~s~~ of the Commission **in Article 59d(5)**, shall apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.

   ~~However, Article 59c(2), second subparagraph, and Article 59c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.~~

4. The Commission **may adopt** ~~shall be empowered to lay down by means of~~ implementing acts ~~rules~~ regarding the **corrective or restrictive actions**~~follow-up actions~~ to be taken**, the procedures to be followed and the specific labelling and traceability requirements** with respect to construction products placed on the market in accordance with Articles 59b to 59~~f~~**d** These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)

Article 59b

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

1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1).

2. The notified bodies shall process requests for third party tasks related to the assessment and verification of constancy of performance of construction 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 59a.**

~~3. All pending applications for the performance of third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications regarding construction products, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for third party tasks related to the assessment and verification of constancy of performance of construction 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 59a.~~

4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction 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 respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.~~

Article 59c

Derogation from the third party assessment procedures for assessment and verification of constancy of performance

1. By way of derogation from Article 28(1), the competent national authority may exceptionally authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in that Article have not been carried out by a notified body.

2. The manufacturer of a construction product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the construction product concerned achieves the declared performance and shall be responsible for the fulfilment of all the procedures for the assessment and verification of constancy of performance indicated by the national competent authority.

The manufacturer shall also deploy all reasonable measures to ensure that the construction 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 construction products may be placed on the market, including:

(a) a description of the procedures, to be followed in order to demonstrate that the construction product achieves the declared performance and complies with this Regulation, as applicable;

~~(b) the specific requirements regarding the safety as well as the traceability, including labelling, of the concerned construction product;~~

~~(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 continuous performance of third party tasks related to the assessment and verification of constancy of performance with respect to the concerned construction product;~~

~~(e) measures to be taken with respect to the construction product concerned upon expiry of the authorisation in order to ensure that the construction product concerned is brought back in compliance with all the requirements of this Regulation.~~

~~4. By way of derogation from Article 54a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation issued referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.~~

~~5. Construction 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.~~

~~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 Regulation with respect to such construction products.~~

~~7. Member States shall inform the Commission s of any decision to authorise the placing on the market of construction products in accordance with paragraph 1.~~

~~8. The application of Articles 59a to 59f and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant procedures for the assessment and verification of constancy of performance required by Article 28 on the territory of the Member State concerned.~~

Article 59d

Assessment and declaration of performance based on standards and common specifications

1. Where construction products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts**, listing appropriate standards or** establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases:

   (a) ~~where~~ no reference to harmonised standards covering the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics is published in the *Official Journal of the European Union* in accordance with Article 17(5);

   (b) ~~where~~ the severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the *Official Journal of the European Union* in accordance with Article 17(5).

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

(a) publish the references to relevant applicable international standards that include assessment methods for the declaration of performance in accordance with paragraph 3;

(b) if there are no relevant applicable international standards as referred to in point a of this paragraph published in the *Official Journal of the European Union* in accordance with Article 17(5) of this Regulation that cover the essential characteristics referred in paragraph 1, publish the references to the European standards that include assessment methods for the declaration of performance in accordance with paragraph 3;

(c) if there is no relevant applicable international or European standard as referred to in points a and b of this paragraph published in the *Official Journal of the European Union* in accordance with Article 17(5) of this Regulation that cover the essential characteristics referred in paragraph 1, establish common specifications established by the Commission that include assessment methods for the declaration of performance 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 include assessment methods for the declaration of performance 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 Standing Committee on Construction and~~ in accordance with the examination procedure referred to in Article 64(2a). They shall apply ~~to construction 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. **Before** ~~In the early~~ prepara~~tion~~**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 **take into account** ~~gather~~ the views of relevant bodies or expert groups established under ~~relevant sectoral Union legislation~~**this Regulation and shall duly consult all relevant stakeholders**. ~~Based on that consultation, the Commission shall prepare the draft implementing act.~~

3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the **standards and** common specifications ~~adopted pursuant to~~ **referred to in** paragraph 1 ~~of this Article~~, **or parts thereof,** may be used for assessing and declaring the performance of construction products covered by those **standards or** common specifications in relation to their essential characteristics. **Declaration of performance based on 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 59a(3), first subparagraph, **unless there is sufficient reason to believe that construction products covered by those standards or common specifications present a risk to the health and safety or fail to achieve the declared performance**, declaration of performance **of construction products which have been placed on the market** in compliance with the **standards or** common specifications referred to in paragraph 1 ~~of this Article regarding construction products which have been placed on the market~~ shall ~~not be affected by~~ **remain valid after** the ~~subsequent~~ expiry or repeal of the 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]**~~, which has laid down those common specifications, unless there is sufficient reason to believe that construction products covered by those common specifications present a risk or do not achieve the declared performance~~.

5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof **by submitting** ~~with~~ 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 59e*~~

~~**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 methods and the criteria for assessing the performance of construction products 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 Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products 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 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 59a(3), first subparagraph, unless there is sufficient reason to believe that the construction 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 construction products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation 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 59f

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for construction 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 construction products designated as crisis-relevant goods.'

(~~2~~**3**) In Article 64, 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 5a

Amendments to Regulation (EU) 2023/1230

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

(1) In Article 3 the following points is are added:

"(37) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation]";

(38) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].";

(2) The following Chapter IVa is inserted after Chapter IV:

‘CHAPTER IVa

EMERGENCY PROCEDURES

Article 25a

Application of emergency procedures

1. Articles 25b to 25e 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 machinery and related products covered by this Regulation.

2. Articles 25b to 25e apply exclusively to machinery and related products, which have been designated as crisis-relevant goods pursuant to Article 14 of [the SMEI Regulation].

3. Articles 25b to 25e, except as regards the power of the Commission in Article 25d(5), shall apply only during the Single Market emergency mode activated in accordance with Article 14 of [the SMEI Regulation].

However, Article 25c(4) shall apply during the Single Market emergency mode and after its deactivation or expiry.

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

Article 25b

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

1. This Article shall apply to all types of machinery and related products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 25 requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of machinery and related 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 25a.

3. The prioritisation of applications for conformity assessment of machinery and related products pursuant to paragraph 2 shall not give rise to disproportionate additional costs for the manufacturers, who have lodged those applications.

Article 25c

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

1. By way of derogation from Article 25, 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 and related products which have been designated as crisis-relevant goods and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 25, 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 the conformity with the essential requirements laid down in Annex III to this Regulation, the Commission shall without delay 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 specific machinery or the related products may be placed on the market or put into service. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).

The specific machinery or the related products subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market or put into service as a "crisis-relevant 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.

1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 48(4).

1c. **As long as 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 or the related products subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the machinery or the related products concerned comply with all the applicable essential requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.**

3. **Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery or the related products may be placed on the market or put into service. The authorisation shall at least set out the following:**

(a) **a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;**

(b) **any specific requirements regarding the traceability of the machinery and the related products concerned;**

(c) **an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated in accordance with Article 14 [the SMEI Regulation].**

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the machinery and the related products concerned;

(e) measures to be taken with respect to the machinery or the related products placed on the market upon expiry of the Single Market emergency.

4. By way of derogation from Articles 4, 23 and 24, machinery or the related products, for which an authorisation has been granted in accordance with paragraph 1 shall not bear the CE marking and Article 4 shall not apply.

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

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

6. The use of the authorisation procedure set out in paragraphs 1 to 1c does not affect the application of the relevant conformity assessment procedures laid down in Article 25 on the territory of the Member State concerned.

Article 25d

Presumption of conformity based on standards and common specifications

1. Where machinery or the related products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing common specifications for such machinery or the related products to cover the essential requirements set out in Annex III in either of the following cases:

(a) no reference to harmonised standards covering the relevant essential requirements set out in Annex III 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 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 in this Regulation 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 Annex III to this Regulation, 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 Annex III to this Regulation, 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 in accordance with the examination procedure referred to in Article 48(3). They shall apply 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. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert group established under the Regulation.

3. Without prejudice to Article 20, machinery and the related products which are in conformity with the standards or common specifications referred to in paragraph 1, or parts thereof, shall be presumed to be in conformity with the essential requirements set out in Annex III covered by those standards, 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 date the Single Market Emergency mode expires or is deactivated.

4. By way of derogation from Article 25a(3), first subparagraph, unless there is sufficient reason to believe that the machinery and the related products covered by the standards or common specifications referred to in paragraph 1 present a risk to the health or safety of persons, the machinery and the related products which are in conformity with those standards or common specifications and which have been placed on the market or put into service shall be deemed compliant with the essential requirements set out in Annex III to this Regulation 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 requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, if appropriate, amend or repeal the implementing act listing the standard or establishing the common specification in question.

Article 25e

Prioritisation of market surveillance activities and mutual assistance among authorities

1. The Member States shall prioritise the market surveillance activities for machinery and the related 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 machinery and the related products designated as crisis-relevant goods.'

Article 6

Entry into force

~~*Entry into force*~~

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

It shall apply from [*OP- please insert the date identical to that of the entry into application of the SMEI Regulation*].

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX II

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 Committee[11],

Having regard to the opinion of the Committee of the Regions[12],

[11] OJ C , , p. .
[12] OJ C , , p. .

Acting in accordance with the ordinary legislative procedure[13],

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.

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13 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/EC[14], 2006/42/EC[15], 2010/35/EU[16], ~~2013/29/EU[17],~~ ~~2014/28/EU[18]~~, 2014/29/EU[19], 2014/30/EU[20], ~~2014/31/EU[21], 2014/32/EU[22],~~ 2014/33/EU[23], 2014/34/EU[24], 2014/35/EU[25], 2014/53/EU[26] and 2014/68/EU[27] of the European Parliament

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14 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).

15 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).

16 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).

17 ~~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).~~

18 ~~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).~~

19 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).

20 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).

21 ~~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).~~

22 ~~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).~~

23 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).

24 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).

25 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).

26 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 Council[28].

(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 proprotionate 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.**

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27 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).

28 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 irrespectively 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 Directive**s** 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 1025/2012[29] **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 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, 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.~~

[29] 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~~.~~**.**

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 1~~9a~~**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 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. 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).

1c. As long as 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 paragraph**s** 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.'

(~~2~~**3**) Article 18~~,~~ 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.~~’~~

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:

‘*Article 21b*

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 goodsshall 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.~~

Article 21d

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 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. 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).

1c. As long as 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 paragraph**s** 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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**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 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 th~~ose~~ **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 t~~**T**he 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 **2**~~3~~ 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 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. 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).

1c. As long as 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 issue**d**~~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 paragraph**s** 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.**'**

(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 42c 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.

Article 42c

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.

Article 42e

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.’

Article 5

Amendments to Directive 2014/28/EU

In Directive 2014/28/EU, the following 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 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.

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 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 20requiring 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.~~

~~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 shall not give rise to any 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.~~

~~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 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:~~

~~(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 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;~~

~~(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 upon expiry of the authorisation 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 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.~~

~~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 explosives.

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 paragraph 1 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.

Article 45d

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 conside rthat 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.

Article 45e

Adoption of common specifications conferring a presumption of conformity

1. Where explosives, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts for such explosives establishing common specifications 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 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.

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]. 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 19, explosives 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 II 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 explosives covered by the 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 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 II, 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 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.~~

~~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.~~

Article 38c

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 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. 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).

1c. As long as 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 paragraph**s** 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..

Article 38d

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.

Article 38e

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

1. Where vessels~~,~~ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts ~~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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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, vessels which are in conformity with **the standards or** common specifications ~~adopted pursuant~~ **referred** to **in** paragraph ~~2~~**1** ~~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 th~~ose~~ **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 t~~**T**he 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 38f

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]*.

Article 38g

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.~~

Article 40c

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 14have 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 3also 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.~~

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 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.

Article 40e

~~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 requirements set out in Annex I, publish the references to the European standards that provide presumption of confomity 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 Annex I; establish common specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**1** ~~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 th~~ose~~ **standards or** common specifications **and** which have been placed on the market shall be deemed compliant with ~~this Directive~~ **the essential 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 t~~**T**he 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 40c 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.

Article 40c

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 13have 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 authorisationand 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.

Article 40e

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.'~~

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 45c 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 17requiring 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.

Article 45c

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.~~

Article 45d

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.

Article 45e

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, nnless 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.'~~

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 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 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. 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).

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 paragraph**s** 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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**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 th~~ose~~ **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 t~~**T**he 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).

Article 38b

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.~~

Article 38c

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 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. 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).

1c. As long as 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 paragraph**s** 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.

Article 38d

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:

(b) 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;

(c) 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.

Article 38e

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

1. Where products~~,~~ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts **listing appropriate standards or** establishing common specifications for such products to cover the 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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**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 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 th~~ose~~ **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 t~~**T**he 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 38f

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 ~~l~~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).

Article 22b

~~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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**1** ~~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 th~~ose~~ **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 t~~**T**he 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 22c

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).

Article 43b

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-relevantgood, 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.~~

Article 43c

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 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. 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).

1c. As long as 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 paragraph**s** 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 025/2012.~~

Article 43e

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

1. Where radio equipment~~,~~ has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts **listing appropriate standards or** establishing common specifications for such radio equipment to cover the 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 1**4**~~5(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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**1** ~~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, **u**~~n~~nless 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 th~~os~~e **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 t~~**T**he 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 14~~5~~

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~~ **43**c(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 14shall 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 beenlodged 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 ~~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 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 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. 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).

1c. **As long as 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 paragraph**s** 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.~~

Article 43e

~~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 I~~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~~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 1**4**~~5(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~~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 confomity 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 specificactions established by the Commission that provide presumption of confomity 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** prepara~~tion~~**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 ~~2~~**1** ~~of this Article~~, **or parts thereof,** shall be presumed to be in conformity with the essential safety requirements set out in Annex ~~I~~**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 43a(3), first subparagraph, ~~n~~**u**nless 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 th~~ose~~ **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 t~~**T**he 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 safety requirements set out in Annex II, ffor 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, nnless 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]*.

Article 43g

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**.

2~~3~~. **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	*For the Council*
The President	*The President*