Council of the
European Union

Brussels, 16 February 2024
(OR. en)

6336/24

Interinstitutional Files:
2022/0278(COD)
2022/0280(COD)
2022/0279(COD)

MI 141
COMPET 147
IND 67
CODEC 366
CONSOM 57
IPCR 7

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	6288/24
Subject:	Regulation on the Single Market Emergency Instrument Regulation amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures due to a Single Market emergency Directive 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 due to a Single Market emergency. - Letter to the Chair of the European Parliament IMCO Committee

Following the Permanent Representatives Committee meeting of 16 February 2024 which endorsed the final compromise text with a view to agreement, delegations are informed that the Presidency sent the attached letter, together with its Annex, to the Chair of the European Parliament IMCO Committee.

SGS 24 / 000911

Council of the
European Union

Brussels, 16 February 2024

Ms Anna CAVAZZINI
Chair of IMCO Committee
European Parliament
Rue Wiertz 60
BE – 1047 Brussels

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98 (doc. 12573/22)

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 (doc. 12576/22 + ADD1-5)

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 (doc. 12572/22 + ADD1-5)

Dear Ms Cavazzini,

Following the informal negotiations between the representatives of the three institutions, a draft overall compromise package was agreed today by the Permanent Representatives Committee.

I am therefore now in a position to confirm that, should the European Parliament adopt its position at first reading, in accordance with Article 294 paragraph 3 of the Treaty, in the form set out in the compromise package contained in the Annex to this letter (subject to revision by the legal linguists of both institutions), the Council would, in accordance with Article 294, paragraph 4 of the Treaty, approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.

Rue de la Loi/Wetstraat 175 – 1048 Bruxelles/Brussel – Belgique/België
Tel./Tél. +32 (0)2 281 61 11

ANNEX

▌

▌REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL▐

establishing a *framework of measures on the* **emergency** *and resilience of the internal market and amending* **Council Regulation** *(EC) No 2679/98 (Internal Market Emergency and Resilience Act)*

(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 ***21, 46 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[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

---

[1] OJ C , , p. .
[2] OJ C , , p. .

Whereas:

(1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the ***free movement of goods, persons and services in the internal*** market and its supply chains can be severely affected***. This may have consequences on cross-border trade between Member States, thus creating obstacles to the proper functioning of the internal market. Furthermore, during those crises,*** appropriate crisis management tools and coordination mechanisms ***were*** either lacking, ***did*** not cover all aspects of the ***internal*** market or ***did*** not allow for a timely ***and effective*** response to such ***crises***.

(2) ***In the early phase of the COVID 19 crisis Member States introduced barriers to free movement on the internal market as well as diverging measures on the supply of goods and services that were of critical importance or were indispensable for responding to the crisis, which could not always be justified.*** Ad-hoc measures taken by the Commission in order to re-establish the functioning of the ***internal*** market ***based on the existing rules were not sufficient. The Union was not sufficiently prepared to ensure efficient manufacturing, procurement and distribution of crisis-relevant non-medical goods such as personal protective equipment. Measures*** to ensure the availability of crisis-relevant non-medical goods during the COVID-19 ***crisis*** were necessarily reactive***.*** The pandemic also revealed insufficient ***information sharing and*** overview of manufacturing capacities across the Union as well as vulnerabilities related to the ***intra-EU and*** global supply chains.

(2a) Furthermore, uncoordinated measures restricting the free movement of persons had a particular impact on sectors that rely on mobile workers, including workers in border regions, who played an essential role in the internal market during that time.

(3) ***The Council could through the integrated political crisis response (IPCR) exchange information and coordinate certain actions with regard to the COVID 19 crisis, while Member States acted independently in other situations. However,*** actions by the Commission were delayed by several weeks due to the lack of ▌ Union wide contingency planning measures and ***of clarity*** as to which ▌ national ***authority*** to contact to find rapid solutions to the impact on the ***internal*** market ***caused*** by the crisis. In addition***,*** it became clear that uncoordinated restrictive actions taken by the Member States would further aggravate the impacts of the crisis on the ***internal*** market. It emerged that there is a need for arrangements between the Member States and Union authorities as regards contingency

planning, technical level coordination and cooperation and information exchange. ***Additionally, it became clear that the lack of effective coordination between Member States exacerbated the shortages of goods and created more obstacles to the free movement of services and persons.***

(4) Representative organisations of economic operators have suggested that economic operators did not have sufficient information on the ***restrictions to free movement introduced and*** crisis response measures of the Member States during the ***pandemic. This was partly due to a lack of transparency from Member State authorities***, partly due to ***economic operators*** not knowing where to obtain such information***. Other reasons were*** language constraints and the administrative burden implied in making repeated inquiries in all the Member States, especially in a constantly changing regulatory environment. This prevented them from making informed business decisions as to what extent they ***could exercise*** their free movement rights or continue cross-border business operations during the crisis. It is necessary to improve the availability of information on national and Union level ***restrictions to free movement and*** crisis response measures***.***

(4a) Yet, despite the initial lack of coordination, the internal market rules played a key role in mitigating the negative impact of the crisis and in ensuring a swift recovery of the economy of the Union, namely by precluding unjustified and disproportionate national restrictions contained in the unilateral responses by the Member States and by providing a strong incentive to find common solutions, thus promoting solidarity.

(5) These recent events have also highlighted the need for the Union to be better prepared ***and coordinated*** for possible future crises, especially as we consider the continuing effects of climate change and resulting natural disasters as well as global economic and geopolitical instabilities. ***Other crises, which could require a quicker response to prevent barriers to the free movement in the internal market and avoid severe disruptions of supply chains that are indispensable in the maintenance of activities in the internal market, include for example forest fires, earthquakes or large-scale cyber attacks. The fact that all those crises constitute exceptional and sudden events of extraordinary nature and scale, implies that those events are reasonably unexpected.*** Given the fact that it is not known which kind of crises could come up next and produce severe impacts on the ***internal*** market and its supply chains in the future, it is necessary to provide for an instrument that would apply with regards to impacts on the ***internal*** market of a wide range of crises.

(6) The impact of a crisis on the ***internal*** market can ***hinder the functioning of internal market in two ways. It can give rise*** to obstacles to ***the*** free movement ***or it can cause disruptions to the supply chains. The latter can exacerbate shortages of goods and services on the internal*** market ***and hinder production, thus also disrupting proper*** functioning ***of the***

internal market as well as lead to the emergence or likely emergence of diverging national measures to address those issues regarding the supply chains in the internal market, leading to an internal market ***emergency mode. This*** Regulation should address ***these*** types of impacts on the ***internal*** market ***and introduces measures to avoid obstacles to the free movement or supply chain disruptions that create shortages of crisis-relevant goods and services. Such impact on the supply chains could hinder production and ultimately lead to additional barriers to trade and to the distortion of competition between Member States and between private operators***.

(6a) In order to avoid unnecessary administrative burden on Member States, incidents reported under the ad hoc alert mechanism for early warning should be defined in such a manner that they exclude events of a negligible foreseeable consequence on the free movement of goods, services and persons, including workers, or on the supply chains of goods and services that are indispensable for the maintenance of vital societal or economic activities in the internal market.

▌

(7) ***In order to ensure that the framework of measures laid down by this Regulation can deploy their full effects in the context of the internal*** market ***vigilance and the internal market emergency modes, the Commission should be empowered to set out detailed arrangements regarding crisis preparedness, cooperation, exchange of information and crisis communication. This contingency framework*** should ***set out the specific technical and operational aspects of the mechanisms of exchange of information between the Commission and the Member States. Furthermore, the contingency*** framework ***should lay down the arrangements for the operational coordination between the Commission and the Member States of the crisis communication. In this context, a dedicated inventory of the all the respective competent authorities of the Member States, involved in the implementation of the framework laid down by this Regulation should be set up*** on the ***basis of the information communicated by the Member States. This inventory should indicate in particular the respective competent authorities as well as their assigned roles and responsibilities during the vigilance and emergency modes in accordance with national law. The detailed arrangements between the Commission and the Member States should also cover the secure exchange of information concerning the consultation of the economic operators and social partners with respect to their respective initiatives and actions to mitigate and respond to the effects of a potential crisis***.

(8) The ▌ measures set out ***in*** this Regulation should be deployed in a coherent, transparent, efficient, proportionate and timely manner, having due regard to the need to maintain vital societal functions, ▌ including public security, safety, public order, or public health***. This Regulation should not affect the competences of Member States for example with respect to national policies of public health and should be without prejudice to the*** responsibility of the Member States to safeguard national security and their power to safeguard other essential state functions, including ensuring the territorial integrity of the state and

maintaining law and order. ***This Regulation should therefore be without prejudice to matters related to national security and defence.***

(9) To this end, this Regulation provides:

- the necessary means to ensure the continued functioning of the Single Market, the businesses that operate on the ***internal*** market and its strategic supply chains, including the free ***movement*** of goods, services and persons***, including workers,*** in times of crisis and the availability of ***crisis-relevant*** goods and services to citizens, businesses and public authorities at the time of crisis;

- a forum for adequate coordination, cooperation and exchange of information; and

- the means for the timely accessibility and availability of the information which is needed for a targeted response and adequate market behaviour by businesses and citizens during a crisis.

(10) Where possible, this Regulation should allow for anticipation of events and crises ***by allowing the Union to continue*** building on on-going analysis concerning strategically important areas of the ***internal*** market economy ▌ .

(10a) By reinforcing the resilience and preparedness of European industry with regards to critical raw materials, the Critical Raw Materials Act complements this Regulation, which allows the Commission in internal market vigilance or internal market emergency mode to activate targeted measures when a threat to or a disruption of the supply of goods of critical importance emerges, which may include critical raw materials.

(11) This Regulation should not duplicate the existing framework for medicinal products, medical devices or other medical counter-measures under the EU Health Security Framework, including Regulation (EU) ***2022/2371 of the European Parliament and of the Council***[3], Council Regulation (EU) ***2022/2372***[4]***, Regulation (EU) 2022/2370 of the European Parliament and of the Council***[5] ***and*** Regulation (EU) ***2022/123 of the European Parliament and*** of the ***Council***[6]***regarding crisis preparedness and response in the area of health***. ***This EU Health Security Framework should take precedence over this Regulation as regards the supply chain disruptions and shortages of medicinal products, medical devices or other medical counter-measures where the conditions of that framework are met.*** Therefore, medicinal products, medical devices or other medical counter-measures ***as defined by Regulation (EU) 2022/2372 [SCBDH Regulation], and Regulation (EU) 2022/2372 [the Emergency Framework Regulation]***, when they have been ***included in*** the list ***of the*** Article ***7(1) of Regulation (EU) 2022/2372 [***the Emergency Framework Regulation***], should*** be excluded from the scope of this Regulation, except in relation to the provisions relating to free movement ***of goods, services and persons, including workers,*** during the ***internal*** market emergency, and in particular those designed to re-establish and facilitate free movement ▌ .

▌

(12) This Regulation should ***be without prejudice to the*** Integrated Political Crisis Response ***arrangements*** operated by the Council under Council Implementing Decision (EU) 2018/1993***. This Regulation should complement the Integrated Political Crisis Response***

---

[3] ***Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).***

[4] ***Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64).***

[5] ***Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1).***

[6] ***Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).***

arrangements operated by the Council under Council Decision 2014/415/EU[7] as regards its work on ***internal*** market impacts of cross-sectoral crises that require ***decision-making in relation to contingency planning and implementation of vigilance and emergency measures***.

[7] ***Council Decision 2014/415/EU of 24 June 2014 on the arrangements for the implementation by the Union of the solidarity clause (OJ L 192, 1.7.2014, p. 53).***

(13) This Regulation should be without prejudice to the Union Civil Protection Mechanism ('UCPM'). This Regulation should ***complement*** the UCPM and should support it, where ***necessary***, as regards availability of critical goods and free movement of civil protection workers, including their equipment, for crises that fall into the remit of that mechanism.

(14) This Regulation should be without prejudice to ***Regulation (EU) 2016/399 of the European Parliament and of the Council[8], including its general framework for the temporary introduction or prolongation of internal border controls and the notification system for the temporary reintroduction of internal border controls***.

(15) ***This Regulation should be without prejudice to Articles 55 to 57 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, implemented by Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed. This*** Regulation should be without prejudice to the European Food Security Crisis preparedness and response Mechanism (EFSCM). Nevertheless, food products should be governed by the ***free movement*** provisions of this Regulation, including those ▌ concerning restrictions to free movement rights ▌ The measures concerning food products ▌ may be also reviewed for their compliance with any other relevant provisions of ***Union*** law.

(15a) This Regulation is without prejudice to the Commission entering into consultations or cooperation, on behalf of the Union, with relevant authorities of third countries, in accordance with Union law, with particular attention paid to developing countries, with a view to seeking cooperative solutions to avoid supply chain disruptions, in compliance with international obligations. This may involve, where appropriate, coordination in relevant international fora.

(15b) One of the challenges identified during the Covid 19 crisis was the lack of network for preparedness and information sharing between the Member States and also between the Member States and the Commission. Therefore, the achievement of the objectives pursued

---

8 ***Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).***

by this Regulation should be supported by a governance mechanism. At Union level, this Regulation should establish an Internal Market Emergency and Resilience Board, composed of representatives of the Member States and chaired by the Commission, to facilitate a smooth, effective and harmonised implementation of this Regulation, cooperation and the exchange of information. The Internal Market Emergency and Resilience Board should provide advice to and assist the Commission on specific questions, including the consistent implementation of this Regulation, facilitating cooperation among Member States as well as analyse and discuss relevant topics relating to the imminent or ongoing crisis.

(15c) The Commission should chair the Internal Market Emergency and Resilience Board and provide its secretariat. Each Member State should appoint a representative and an alternate representative. The Chair should invite a representative from the European Parliament as a permanent observer. To receive important advice on the activities of the Internal Market Emergency and Resilience Board and allow appropriate participation of experts with specific expertise, the Chair should be able to invite experts and observers to take part in the work of the Board and to attend specific meetings, on an ad-hoc basis, where such attendance is relevant considering the agenda of the meeting. With a view to ensure a coherent and coordinated Union response to various crises which may have an impact on the functioning of the internal market, the Chair may also invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the Internal Market Emergency and Resilience Board. With a view of promoting international cooperation, the Chair may invite representatives of international organisations and third countries to take part as observers in meetings of the Board in accordance with the relevant bilateral or international agreement. Observers may contribute to the discussions with relevant expertise, information and insights but they should not take part in the formulation of opinions, recommendations or advice of the Internal Market Emergency and Resilience Board.

(15d) The Internal Market Emergency and Resilience Board should have specific tasks in the context of the contingency framework, the internal market vigilance mode and the internal market emergency mode. These include the exchange of views and providing advice to the Commission with respect to the assessment of the criteria which are to be taken into consideration when activating the different modes as well as with respect to the assessment whether the specific preconditions for the deployment of concrete response measures are met. The Commission should take the utmost account of opinions, recommendations or reports by the Internal Market Emergency and Resilience Board.

(15e)In the interest of guaranteeing the confidentiality of the received information under this Regulation, the Internal Market Emergency and Resilience Board should provide in its Rules of Procedures that its members and observers should not disclose trade and business secrets and other sensitive and confidential information acquired or generated in application of this Regulation and respect equivalent professional secrecy obligations as Commission staff members.

(15f) In order to guarantee greater transparency, coordination and accountability, particularly in times of crises, the European Parliament should be able to invite the Chair of the Internal Market Emergency and Resilience Board to appear in front of its competent Committee. The Commission should take into account elements arising from the views expressed through the Emergency and Resilience dialogue with respect of this Regulation, including the relevant resolutions of the European Parliament. The European Parliament should be informed of any Council implementing act proposed or adopted as soon as possible.

(15g) Member States should also appoint a Central Liaison Office that should work as a focal point in communication with other Member States and the Commission as regards contacts for relevant authorities in the Member States, compiling information from those authorities, and should also be responsible for coordination and information exchange. The Central Liaison Office to be appointed can be an already existing authority in the Member State.

(15h) This Regulation is without prejudice to the possibility of the Commission to assess whether it is appropriate to impose restrictions to exports of goods in line with the international rights and obligations of the Union under Regulation (EU) 2015/479 of the European Parliament and of the Council[9].

(15i) This Regulation is without prejudice to measures taken pursuant to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007.

(15j) This Regulation applies without prejudice to and is complementary with Directive (EU) 2022/2557 on the resilience of critical entities, which lays down harmonised minimum rules to ensure that services essential for the maintenance of vital societal functions or economic activities are provided in an unobstructed manner in the internal market, to enhance the resilience of critical entities providing such services, and to improve cross-border cooperation between competent authorities.

(15k) An information exchange relating to ad hoc alerts should be possible through the network created between the Central Liaison Offices and the Union Central Liaison Offices. These ad hoc alerts should be notified to the Commission in cases of significant incidents in order to allow the Union to better follow the development of the potential, imminent crisis or crisis as such thus being able to have better preparedness should the crisis emerge or develop.

---

9 *Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports (OJ L 83, 27.3.2015, p. 34.)*

(15l) With the objective to be better prepared for and more resilient during potential future crises which may cause severe negative impacts on the free movement of goods, services and persons, including workers or cause disruptions to the supply chains of goods and services in the internal market, the Commission should encourage and facilitate the drawing up of voluntary crisis protocols by economic operators. Economic operators remain free to decide whether to take part in such voluntary crisis protocols. The participation in such voluntary crisis protocols should not give rise to disproportionate administrative burden. The voluntary crisis protocols should set out the specific parameters of the disruptions that are considered, as well as a distribution of the specific roles of each participant, a description of the mechanisms of activation of such protocols and the associated actions. Relevant stakeholders, including Member States' authorities, Union bodies, offices and agencies and civil society organisations may also be involved in the drawing up of such voluntary crisis protocols. In determining the parameters of the disruptions to be considered, economic operators should be able to build on their past experiences with free movement and supply chain disruptions caused by various crises.

(15m) With the view of drawing from the experiences of past crises, the Commission should develop and manage training programmes and materials for public and private stakeholders, including economic operators. Participation in such training programmes and simulations should remain voluntary.

(15n) As part of crisis preparedness, this Regulation should allow for anticipation of events and crises for which stress tests and simulations would be carried out, building on ongoing analysis concerning critically important areas of the internal market economy and the Union's continuous foresight work. In particular, the Commission should develop scenarios and parameters in specific areas that capture the particular risks associated with a crisis. In order to ensure the crisis-preparedness of all actors, it is necessary to set out rules on stress tests to be conducted at least every two years, and on trainings and crisis protocols involving not only relevant national authorities, but also stakeholders such as businesses, social partners and experts. In this context, the Commission should facilitate and encourage the development of strategies for emergency preparedness, including strategies for crisis communication and exchanging information about applicable restrictions in challenging circumstances. The identification of the specific focus areas should be based on existing indicator-based tools which monitor the evolution

of supply chains in the EU with a view of identifying potential distress, taking into account relevant specific criteria such as the trade flows, demand and supply, concentration of supply, Union and global production and production capacities at different stages of the value chain and the interdependencies between economic operators.

(16) In order to account for the exceptional nature of and potential far-reaching consequences for the ▌ operation of the ***internal*** market of ***internal market vigilance or of an internal*** market emergency, implementing powers should exceptionally be conferred on the Council for the activation of ***the internal*** market ***vigilance or*** emergency mode pursuant to Article ***291(2)*** of the Treaty on the Functioning of the European Union ***(TFEU)***. ***The Council implementing act for the activation of the internal market vigilance mode should contain elements which are intrinsically linked to the assessment of the fulfilment of the preconditions justifying the activation, namely an assessment of the potential impact of the crisis on the free movement of goods, services and persons including workers in the internal market and on its supply chains, a list of the goods and services of critical importance which are indispensable in the maintenance of vital societal or economic activities in the internal market and the vigilance measures to be taken. Furthermore, where the activation of the internal market emergency mode also requires the adoption of a list of crisis-relevant goods and services, such a list should be adopted at the same time as the activation and can therefore be intrinsically linked to the activation. For this reason, implementing powers should also be conferred on the Council for the adoption of the list of crisis-relevant goods and services and its update. It should be possible to extend the internal market vigilance or emergency mode through a Council implementing act on a proposal from the Commission. Should it transpire that there is no need for either of the modes to be active, then the respective mode should be deactivated.***

▌

▌

▌

▌

(20) ***For national measures which are not harmonised under this Regulation and which affect when adopted and applied in response to an internal market emergency the*** free movement of goods or persons, ▌ or the freedom to provide services ▌ during ***internal*** market emergencies, ***Member States*** should ***ensure that they fully comply with the Treaty and other provisions of Union law such as Directive 2004/38/EC, Regulation No 492/2011, Directive 2006/123/EC, Directive 2005/36/EC and Directive 2015/1535***. ***If Member States adopt such restrictions, they*** should ***be justified and*** respect the principles of proportionality

and non-discrimination ***in accordance with Union law. Furthermore, in line with these principles, such measures should not create an unnecessary administrative burden and Member States*** should take ***all possible measures to limit any administrative burden of measures taken to respond to internal market emergency.***

In addition, any such measures should take adequately into account the situation of ***cross-border*** regions ***and outermost regions, especially for cross-border workers. Member States should remove measures taken to respond to internal market emergency that restrict free movement as soon as they are no longer necessary. In general, national measures restricting free movement, which are not harmonised under this Regulation would be in principle no longer justified or proportionate when the internal market emergency mode is deactivated and should be therefore removed***.

(20a) This Regulation should not be construed as authorising or justifying restrictions to the free movement of goods, services and persons contrary to the Treaty or other provisions of Union law. For example, the fact that some restrictions are explicitly prohibited during an internal market emergency mode should not be construed as justifying such restrictions outside this mode or as justifying other possible restrictions incompatible with EU law that are not explicitly prohibited by this Regulation.

(20b) Article 21 TFEU lays down the right of EU citizens to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. The detailed conditions and limitations are laid down in Directive 2004/38/EC[10]. That Directive sets out the general principles applicable to these limitations and the grounds that may be used to justify such measures. These grounds are public policy, public security or public health. In this context, restrictions to the freedom of movement can be justified if they are proportionate and non-discriminatory. This Regulation is not intended to provide for additional grounds for the limitation of the right to free movement of persons beyond those provided for in Chapter VI of Directive 2004/38/EC.

(20c) As regards the measures for facilitating free movement of persons and any other measures affecting the free movement of persons provided under this Regulation, they are based on Article 21 TFEU and complement Directive 2004/38/EC at the time of internal market emergencies. Such measures should not result in authorising or justifying restrictions to free movement contrary to the Treaties or other provisions of Union law.

(20d) Article 45 TFEU lays down the right to free movement of workers, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. Article 46 TFEU is the legal basis for the adoption of measures required to bring about freedom of movement for workers as defined in Article 45 TFEU. This Regulation contains provisions which complement the existing measures in order to reinforce free movement of persons, increase transparency and provide administrative

---

10 Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

assistance during internal market emergencies. Such measures include setting up and making available of the single points of contact to workers and their representatives in the Member States and at Union level during the internal market vigilance and emergency modes under this Regulation.

(20e) It is appropriate to prohibit certain national measures which restrict free movement or the freedom to provide services and which should not be imposed during, and in response to, an internal market emergency, since they are manifestly disproportionate. Therefore, any measures taken by Member States relating thereto should be assessed in the light of those harmonising provisions and not the Treaty or other provisions of Union law.

(20f) In particular, Member States should refrain from introducing measures that constitute a discrimination based on nationality or, in the case of companies, location of their registered office, central administration or principal place of business.

(20g) Member States should refrain from taking measures that make it impossible for beneficiaries of the right to free movement to return to their Member State of residence should they find themselves in another Member State at the outbreak of a crisis.

(20h) Member States should refrain from taking measures that make it impossible for beneficiaries of the right to free movement to travel to other Member States for imperative family reasons if such travel remains permitted within the Member State adopting the measure despite the circumstances being the same.

(20i) This Regulation should not prevent the Member States from letting their nationals and residents return to their territory during internal market emergencies. To facilitate such travel, other Member States should allow such nationals and residents to exit their territory to travel to the Member State of nationality or residence, or to transit through its territory in order to reach the Member State of nationality or residence.

(20j) Restrictions to free movement, including in the form of administrative requirements and procedures such as declaration, registration or authorisation procedures, are prohibited, unless they comply with Union law. When justified and proportionate administrative requirements and procedures have been adopted in line with Union law, Member States should, during an internal market emergency, prioritise facilitating compliance with such requirements and processing such procedures for persons involved in the production or supply of crisis-relevant goods or services and the Commission should, to that end and when to do so is necessary to facilitate the free movement of such providers or certain categories thereof, put in place arrangements, including digital arrangements and templates.

(21) ***To ensure effective coordination and information exchange in the context of the contingency framework, as well as in the context*** of the ***internal*** market ***vigilance and*** emergency ***modes, this Regulation lays down*** an obligation for ***Member States to designate central liaison offices, responsible for contact with the Union level central liaison office designated by the Commission and with the central liaison offices of other*** Member States***.*** ***Each central liaison office should compile the inputs from relevant competent authorities***

of its Member State, including, where relevant, at regional and local level. Such liaison offices should also transmit all crisis-relevant ***information to the single points of contact in the Member States in real time where possible***.

(21a) This Regulation lays down obligations with a view to ensuring transparency in relation to national measures adopted during an internal market emergency mode that restrict the right to free movement of persons. Any such restrictions must comply with Union law, notably Directive 2004/38/EC. Those obligations should be without prejudice to any existing information or notification obligations that continue to apply in full.

Free movement of persons is of paramount importance for the proper functioning of the internal market. Experience from the COVID-19 crisis shows that restrictions to that right can have spill-over effects for all other fundamental freedoms. Lack of information on crisis-related restrictions to free movement of persons can cause Union citizens and economic operators additional difficulties in managing their activities during a crisis. Currently, there is no applicable transparency system in force that could provide Union citizens and economic operators with information on free movement of persons restrictions.

Member States should communicate to the Commission and other Member States the full text of the national legislative or regulatory provisions introducing restrictions on the exercise of the right to free movement of persons in response to the crisis, as well as the modifications thereof, without delay after their adoption. This should be accompanied by the reasons for such measures, including reasons demonstrating that the measure is justified and proportionate, as well as any underlying scientific or other data supporting their adoption, the scope of such measures, and the date of adoption and date of application and duration of those measures.

To make sure that Union citizens and economic operators can obtain reliable information regarding restrictions to free movement, Member States should provide the public with clear, comprehensive and timely information explaining such measures, notably their scope, entry into application and duration, as soon as possible. This information should also be provided to the Commission. On this basis, the Commission should publish relevant information on a dedicated website available in all official languages of the Union.

▌

(23) In order to ensure that the specific internal market emergency measures provided for in this Regulation are used only where this is indispensable for responding to a particular internal market emergency, such measures should require ▌ activation by means of Commission implementing acts, which indicate the reasons for such activation and the crisis-relevant goods or services that such measures apply to.

(24) Furthermore, in order to ensure the proportionality of the implementing acts and due respect for the role of economic operators in crisis management, the Commission should only resort

to the ***dual*** activation of the ***internal*** market emergency mode, where economic operators are not able to provide a solution on a voluntary basis within a reasonable time. Why this is the case should be indicated in each such act, and in relation to all particular aspects of a crisis.

(24a) To ensure that the Board receives appropriate information about potential internal market emergency, it is necessary to provide for monitoring. Such monitoring concerns supply chains or goods and services of critical importance for which the vigilance mode has been activated and the free movement of persons who are involved in the production and supply of such goods and services. Monitoring of the supply chains of goods and services of critical importance should be carried out by the competent authorities of the Member States on the basis of voluntary requests for information about factors impacting the availability of the selected goods and services of critical importance such as production capacity, availability of the necessary workforce, stocks, suppliers limitations, possibilities for diversification and substitution, demand conditions, bottlenecks. The voluntary request for information should be addressed to all actors along the relevant supply chain of goods and services of strategic importance and other relevant stakeholders established in Member States national territory. Collecting information about free movement disruptions from the economic operators along the supply chains of goods and services of critical importance is particularly important because the lack of appropriate workforce is one of the prevailing causes of supply chain disruptions. The monitoring by Member State authorities of disruptions to the free movement of persons involved in the production and supply of goods and services should be understood broadly, covering workers, service providers, business representatives and other persons involved in the research, development and placing products on the market. Competent authorities of the Member States should provide the gathered information to the Commission and the Board via the central liaison offices. This information should enable the Board to advise the Commission on the necessity of activation of the internal market emergency mode.

(24b) To enable precise assessments whether the deployment of specific internal market emergency response measures would allow to reduce the severe shortages of crisis-relevant goods or services the threat thereof in an internal market emergency, the Commission should be able to request information from economic operators in supply chains of crisis-relevant goods and services. Such information requests should, where appropriate, concern production capacities and stocks of crisis-relevant goods in production facilities located both in the Union and in the third countries where those economic operators operate, with which they contract or from which they purchase supplies; the schedule or an estimation of the expected production output for the following three months for each production facility located in the Union as well as

production facilities which are located in third countries where those economic operators operate or have purchase contracts with as well as information about any relevant supply chain disruptions or shortages. To ensure full involvement of the Member State where the undertaking has its production site, the Commission should forward, without delay, a copy of the information request to that Member State and, if the competent authority of the Member State so requests, the Commission should share the acquired information with that Member State through secure means.

(25) Information requests to economic operators should be used by the Commission only where the information which is necessary for responding adequately to the ***internal*** market emergency, such as information necessary for procurement by the Commission on behalf of the Member States or estimating the production capacities of manufacturers of crisis-relevant goods the supply chains of which have been disrupted, ***is not yet available to the Commission and*** cannot be obtained from publicly available sources or as a result of information provided voluntarily. ***When activating an information request by means of an implementing act, the Commission should ensure that the benefit for the public interest outweighs the possible inconveniences that the concerned economic operators may sustain. The Commission should take into consideration the burden that such an information request may represent in particular for small and medium-sized enterprises (SMEs) and should modulate the timelines for reply accordingly. When the processing of an information request by an economic operator has the potential to significantly disrupt its operations, the said economic operator should be allowed to refuse to supply the requested information. The economic operator should be obliged to provide to the Commission the reasons for any refusal to supply requested information. Such reasons should include, in particular, the risk of liability for breach of contractual non-disclosure obligations based on contracts governed by the law of a third country or the risk of disclosing information related to national security in the case of goods with possible uses in the context of national security, which could include national reserves.***

(25a) The maximum time limit for an economic operator to reply to an information request should be 20 working days. The specific individual time limit should be set on a case-by-case basis and could be shorter. The economic operator should be allowed to request a one-time extension which could, subject to the explicit agreement by the Commission, extend the overall time limit beyond 20 days. It should be provided that any request for an extension of the time limit by the economic operator should be submitted to the Commission in accordance with the communication arrangements specified within the individual decision. It should also be provided that until the Commission has responded to the request for extension, the initial time limit should be regarded as fully applicable.

(26) The activation of the ***internal*** market emergency mode, where needed, should also ***enable the triggering of*** the application of certain crisis-response procedures which introduce adjustments to the rules governing the design, manufacture, conformity assessment and the placing on the market of goods subject to Union harmonised rules ***as well as to certain rules governing the goods subject to the EU general product safety framework***. These crisis-response procedures should enable products, designated as crisis-relevant goods to be placed swiftly on the market in an emergency context. ***In the case of harmonised products,*** the conformity assessment bodies should prioritise the conformity assessment of crisis-relevant goods over any other ongoing applications for other products. ▌Where there are undue delays in the conformity assessment procedures ***of crisis-relevant goods***, the ▌ competent authorities ***in the Member States*** should be able to issue authorisations for ***such goods*** which have not undergone the applicable conformity assessment procedures to be placed on their respective market, provided that they comply with the applicable safety requirements. Such authorisations ***should*** be only valid on the territory of the issuing Member State ***until their validity is extended to the territory of the Union by means of a Commission implementing act. The validity of such derogatory authorisation should be*** limited to the duration of the ***internal*** market emergency. In addition, ***with a view to facilitating*** the increase in supply of ***harmonised and non-harmonised*** crisis-relevant ***goods***, certain flexibilities should be introduced with respect to the ***mechanisms of presumption of conformity and*** presumption of conformity ***with the general safety requirement respectively***. In the context of ***an internal*** market emergency, the manufacturers of crisis-relevant goods should be able to rely also on national and international standards, which provide an equivalent level of protection to the ▌ European standards ***whose references have been published in the Official Journal of the European Union. With respect to the harmonised goods alone,*** in cases where the later do not exist or the compliance with them is rendered excessively difficult by the disruptions to the ***internal*** market, the Commission should be able to issue common technical specifications ***providing a presumption of conformity*** in order to provide ready-to-use technical solutions to the manufacturers.

(27) The introduction of these crisis-relevant adjustments to the relevant sectorial Union harmonised rules requires targeted adjustments to the following ***16*** frameworks ▌ Directive 2000/14/EC, Directive 2006/42/EU, Directive 2010/35/EU, Directive ▌ 2014/29/EU, Directive 2014/30/EU, Directive ▌ 2014/33/EU, Directive 2014/34/EU, Directive 2014/35/EU, Directive 2014/53/EU, Directive 2014/68/EU, Regulation (EU) 2016/424,

Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) ***305/2011, Regulation (EU) 2023/988*** and Regulation (EU) ***2023/1230. The amendments laying down emergency response procedures in each of the respective frameworks should only become applicable where they are specifically activated***. The activation of the emergency procedures ***under each respective framework*** should be conditional upon the activation of the ***internal*** market emergency ***mode under this Regulation*** and should be limited to ▌ products designated as crisis-relevant goods ***and limited in time to the duration of the internal market emergency***.

(28) In cases where there are substantial risks to the functioning of the internal market or in cases of severe ***and persistent*** shortages or an exceptionally high demand of ***crisis-relevant goods***, measures at Union level aimed to ensure the availability of crisis-relevant ***goods***, such as priority rated ***requests*** may prove to be indispensable ***to ensure the proper functioning of the internal market and its supply chains.***

(28a) As an instrument of last resort to ensure the maintenance of vital societal economic activities in the internal market where the production or supply of crisis-relevant goods could not be achieved by other measures, the Commission can address requests to economic operators established in the Union to produce or supply crisis-relevant goods. When issuing a request, the Commission should take into account the possible negative impacts on competition in the internal market and the risk of exacerbating the market distortions. Furthermore, the choice of the recipients and beneficiaries of the requests should not be discriminatory.

(28b) The priority-rated request should be taken based on objective, factual, measurable, and substantiated data. It should have regard for the ***legitimate interests of the undertakings and the cost and effort required for any change in production sequence. The priority-rated request should clearly specify that the choice to accept or refuse the request remains entirely with the economic operator. Where the economic operator chooses to refuse the priority-rated request, the economic operator is also free to decide whether to provide an explicit rejection and whether to provide a justification when communicating its rejection*** to the ***Commission.***

(28c) When accepted, the obligation to perform the priority-rated request should take precedence over any performance obligation under private or public law. Each priority-rated request should be placed at a fair and reasonable price. The calculation of such price may be carried out on the basis of average market ***prices over recent years, subject to reasons being given for any increase or decrease, for example taking into account inflation or input costs. In light of the importance to ensure the supply of crisis-relevant goods, which are indispensable for the maintenance of vital societal economic activities in the internal market, compliance with the obligation to perform a priority-rated request should not entail liability for damages towards third parties for any breach of contractual obligations governed by the law of a Member State that may result, to the extent the violation of contractual obligations was necessary for compliance with the mandated prioritisation. Economic operators potentially within scope of a priority-rated order may anticipate this possibility in the conditions of their commercial contracts. Without prejudice to the applicability of other provisions, the liability for defective products, provided for by Council Directive 85/374/EEC, is not affected by this liability exemption.***

(28d) Where the economic operator has expressly accepted a priority-rated request and the Commission has adopted an implementing act following such an acceptance, the economic operator should comply with all the conditions of that implementing act. Non-compliance by the economic operator with the conditions laid down in the implementing act should result in a loss of the benefit of a waiver of contractual liability. When the non-compliance is intentional or attributable to gross negligence, the economic operator may also be subject to a fine, subject to the proportionality principle. Economic operators which have not explicitly accepted a priority-rated request cannot be subject to any sanctions or fines.

(29) ***In addition to the current possibility for joint procurement between the Commission and one or more Member States foreseen in the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[11] (Financial Regulation) , one or more Member States should also be able to request the Commission to procure in their name or on their behalf,*** in order to leverage the purchasing power and negotiating position of the Commission during the ***internal*** market vigilance mode and the ***internal*** market emergency mode***.***

Such procurement should mean the acquisition by means of a contract of crisis-relevant works, supplies or services and the acquisition or rental of land, buildings or other immovable property for responding to the crisis, by the contracting authority from economic operators chosen by that contracting authority. The Commission should be able to conduct the relevant procurement procedure in the name of or on behalf of Member States ***based on an agreement between the parties, or act as a wholesaler, by buying, stocking and reselling or donating supplies and services, including rentals, to the participating Member States or partner organisations it has selected.***

It became clear during the COVID-19 pandemic that the Commission should be able to ***procure crisis-relevant goods and services jointly with third countries, such as the EFTA states and the European microstates.***

---

[11] ***Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).***

Any joint procurement procedures launched for the acquisition of crisis-relevant goods and services or goods and services of critical importance should not negatively affect the functioning of the internal market and should not constitute discrimination or a restriction of trade, nor should such procurement procedures cause distortion of competition or have any direct financial impact on the budget of the countries that do not participate in the joint procurement procedure.

It is also essential to ensure that Member States coordinate their actions with the support of the Commission ***and the Board prior to launching procedures for the procurement of crisis-relevant goods and services. During contingency phase, Member States should put in place a system which would allow to identify during emergencies which contracting authorities subject to Directive 2014/24/EU of the European Parliament and of the Council[12] are procuring the crisis-relevant goods and services. Member States should be able to rely on the central liaison offices for collection and transmission of information about ongoing and intended procurement by the contracting authorities and contracting entities in*** their ***territory for the purposes of compliance with the coordination clause under this Regulation.***

The agreement governing the Commission's procurement on behalf ***of or in the name of one or more Member States or joint procurement between the Commission and one or more Member States should where appropriate, provide for an exclusivity clause, under which participating countries commit to not procuring the goods or services in question through other channels and to not running parallel negotiation processes***.

Where such an exclusivity clause is provided for, it should stipulate that where Member States have additional procurement needs and such procurement does not undermine the ongoing joint procurement or procurement on behalf of or in the name of the Member States according to the assessment of the Commission, the participating Member States may launch their own procurement procedure. Having in mind the purpose of the exclusivity clause not to undermine the ongoing joint procurement or procurement on behalf of or in the name of the Member States, which would not be affected by a de minimis procurement, it may be permitted for Member States' contracting authorities and contracting entities to launch a procurement procedure which falls below the thresholds of Directives 2014/24/EU and 2014/25/EU. Given that procurement from an economic operator that is not participating in the ongoing tender would not undermine the ongoing procurement, the exclusivity clause laid down in Article 39 should also not apply to this kind of procurement.

---

[12] ***Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).***

Where a Member State decides to participate in joint procurement or procurement on behalf of or in the name of Member States for acquiring crisis-relevant goods and services, it should be able to use the central liaison offices provided for in this Regulation to inform all contracting authorities and contracting entities in its territory of such ongoing procurement, which will trigger the application of the exclusivity clause.

Transparency is a core principle of effective public procurement that improves competition, increases efficiency and creates a level playing field. The European Parliament should be informed about procedures concerning joint procurements under this Regulation and, upon request, be granted access to the contracts concluded as a result of those procedures, subject to the adequate protection of secrecy and protection of any personal data, the national security of the Member States and commercially sensitive information, including business secrets.

(29a) The Member States should act in solidarity during crisis and may therefore, when the emergency mode has been activated, be encouraged by the Commission to share the crisis-relevant goods and services that the Member State in question might have at their disposal to be distributed to another Member State in need. The Commission should help to coordinate this distribution.

(30) Where ***the Commission is informed by one or more Member States of shortages of crisis-relevant*** goods ***and services or a risk thereof***, the Commission should be able to recommend to the Member States ▌ to take measures ***aimed at ensuring the swift increase of the availability of crisis-relevant goods and services. The Commission should consider the impact of the envisaged measures on the concerned economic operators. Such recommendations may include measures aimed at facilitating the expansion, repurposing or establishment of new production capacities for*** crisis-relevant goods or ***new capacities related to crisis-relevant service activities as well as aimed at accelerating the relevant and applicable approval, authorisation and registration requirements***.

▌

▌

(32a) It is necessary to provide information holders with safeguards that the information that they have provided as a result of the application of this Regulation is processed and used respecting the principles of necessity and proportionality. Information received via monitoring, information requests and priority rated requests, may therefore only be used by any Union institution or body, Member State authority and their staff as well any individuals, including the members and observers of the Internal Market Emergency and Resilience Board, only for the purpose for which it was requested.

(32b) Given that the Internal Market Emergency and Resilience Board acts as an advisory body to the Commission, it must respect the Commission's principles, standards and rules for protecting classified information and sensitive non-classified information including, inter alia, provisions for processing and storage of such information as set out in Commission Decisions (EU, Euratom) 2015/443[13] and (EU, Euratom) 2015/444[14]. Staff members of

[13] ***Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).***

the Commission and other Union institutions and bodies that have access to the classified information and sensitive non-classified information relating to the work of the Board are bound by the confidentiality requirements under Article 339 TFEU, even after their duties have ceased.

---

[14] ***Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).***

(33) ***Where the Commission is informed by one or more Member States of shortages of crisis-relevant goods and services, the Commission should transmit the information to all competent authorities of the Member States and streamline the coordination of the response.*** Furthermore, to ensure availability of crisis-relevant goods ***and services*** during ***an internal market emergency and with a view to ending the internal*** market emergency, the Commission may recommend that ***the*** Member States distribute ***those crisis-relevant goods or services***, having ▌ due regard to the principles of solidarity, necessity and proportionality.

(34) Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, such processing should comply with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/1725 of the European Parliament and of the Council[15] and Regulation (EU) 2016/679 of the European Parliament and of the Council[16].

(35) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards ***specifications of the contingency framework regarding preparedness cooperation, exchange of information and crisis communication for the internal market vigilance and emergency modes. Moreover***, implementing powers should be conferred on the Commission as regards ***the possibility to adopt administrative arrangements and templates for facilitating free movement of persons***. Moreover, implementing powers should be conferred on the Commission as regards activation of specific emergency response measures at the time of an internal market emergency, to allow for a rapid and coordinated response. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[17].

---

[15] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

[16] Regulation (EU) 2016/769 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

[17] ***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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).***

(35a) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the impacts of the crisis on the internal market, imperative grounds of urgency so require.

(36) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union (the 'Charter'). In particular, it respects the right to privacy of the economic operators enshrined in Article 7 of the Charter, right to data protection set out in Article 8 of the Charter, the freedom to conduct business and the freedom of contract, which are protected by Article 16 of the Charter, the right to property, protected by Article 17 of the Charter, right to collective bargaining and action protected by Article ***28*** of the Charter and the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter. ▌

(36a) Since the objective of this Regulation, namely to ensure the smooth and undisrupted functioning of the internal market by putting in place contingency, vigilance and emergency measures across the internal market in order to facilitate the coordination of the response measures in the case of a crisis, cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. The Regulation should not affect the autonomy of the social partners as recognised by the TFEU.

(36b) This Regulation should not be interpreted as affecting the right to environmental protection, the right of collective bargaining and the right to take collective action in accordance with the Charter of Fundamental Rights of the European Union ('the Charter'), including the right of workers and employees to take collective action to defend their interests, including strike action, and the right or freedom to strike or to take other action covered by the specific industrial relation systems in Member States in accordance with national law or practice.

(36c) Other Union legal acts, such as those providing for obligations on economic operators to make data available to public sector bodies, do not affect this Regulation. Therefore where other Union legal acts also contain provisions on information requests by the Commission which have the same purpose as those provided for under this Regulation after the emergency mode has been activated by the Council, only the relevant provisions of this Regulation should apply.

(37) The Union remains fully committed to international solidarity and strongly supports the principle that any measures deemed necessary taken under this Regulation, including those necessary to prevent or relieve critical shortages, are implemented in a manner that is targeted, transparent, proportionate, temporary and consistent with WTO obligations.

(38) The Union framework ***should*** include interregional elements to establish coherent, multi-sectoral, cross-border ***internal*** market vigilance and emergency response measures, in particular considering the resources, capacities and vulnerabilities across neighbouring regions, specifically border regions.

(41g) It is necessary to lay down rules on digital tools in order to ensure preparedness for responding to possible future emergencies in a timely and efficient manner to guarantee the continued functioning of the internal market, the free circulation of goods, services and persons in times of crisis and the availability of crisis-relevant goods and services to citizens, businesses and public authorities. This Regulation should also set out rules for digital tools ensuring prioritisation and acceleration of authorisation, registration or declaration procedures to facilitate the free movement of persons and the secure transmission and exchange of information. The Commission and the Member States should reuse or expand to the extent possible their existing digital tools. When this is not possible, the Commission and the Member States should establish, where necessary and justified, new digital tools. The Commission should set out the technical aspects of such tools or infrastructures by means of implementing acts. Furthermore, in order to enhance involvement of all economic actors, in particular businesses and civil society, the

Commission should set up a stakeholder platform to facilitate and encourage voluntary response to internal market emergencies.

(41j) The Commission should carry out a regular evaluation of the functioning and effectiveness of this Regulation and submit a report to the European Parliament and the Council, including an evaluation of the work of the Board, stress tests, training and crisis protocols, the criteria for the activation of the emergency mode as well as the use of digital tools. Furthermore, reports should be submitted by 4 months after the deactivation of the internal market vigilance and emergency modes. Those reports should include an evaluation of the measures implemented under this Regulation in relation to the crisis that lead to such an activation, in particular on the effectiveness of those measures. Those reports could suggest any improvements if necessary, and be accompanied, where appropriate, by relevant legislative proposals.

▌

▌

▌

(41n) Council Regulation (EC) No 2679/98 provides for a mechanism for bilateral discussions and notification of obstacles to the functioning of the internal market. In order to avoid the duplication of rules where the internal market emergency mode has been activated, that Council Regulation should therefore be amended accordingly. Regulation (EC) No 2679/98 should not in any way affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States, in accordance with national law or practice. It should also be without prejudice to the right to negotiate and to conclude collective agreements, to take collective action in accordance with national law or practice.

▌

Part I

Title I

Scope

Article 1

Subject matter *and objectives*

1. This Regulation establishes a framework of ***harmonised*** measures to ***effectively*** anticipate, prepare for and respond to ***the impact of crises on the internal*** market.

1a. The framework referred to in paragraph 1 aims to:

(a) safeguard and facilitate the free movement of goods, services and persons, including workers;

(b) ensuring the availability of goods and services of critical importance and crisis-relevant goods and services in the internal market where the Member States have adopted or are likely to adopt divergent national measures; and

(c) prevent the creation of obstacles to the proper functioning of the internal market.

2. ***This Regulation lays down, in particular***:

(a) ***rules on the establishment and functioning of an Internal Market Emergency and Resilience Board to assist and advise the Commission in*** anticipating, preventing or responding to the impact of a crisis on the ***internal*** market;

▌

(c) contingency measures aiming at anticipation***, planning and resilience***;

(d) measures ***during the internal*** market ***vigilance mode for addressing the impacts of a crisis that has the potential to escalate into an internal market emergency;***

(e) measures***, during the internal market emergency mode,*** for addressing ***a crisis on the internal*** market***, including facilitating the free movement of goods, services and persons***, including ***workers, during internal market*** emergency ***mode;***

(ea) rules on public procurement during the internal market vigilance and emergency modes;

(eb) rules on the provision of digital tools and the cooperation between the competent authorities.

Article 2

Scope

1. This Regulation ***applies to goods, services and persons, including workers within the internal*** market .

2. This Regulation shall not apply to the following:

(a) medicinal products as defined in Article ***1, point*** 2 of Directive 2001/83/EC ***of the European Parliament and of the Council***[18];

(b) medical devices as defined in Article 2, point (e), of Regulation (EU) 2022/123 of the European Parliament and of the Council[19];

(c) other medical countermeasures as defined in Article 3, point ***(10)***, of Regulation (EU) ***2022/2371 and included in the list established in accordance with Article 7(1) of Regulation (EU) 2022/2372***;

---

[18] ***Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).***

[19] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, OJ L 20, 31.1.2022, p. 12.

(d) semiconductors as defined in Article ***2, point (1) of Regulation EU) 2023/1781*** of the European Parliament ***and of the Council***[20];

(e) energy products as defined in Article 2, paragraph 1, of ***Council*** Directive 2003/96/EC[21], electricity as defined in Article 2, paragraph 2 of that Directive and other products as referred to in Article 2, paragraph 3, of that Directive***;***

(f) financial services, such as banking, credit, insurance and re-insurance, occupational or personal pensions, securities, investment funds, payment and investment advice, including the services listed in Annex I to Directive ***2013/36/EU***[22], as well as settlement and clearing activities and advisory, intermediation and other auxiliary financial services***;***

(g) defence-related products as defined in Article 3 paragraph 1 of Directive 2009/43/EC of the European Parliament and the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community or as defined by national law of Member States in compliance of Union law;

3. By way of derogation from paragraph 2, points (a), (b) and (c), Articles 16 to ***19*** and Article 41 ▌ shall apply to the products referred to in those points.

▌

4. ***This Regulation is without prejudice to other legal acts of the Union laying down specific rules on crisis response or crisis management, such as:***

---

[20] ***Regulation (EU) 2023/1781 of the European Parliament and of the Council of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act) (OJ L 229, 18.9.2023, p. 1)***

[21] ***Council Directive 2003/96/EC of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity (***OJ L 283, 31.10.2003, p. 51***)***.

[22] ***Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).***

(a) ***Union*** Civil Protection Mechanism set out in Decision No 2013/1313/EU ***of the European Parliament and of the Council***[23];

(b) ***Regulation (EU) 2015/479;***

(c) ***Regulation (EU) 2022/2371 on serious cross-border threats to health, the HERA*** Crisis ***Regulation (EU) 2022/2372;***

[23] ***Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).***

(d) the Integrated Political Crisis Response (IPCR) arrangements operated by the Council under Council Implementing Decision (EU) 2018/1993 and Council Decision 2014/415/EU establishing the Integrated Political Crisis Response (IPCR) arrangements including the political coordination role of the IPCR.

5. This Regulation is without prejudice to Union competition rules , including antitrust, merger and State aid rules.

8. This Regulation is without prejudice to the responsibility of the Member States to safeguard national security or their power to safeguard essential state functions, including ensuring the territorial integrity of the State and maintaining law and order. ***In particular, national security remains the sole responsibility of each Member State.***

8a. This Regulation shall not affect the exercise of fundamental rights, in accordance with the Charter of Fundamental Rights of the European Union (the 'Charter'). In particular the right to strike or the right to take other action covered by the specific industrial relations systems in Member States, in accordance with national law and practice. It also shall not affect the right to negotiate, to conclude and enforce collective agreements, or to take collective action in accordance with national law and practice.

▌

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'crisis' means an exceptional***,*** unexpected and sudden, natural or man-made event of extraordinary nature and scale that takes place inside or outside of the Union ***which has or may have a severe negative impact on the functioning of the internal market and disrupts the free movement of goods, services and persons or its supply chains***;

(2) ***'internal*** market vigilance mode' means a framework for addressing ***the*** threat of ***a crisis,*** which has the potential to escalate into ***an internal*** market emergency within the next six months;

(3) '***internal*** market emergency ***mode***' means a ***framework for addressing*** a crisis ***with significant negative impact*** on the ***internal*** market that severely disrupts the free movement ***of goods, services and persons or, where such a severe disruption has been or is likely to be subject to divergent national measures, the functioning of the supply chains***;

(4) '***critically*** important areas' means those areas with critical importance to the Union and its Member States, in that they are of systemic and vital importance for ***upholding*** public security, public safety, public order or public health, and ***if there is a*** disruption, failure, loss or destruction of which ***it can*** have a significant ***negative*** impact on the functioning of the ***internal*** market ***in times of a threat of a crisis***;

(5) ‘goods and services of ***critical*** importance’ means goods and services that are ***non-substitutable, non-diversifiable or*** indispensable ***in the maintenance of vital societal or economic activities in order to ensure the proper functioning of the internal market and its supply chains in critically important areas***;

(6) ‘crisis-relevant goods and services’ means goods and services that are ***non-substitutable, non-diversifiable or indispensable in the maintenance of vital or societal economic activities in order to ensure the proper functioning*** of the ***internal market, including the functioning of its supply chains and that are considered essential for responding to a crisis***;

▌

▌

(7a) ‘significant incidents’ means incidents that significantly disrupt or have the potential to significantly disrupt the functioning of the internal market and its supply chains;

(7b) ‘relevant economic operator’ means an economic operator along the supply chain that has the ability or capacity to produce or distribute any of the following:
(a) goods and services of critical importance; (b) crisis-relevant goods or services; (c) components for the goods referred to in point (a) and (b);

Title II
Governance

Article 4

Internal Market Emergency and Resilience Board

1. An ***Internal Market Emergency and Resilience Board (the 'Board')*** is established.

2. The ***Board*** shall be composed of one representative from each Member State ***and one representative from the Commission***. Each Member State shall ***appoint*** a representative and an alternate representative. ***In addition, Member States may appoint a sector-specific ad hoc representative if this is appropriate depending on the nature of the crisis.***

3. The Commission shall chair the ***Board and provide*** its secretariat.

The Chair shall invite a representative ***from*** the European Parliament ***as a permanent observer to the Board.***

The Chair may invite experts with specific expertise to take part, as observers, in the work of the Board and to attend specific meetings, on an ad-hoc basis, where such attendance is relevant considering the agenda of the meeting. Such experts ***may include representatives of economic operators, stakeholder organisations and social partners***.

The Chair shall invite the representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the ***Board.***

The Chair shall invite representatives of international organisations and third countries in meetings of the Board in accordance with the relevant bilateral or international agreements.

Observers shall not have voting rights and shall not participate in the formulation of opinions, recommendations or advice of the Board. Where appropriate, the Chair may invite those observers to contribute with information and insights.

▌

3a. ***The Board shall meet at least three times a year. At its first meeting, on a proposal by and in agreement with the Commission, the Board shall adopt its rules of procedure.***

▌

3b. ***The Board may adopt opinions, recommendations or reports in the context of its tasks set out in Article 4a. The Commission shall in a transparent manner take the utmost account of opinions, recommendations or reports by the Board.***

▌ Article 4a

Tasks of the Board

1. For the purpose of contingency planning under Articles 6 to 8, the ***Board*** shall assist and advise the Commission as regards the following tasks:

(a) proposing arrangements for administrative cooperation ***to facilitate the exchange of information*** between the Commission and the Member States at the time of the ***internal*** market vigilance and emergency modes that would be contained in the ***contingency framework referred to in Article 6***;

(b) ***assessing*** incidents that the Member States have alerted the Commission ***in accordance with in Article 8 and their impact on the internal market and its supply chains;***

▌

(bb) gathering foresight on the possibility of a crisis occurring, conducting data analysis and providing market intelligence;

(bc) consulting the representatives of economic operators, including SMEs, and the industry, as well as, where relevant, social partners, in order to collect market intelligence in line with Article 40a;

(bd) analysing aggregated data received by other crisis-relevant bodies at Union and international level;

(be) maintaining a repository of national and Union crisis measures that have been used in previous crises and that have had an impact on the internal market and its supply chains;

(bf) advising on the identification and implementation of the measures chosen to anticipate and plan, while strengthening the internal market's resilience, in accordance with Articles 6 to 8.

2. For the purpose of ***the internal*** market vigilance mode as referred to in Article 9, the ***Board*** shall assist ***and advise*** the Commission in the following tasks:

(a) establishing whether the ***criteria for activation or deactivation of the vigilance mode have been fulfilled in order to determine whether the crisis*** threat referred to in Article 3(2) is present, and the scope of such threat;

▌

▌

▌

(e) ***coordinating and*** facilitating exchanges and sharing of information, including with other relevant bodies and other crisis-relevant bodies at Union level ***and in Member States***, as well ***as third*** countries, as appropriate, with particular attention paid to developing countries, and international organisations;

▌

▌

(fa) analysing and discussing the effect of the crisis on the internal market, with due regard to the situation in border regions, with a view to finding possible solutions.

3. For the purposes of the ***internal*** market emergency mode as referred to in Article 14, the ***Board*** shall assist ***and advise*** the Commission in the following tasks:

(a) analysing crisis-relevant information gathered by Member States or the Commission;

(b) establishing whether the criteria for activation or deactivation of the emergency mode have been fulfilled;

(c) advising on the ***identification and*** implementation of the measures chosen to respond to ***internal*** market emergency at Union level;

(d) performing a review of national crisis measures;

(e) ***coordinating and*** facilitating exchanges and sharing of information, including with other crisis-relevant bodies at Union level, as well as, as appropriate, third countries, with particular attention paid to ***EFTA members, candidate countries to the EU,*** developing countries, and international organisations***;***

(ea) analysing and discussing the effect of the crisis on the internal market, with due regard to the situation in border regions, with a view to finding possible solutions; and

(eb) establishing, where appropriate, a list of categories of persons involved in the production or supply of crisis-relevant goods and services for whom it is necessary to establish common templates and forms which can be used by the Member States on a voluntary basis.

4. The Commission shall ensure the participation of all bodies at Union level that are relevant to the respective crisis. The ***Board*** shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies at Union level ***and the European Critical Raw Materials Board established by Regulation (EU) .../2024***[+][25]. The Commission shall ensure coordination with the measures implemented through other Union mechanisms, such as the Union Civil Protection Mechanism (UCPM)***, the Integrated Political Crisis Response (IPCR) arrangements,*** or the EU Health Security Framework ***and the European critical raw materials framework. The Board*** shall ensure information exchange with the Emergency Response Coordination Centre under the UCPM ***and the Integrated Situational Awareness and Analysis (ISAA) support capability under the IPCR.***

[+] ***OJ: Please insert in the text the number of this Regulation contained in document PE-CONS 78/23 .../... (2023/0079(COD)).***

[25] ***Regulation (EU) .../2024 of the European Parliament and of the Council (...)establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020. (OJ ...)***

4a. The Board shall, in cooperation with the Commission, adopt annually its activity report and transmit it to the European Parliament and the Council.

Article 4b

Emergency and Resilience Dialogue

1. In order to enhance the dialogue between the institutions of the Union in the context of this Regulation, and to ensure greater transparency, accountability and coordination, the competent committee of the European Parliament may invite the Commission in its capacity as Chair of the Internal Market Emergency and Resilience Board to appear before the committee to provide information on all matters falling within the scope of this Regulation, in particular, after each meeting of the Board and after each deactivation of the vigilance or emergency modes.

2. The European Parliament shall be informed as soon as possible of any Council implementing acts proposed or adopted pursuant to this Regulation.

3. The Commission shall take into account any elements arising from the views expressed through the emergency and resilience dialogue, including the relevant resolutions of the European Parliament.

Article 4c

Emergency and resilience platform

1. The Commission shall establish a stakeholder platform in order to facilitate sector-specific dialogue and partnerships by bringing together key stakeholders, namely representatives of economic operators, social partners, researchers and civil society. In particular, that platform shall provide a functionality that allows interested stakeholders to:

(a) indicate voluntary actions needed to successfully respond to an internal market emergency;

(b) provide scientific advice, opinions or reports on crisis-related issues;

(c) contribute to the exchange of information and best practices. in particular as regards the free movement of goods, services and persons and the avoidance of divergent national measures which could create cross-border restrictions.

2. The Commission and the Board shall take into account the outcomes of the sector-specific dialogue and partnerships, as well as any relevant input provided by stakeholders in accordance with paragraph 1 in the implementation of this Regulation.

Article 5

Central liaison offices

1. ***Each*** Member ***State*** shall designate ***a*** central liaison office ▌ .

1a. The central liaison office of a Member State shall be responsible for contacts, coordination and information exchange with:

(a) the central liaison offices of other Member States and the Union level central liaison office referred to in paragraph 2;

(b) the relevant competent authorities in that Member State, in particular with the national single point of contact in Article 21.

1b. In order to perform its tasks under this Regulation, the central liaison office of a Member State shall compile input from the relevant competent authorities in that Member State.

▌

2. The Commission shall designate a Union level ▌ liaison office ▌ .

2a. The Union level liaison office shall be responsible for ensuring the coordination and information exchange with the central liaison offices of the Member States for the management of the internal market vigilance and emergency modes, including as regards crisis-relevant information.

Part II

Internal market contingency planning

Article 6

Contingency framework

1. The Commission***,*** taking ***due*** consideration ***of*** the opinion of the ***Board*** and the input of relevant Union level bodies, ***may*** adopt ***an implementing*** act to ***set out the detailed arrangements for a contingency framework*** regarding crisis ***preparedness,*** cooperation, exchange of information and crisis communication for the ***internal*** market vigilance and emergency modes***. That implementing act shall set out the detailed arrangements for***:

   (a) cooperation between ***Member States*** and Union level competent authorities ***in the internal*** market vigilance and emergency modes***;***

   (b) ▌ secure exchange of information; ***and***

   (c) a coordinated approach to ***crisis communication for the internal market vigilance and emergency modes*** vis-à-vis the public with a coordinating role for the Commission;

   ▌

1a. The implementing act referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 42(2).

2. The Commission and the Member States shall ***ensure*** arrangements for ▌ timely cooperation and secure exchange of information between the Commission, the relevant Union-level bodies and the Member States concerning:

(a) an inventory of ***competent authorities of the Member States, the*** central liaison offices designated in accordance with Article 5 and ***the*** single points of contact referred to in Article 21, their contact details, assigned roles and responsibilities during the vigilance and emergency modes ***under*** this Regulation***, in accordance with*** national law;

(b) consultation of the representatives of economic operators ▌ , including SMEs, on their initiatives and actions to mitigate and respond to potential ***internal*** market ***crisis***;

(ba) consultation of social partners on the implications of their initiatives and actions to mitigate and respond to a potential of the crisis on the free movement of workers;

(c) technical level cooperation in the vigilance and emergency modes ▌ ;

(d) risk and emergency communication, with a coordinating role for the Commission, ▌ taking into account already existing structures;

3. In order to ensure the operation of the framework established in accordance with paragraph 1, the Commission may conduct stress tests, simulations and in-action and after-action reviews with Member States, and propose the relevant Union-level bodies and the Member States to update the framework as necessary

3a. In order to promote and facilitate the free movement of goods and services during an internal market emergency mode, the Commission shall assist Member States and coordinate their efforts in laying down single digital forms for the purpose of declaration, registration or authorisation for activities carried out between Member States

Article 6a (new)

Voluntary crisis protocols

1. The Board may recommend the Commission to initiate the drawing up of voluntary crisis protocols by economic operators for addressing crisis under the emergency mode.

2. The Commission shall encourage and facilitate the drawing up of those voluntary crisis protocols by economic operators. Economic operators may decide, on a voluntary basis, whether to participate or not in voluntary crisis protocols.

3. The voluntary crisis protocols shall set out:

(a) the specific parameters of the disruption that the voluntary crisis protocol seeks to address and the objectives it pursues;

(b) the role of each participant under the voluntary crisis protocol and the preparatory measures they are to put in place once the internal market emergency mode has been activated to mitigate and respond to the crisis;

(c) a clear procedure for determining the moment of the activation and the period during which the measures to be taken once the crisis protocol has been activated are to be taken;

(d) actions to mitigate and respond to potential crisis under the emergency mode, strictly limited to what is necessary for addressing them.

4. The Commission shall, as appropriate, involve Member States' authorities, Union bodies, offices and agencies in drawing up the crisis protocols. The Commission may, where necessary and appropriate, also involve civil society organisations or other relevant organisations.

Article 7

Trainings and simulations

1. The Commission shall ***develop and regularly*** organise ▌ training on crisis ***preparation,*** coordination, cooperation and information exchange referred to in Article 6 for the staff of the designated central liaison offices. It shall organise simulations involving the staff of the central liaison offices from all Member States based on potential scenarios of ***internal*** market emergencies.

1a. ***In particular, the Commission shall develop and manage a training programme derived from lessons learnt from previous crises, including aspects of the entire emergency management cycle, in order to provide a rapid response to crises under the vigilance or emergency mode. That programme may include, in particular:***

(a) monitoring, analysing and evaluating all the relevant actions to facilitate the free movement of goods, services and persons;

(b) promoting the implementation of best practices at national and Union level, and, where appropriate, best practices, developed by third countries and international organisations;

(c) developing guidance on knowledge dissemination and the implementation of different tasks at national and, where relevant, regional and local level;

(d) encouraging the use of relevant new technologies and digital tools for the purpose of responding to internal market emergencies.

2. ***The Commission shall develop and make available training programmes and materials for stakeholders, including economic operators. Where relevant, the Commission may invite stakeholders to participate in trainings and simulations.***

2a. ***At the request of a Member State, the Commission may provide advice and support on preparedness and response measures, taking particular account of the needs and interests of that Member State.***

Article 7a

Stress tests

1. ***The Commission, taking into consideration the opinion of the Board, shall conduct and coordinate stress tests, including simulations that aim to anticipate and prepare for a crisis in the internal market.***

In particular, the Commission shall:

(a) develop scenarios and parameters in a specific area that capture the particular risks associated with a crisis, in order to assess the potential impact on the free movement of goods, services and persons in that area;

(b) facilitate and encourage the development of strategies for emergency preparedness;

(c) identify, in cooperation with all actors involved, risk mitigation measures after the completion of the stress tests.

3. ***In order to identify the specific area referred to in paragraph 2, point (a), the Commission, in cooperation with the Board, shall make use of all the existing tools at its disposal, including mapping exercises.***

4. ***The Commission shall conduct stress tests regularly and at least once every two years at Union level. To that end, the Commission shall invite staff from the central liaison offices of all Member States to participate in simulations. The Commission may also invite other relevant actors involved in the prevention of, preparedness for and response to emergencies to participate on a voluntary basis.***

5. ***On the basis of a request by two or more Member States, the Commission may conduct stress tests in specific geographical areas or border regions in those Member States.***

6. ***The Commission shall communicate the results of the stress tests, conducted pursuant to this Article, to the Board and publish a report thereon.***

Article 8

Ad hoc alerts for early warning

1. The central liaison office of a Member State shall notify the Commission and the central liaison offices of other Member States without undue delay of any ▌ significant incidents ▌ .

2. The central liaison offices and any relevant competent authorities ***of the Member States*** shall, in accordance with Union law and national legislation that complies with Union law, ***adopt all measures necessary to*** treat the information referred to in paragraph 1 in a way that respects its confidentiality, protects the security and public order of the ▌ Union or its Member States, and protects the security and commercial interests of the economic operators concerned.

3. In order to determine whether ***incidents should be the object*** of the ***alert referred to in paragraph 1***, the central liaison office of a Member State shall take the following into account:

   (a) the ***market position or*** number of economic operators affected by the ***incident;***

   (b) the duration or anticipated duration of ***the incidents***;

   (c) the geographical area; the proportion of the ***internal*** market affected by the ***incident and its cross-border effects, as well as its impact on*** particularly vulnerable or exposed ***geographical areas such as the*** outermost regions; ***or***

   (d) the effect of ***those incidents*** on non-diversifiable and non-substitutable ***goods***.

▌

▌

▌

▌

▌

Part III

Internal market vigilance

Title I

Vigilance mode

Article 9

Activation

1. Where the Commission, taking into consideration the opinion provided by the ***Board***, considers that the ***conditions laid down*** in Article 3(2) ***are fulfilled***, it shall ***propose to the Council to*** activate the ***internal market vigilance mode. The Council may activate the internal market*** vigilance mode ***by means of a Council implementing act. The*** duration of ***the activation shall be specified in the*** implementing act***, and shall be a maximum of six months***. Such ▌ implementing act shall contain the following:

   (a) an assessment of the potential impact of the crisis ***on the free movement of goods, services and persons, including workers, on the internal market and on its supply chains***;

   (b) ***a*** list of the goods and services of ***critical*** importance concerned***; and***

   (c) the vigilance measures to be taken***, including a justification regarding the necessity and proportionality of such measures***.

1a. When assessing whether the conditions laid down in Article 3(2) are fulfilled to qualify as internal market vigilance, the Commission and the Council shall take into account at least the following criteria:

(a) the anticipated time before the threat escalates into an internal market emergency;

(b) the number or market position of economic operators expected to be affected by the crisis;

(c) the extent to which goods and services of critical importance are expected to be impacted by the crisis; and

(ca) the geographic area expected to be impacted by the crisis, in particular the impact on border regions and outermost regions.

▌

Article 10

Extension and deactivation

1. ***Where*** the Commission ▌ considers that the reasons for activating the vigilance mode pursuant to Article 9(1) remain valid, and taking into consideration the opinion provided by the ***Board, it shall propose to the Council to*** extend the vigilance mode***. Subject to urgent and exceptional changes in circumstances, the Commission shall make best efforts to do so no later than 30 days before the expiry of the period for which the internal market vigilance mode has been activated. On the basis of this proposal, the Council may extend the vigilance mode by no more than*** six months ***at a time*** by means of ***a Council*** implementing act.

2. Where the Commission, taking into consideration the opinion provided by the ***Board***, finds that the ***conditions laid down*** in Article 3(2) ***are*** no longer ***fulfilled***, with respect to some or all vigilance measures or for some or all of the goods and services, it shall ***propose to the Council to*** deactivate the vigilance mode in full or in part***. On the basis of this proposal, the Council may deactivate the vigilance mode*** by means of ***a Council*** implementing act.

▌

Title II
Vigilance measures

Article 11

Monitoring

1. When the vigilance mode has been activated in accordance with Article 9, ▌ competent authorities ***in the Member States*** shall monitor the supply chains of goods and services of ***critical*** importance that have been identified in the implementing act activating the vigilance mode ***and the free movement of persons, including workers, involved in the production and supply of those goods and services***.

2. The Commission shall provide for standardised and secure means for the collection ***of the information and the*** processing of ***that*** information ***in an aggregated manner*** for the purpose of paragraph 1, using electronic means. Without prejudice to national legislation ***in compliance with Union law,*** requiring collected information including business secrets to be kept confidential, confidentiality with regard to the commercially sensitive ***information and*** information affecting the security and public order of the Union or its Member States shall be ensured.

3. Member States shall***, where possible,*** set up***, update*** and maintain an inventory of the ▌ relevant economic operators established on their respective national territory that operate along the supply chains of goods and services of ***critical*** importance that have been identified in the implementing act activating the vigilance mode. ***The contents of the inventory shall be confidential at all times.***

4. On the basis of the inventory set up pursuant to ***paragraph 3 of this Article*** competent authorities ***in the Member States*** shall***, when the information could not be obtained from other sources,*** address requests for voluntary provision of information to the most relevant operators along the supply chains of goods and services ***of critical importance*** identified in the implementing act adopted pursuant to Article 9 and***,*** in their respective national territory. Such requests shall in particular ***state*** which information about factors impacting

the availability of the identified goods and services of ***critical*** importance is requested. Each economic ***operator*** that voluntarily provides information shall do so on an individual basis in line with the Union rules on competition governing the exchange of information. The ▌ competent authorities ***in the Member States*** shall transmit the relevant findings to the Commission and the ***Board*** without undue delay via the respective central liaison office.

5. ▌Competent authorities ***in the Member States*** shall have due regard to the administrative burden on economic operators and in particular SMEs, which may be associated with requests for information***,*** and ensure ***that such administrative burden*** is kept to a minimum ***and that the confidentiality of the information is respected***.

6. ***On the basis of the information collected through the monitoring activities carried out in accordance with paragraph 1, the Commission shall present a report to the Board of the aggregated findings.***

7. The Commission may ask the ***Board*** to discuss the ***aggregated*** findings and prospects of evolution based on ***the information obtained by Member States pursuant to paragraphs 1 and 4 regarding their*** monitoring of supply chains of goods and services of ***critical*** importance***, duly ensuring confidentiality and observing the commercial sensitivity of the information concerned***.

7a. ***The Commission may also share with the Member States relevant information obtained through other monitoring means or systems.***

Part IV

Internal market emergency

Title I

Emergency mode

Article 13

Criteria for activation

1. When assessing ***whether the conditions laid down in Article 3(3) are fulfilled in order to determine the need to activate the internal*** market ***emergency mode, the Commission and the Council*** shall, based on concrete and reliable evidence, ***assess whether the crisis creates one or more obstacles to the free movement of goods, services or persons, having an impact on*** at least ***one sector of vital societal or economic activities in the internal market.***

Where the crisis leads to a disruption to the functioning of supply chains, in addition to the criteria set out in the first subparagraph, the Commission and the Council shall assess whether the goods, services or workers concerned can be diversified or substituted.

1a. When applying paragraph 1, the Commission and the Council shall take into account in particular the following indicators:

(-a) the number of significant incidents notified pursuant to Article 8(1);

(a) ***the fact that*** the crisis has ***triggered the*** activation of any ***of the following: (i) a*** relevant Council crisis response mechanism, ***including the Integrated Political Crisis Response; (ii) the*** Union Civil Protection Mechanism***; or (iii) any of*** the mechanisms set up within the EU Health Security Framework, including ***the emergency framework under*** Regulation (EU) ***2022/2372***;

(b) an estimation of the number ***or market position and market demand*** of economic ***operators*** or users relying on the disrupted sector or sectors of the ***internal*** market for the provision of the goods or services concerned;

(c) ***an estimation of types of*** goods***, services or the number of persons, including workers affected by the crisis***;

(d) the ***actual or potential impact of the crisis*** in terms of degree and duration on economic and ***vital*** societal activities, the environment and public safety;

(e) ***the fact that*** the economic operators affected ***by the crisis*** have not been able to provide a solution in a reasonable time to the particular aspects of the crisis on a voluntary basis***;***

▌

(g) the geographic area***, including border regions and outermost regions,*** that is and could be affected ***by the crisis***, including any cross-border impacts on the functioning of supply chains that are indispensable ***to*** the maintenance of vital societal or economic activities in the ***internal*** market;

(h) the importance of the affected economic ***operators*** in maintaining a sufficient level of supply of the goods or services, taking into account the availability of alternative means for the provision of those goods or services; and

(i) the absence ***or shortage of substitutes for*** goods ▌ or services.

▌

Article 14

Activation

-1. The internal market emergency mode shall only be activated if the criteria laid down in Article 13(1) are fulfilled.

1. The ***internal*** market emergency mode may be activated without the ***internal*** market vigilance mode having previously been activated with regard to the same goods or services. Where the vigilance mode has previously been activated, the emergency mode may replace it partially or entirely.

2. Where the Commission, taking into consideration the opinion provided by the ***Board***, considers there is ***an internal*** market emergency, it shall propose to the Council to activate the ***internal*** market emergency mode ***and, where applicable, to adopt a list of crisis-relevant goods and services***.

3. The Council may activate the ***internal*** market emergency mode***, and where applicable, adopt a list of crisis-relevant goods and services*** by means of a Council implementing act ***on a proposal from the Commission***. The duration of the activation ***shall*** be specified in the implementing act, and shall be a maximum of six months. ***The list of crisis-relevant goods and services may be amended by means of Council implementing act on a proposal from the Commission.***

4. The activation of the ***internal*** market emergency mode regarding certain goods and services does not prevent the activation or continued application of the vigilance mode and deployment of the measures laid down in ***Article 11*** regarding the same goods and services.

▌

▌

Article 15

Extension and deactivation

1. Where the Commission considers, taking into consideration the opinion provided by the ***Board***, that an extension of the ***internal*** market emergency mode is necessary, it shall propose to the Council to extend the ***internal*** market emergency mode. Subject to urgent and exceptional changes in circumstances, the Commission shall ***make best efforts*** to do so no later than 30 days before the expiry of the period for which the ***internal*** market emergency mode has been activated. The Council may extend the ***internal*** market emergency mode by no more than six months at a time by means of ***a Council*** implementing act.

2. Where the ***Board*** has concrete and reliable evidence that the ***internal*** market emergency ***mode*** should be deactivated, it may formulate an opinion to that effect and transmit it to the Commission. Where the Commission, taking into consideration the opinion provided by the ***Board***, considers ***that the internal*** market emergency no longer exists, it shall propose to the Council***,*** without delay***,*** the deactivation of the ***internal*** market emergency mode.

3. The measures taken in accordance with Articles 24 to 33 ▌ shall cease to apply upon deactivation of the ***internal*** market emergency mode. ▌

Title II

▌Free movement during the *internal* market emergency

Chapter I

Measures ▌ facilitating free movement

Article 16

Restrictions to* free movement *during an internal* market emergency *mode

1. ***Without prejudice to Article 17,*** when adopting and applying national measures in response to ***an internal*** market emergency ▌ , Member States shall ensure that ***such measures*** comply with ***Union law, including as regards non-discrimination, justification and proportionality.***

2. ***Member States*** shall ***ensure, in particular, that the measures referred to in paragraph 1 are*** removed as soon as ***they are no longer justified or proportionate***.

▌

3. ***Member States shall ensure that*** any requirement imposed on citizens ***or economic operators does*** not create an undue or unnecessary administrative burden.

▌ ▌

▌

▌

▌ ▌

▌

▌

▌

5. Member States shall ensure that all affected ***citizens and*** stakeholders are informed ***in a clear and unambiguous manner of the*** measures restricting ***the*** free movement of goods, services and persons, including workers and service providers, before their entry into force. Member States shall ensure a continuous dialogue with stakeholders, including communication with social partners and international partners.

Article 17

Prohibited restrictions *on the right to* free movement ▌ during *an internal* market emergency

1. During ***an internal*** market emergency mode and when responding to ***an internal*** market emergency, Member States shall refrain from introducing any of the following:

(-a) any measures which are not limited in time;

(a) ***bans on intra-Union export*** or other measures having equivalent effect on crisis-relevant goods or services listed in an implementing act adopted pursuant to Article ***14(3); or on the transit of crisis-relevant goods listed in an implementing act adopted pursuant to Article 14(3), or measures having equivalent effect***;

(b) ***measures that restrict the intra-Union*** export of goods or ***the cross-border*** provision or receipt of services, or measures having equivalent effect, where those restrictions ***cause*** any of the following***:***

(i) ***disruptions to*** supply chains of crisis-relevant goods and services that are listed in an implementing act adopted pursuant to Article ***14(3),*** or

(ii) ***shortages or an*** increase ***in*** shortages of such goods and services in the ***internal*** market;

(c) ***measures that discriminate beneficiaries of the right to free movement under Union law***, based ▌ on nationality or, in the case of companies, the location of ***their*** registered office, central administration or principal place of business;

▌ ▌

▌

▌

▌ ▌

▌

▌

▌

▌

(d) ***measures that deny*** to beneficiaries of the right ***to*** free movement under Union law, ▌ the right to enter the territory of their Member State of nationality or residence, the right to exit the territory of ***a*** Member ***State*** to travel to ***their*** Member State of nationality or residence, or the right to transit through a Member State in order to reach ***their*** Member State of nationality or residence;

(e) ***measures that prohibit*** business travel linked to the research and development, ***production, placing on the market or related inspections and maintenance of crisis-relevant*** goods that are listed in an implementing act adopted pursuant to Article ***14(3)***;

(f) ***measures that prohibit*** travel ***between Member States*** for imperative family reasons, ***when such travel is permitted within the Member State introducing such a measure***;

▌

(g) ***measures that impose travel restrictions on service providers, business representatives and workers, preventing them from travelling between Member States in order to access to their place of activity or workplace when there are no such restrictions on travel within the Member State introducing such a measure;***

▌

▌

(h) ***measures that impose restrictions preventing the travel of providers of crisis-relevant services*** listed in an implementing act adopted pursuant to Article ***14(3),*** business representatives ***and*** workers ▌ involved in ***the*** production of crisis-relevant goods***, or in the*** provision of crisis-relevant services ▌ listed in an implementing act adopted pursuant to Article ***14(3), or civil protection workers or preventing the transport*** of their ***equipment to the place of their activities.***

▌

I

Article 18

Mitigation* measures *for the free movement of persons

1. During the ***internal*** market emergency mode ***and for the purpose of facilitating the*** free movement of persons referred to in ***points (e) to (h) of*** Article ***17(1), the Commission may,*** by means of implementing acts***, adopt administrative arrangements or provide Member States with digital tools to facilitate the identification of the categories of persons and verification*** of the ***facts referred to in those provisions by the Member States in cooperation*** with the ***other relevant Member States and the Commission***.

2. During the ***internal*** market emergency mode, where the Commission establishes that Member States have put in place templates for attesting that ***an*** individual or economic operator ***fulfils the general requirements stemming from national emergency measures*** and it considers that the use of different templates by each Member ***State*** is an obstacle to the free movement ***of those individuals or economic operators and their equipment***, the Commission may issue, ***by means of implementing acts***, templates ***which may be used by*** all Member States***.***

2a. Without prejudice to relevant Union law and applicable national law and procedures, Member States shall prioritise declaration, registration or authorisation procedures for the providers of crisis-relevant services listed in an implementing act adopted pursuant to Article 14(3).

2b. The Commission shall identify the categories of persons involved in the production or supply of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(3), for which it is necessary to facilitate free movement by establishing by means of implementing acts, after consulting the Board, templates which may be used by the Member States on a voluntary basis.

3. The implementing acts referred to in paragraphs 1***, 2 and 2b*** shall be adopted in accordance with the examination procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the ***internal*** market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

3b. ***Where, in duly justified cases and in accordance with relevant Union law, Member States have introduced restrictions on travel between Member States, the Commission shall coordinate the information exchange between Member States with the aim of making this information publicly available, including, where possible, real-time information.***

3c. ***The Commission shall make information on the mitigation measures it has adopted pursuant to this Article publicly available on a dedicated website.***

Chapter II
Transparency and administrative assistance

Article 19

Transparency

1. ***Where the internal*** market emergency ***mode has been activated in accordance with Article 14(3)***, Member States shall ***communicate*** to the Commission ***and to other Member States via the Union level liaison office the text of any emergency measures in response to the crisis introducing*** restrictions ***on the exercise of the right to*** free movement of persons ***between Member States where such measure is not already covered by an information or notification obligation provided for in other Union legislation, without delay after their adoption,*** together with***:***

   a) the reasons for ***such measures, including reasons demonstrating that the measure is justified and proportionate, as well as any underlying scientific or other data supporting their adoption;***

   b) ***the scope of such measures;***

   c) ***the date of adoption and date of application and duration of*** those measures.

3. Member States ***may communicate to the Commission and the other Member States via the Union level liaison office the draft text of any measures referred in paragraph 1 before their adoption, together with the information referred to in points a) to c) of paragraph 1***.

3a. The communication referred to in paragraph 3 shall not prevent Member States from adopting the measures in question.

4. ***Member States*** shall ***provide the public with clear, comprehensive and timely information explaining the*** measures ***referred to in paragraph 1 as soon as possible*** and shall ***provide that information to the Commission at the same time***.

5. ***The Commission shall, based on the information received pursuant to this Article, publish on a dedicated website, available in all official languages of the Union, relevant information on any restrictions on the exercise of the right to free movement, including information on the scope and duration of national measures in question. The dedicated website may include an interactive map with relevant real-time information on those measures***.

6. The Commission shall ***make the information received pursuant to paragraphs 1, 3 and 4 available to the Board***.

7. ***The information referred to in paragraphs 1, 3 and 4 shall be transmitted via a secure tool provided*** by the Commission ▌ .

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

Article 21

Single points of contact in the Member States

1. Member States shall operate national single points of contact that shall provide citizens, consumers, economic operators and workers and their representatives with the following ▌:

   (a) assistance in requesting and obtaining information about national restrictions of the free movement of goods, services, persons and workers that are related to an activated ***internal*** market emergency ***mode***;

   (b) assistance in the performance of any national level crisis procedures and formalities that have been put in place due to the activated ***internal*** market emergency ***mode***.

2. Member States shall ensure that it is possible for citizens, consumers, economic operators and workers and their representatives to receive, at their request and via the respective single points of contact, information from the competent authorities on the way in which the respective national crisis response measures are generally interpreted and applied. Where appropriate, such information shall include a step-by-step guide. The information shall be provided in clear, understandable and intelligible language. It shall be easily accessible at a distance and by electronic means and shall be kept up to date. ***Member States shall make the information referred to in paragraph 1 also accessible in an official language of the Union that is broadly understood by the largest possible number of cross-border users and shall make best efforts to provide such information in other official languages of the Union, paying particular attention to the situation and needs of the border regions.***

Article 22

Union level single point of contact

1. The Commission shall set up and operate a Union level single point of contact.

2. The Union level single point of contact shall provide citizens, consumers, economic operators, workers and their representatives with the following ▌ :

   (a) assistance in requesting and obtaining information as regards Union level crisis response measures that are relevant to the activated ***internal*** market emergency ***mode*** or which affect the exercise of the free movement of goods, services ***and*** persons***, including*** workers;

   (b) assistance in the performance of any crisis procedures and formalities that have been put in place at the Union level due to the activated ***internal*** market emergency ***mode***;

   (c) ***compiling and publishing*** a list ***of*** all national crisis measures and national contact points.

2a. Sufficient human and financial resources shall be allocated to the Union level single point of contact.

Title III

Internal market emergency response measures

Chapter I

Targeted information requests and availability of crisis-relevant goods and services

Article 23

Requirement of dual activation

1. ***The*** measures included in this Chapter may ***only*** be adopted by the Commission ***when an internal market emergency mode has been activated and a list crisis-relevant goods and, as applicable, services*** has been ***established by the*** Council ***pursuant to*** Article ***14(3)***.

2. An implementing act introducing a measure included in this Chapter shall clearly and specifically list the crisis-relevant goods and services***, from those listed in the implementing act adopted pursuant to Article 14(3)*** to which such ***a*** measure applies. That measure shall apply only for the duration of the emergency mode.

Article 24

Information requests to economic operators

1. ▌The Commission may invite ***the relevant*** economic operators in ***the*** supply chains ***of crisis-relevant goods or services*** to transmit on a voluntary basis ▌ within a set time limit, specific information ***where:***

   (a) there are severe shortages of crisis-relevant goods or services or an immediate threat thereof;

   (b) the information sought is strictly necessary for assessing whether any of the measures laid down in Article 26, or Articles 32 to 37 would be capable of reducing such shortages or the threat thereof;

   (c) the information provided through the Board or through other means from the Member States in the contingency or internal market vigilance mode is not sufficient; and

   (d) the Commission is not able to obtain such information from other sources.

   The Commission, after consulting and in cooperation with the Board, shall assess the existence of the conditions referred to in the first subparagraph.

2. If ***no information is transmitted to the Commission on a voluntary basis within the set time limit pursuant to*** paragraph 1 ***and if the information gathered by the Commission, through the requests for information on a voluntary basis pursuant to paragraph 1, or from any other sources as listed in the contingency or internal market vigilance mode, remains insufficient for assessing whether the deployment of the measures laid down in Article 26, or Articles 32 to 37 would allow reducing the severe shortages of*** crisis-relevant goods ***or*** services ***or the threat thereof and whether any such measures should be taken, the Commission may make a request for information, by means of an implementing act***.

2a. Before adopting such an implementing act, and taking into consideration the opinion of the Board, the Commission shall:

(a) assess the necessity and the proportionality of such an information request for the achievement of the envisaged objectives laid down in paragraph 1(b); This assessment shall be published with the implementing act, if adopted; and

(b) take due account of the administrative burden, which such a request may entail for the concerned economic operators and in particular for small and medium-sized enterprises as defined in the Annex of Commission Recommendation 2003/361/EC (SMEs) and modulate the timelines for submitting the information accordingly.

3. The information requests referred to in ***paragraphs 1 and 2 may only*** concern ***targeted information about***:

(a) ▌ the production capacities and possible existing stocks of the crisis-relevant goods ▌ in production facilities located in the Union and production facilities located in a third country which the ***relevant*** operator ***operates or*** contracts or purchases supply from, while fully respecting trade and business secrets ▌ ;

(aa) the schedule of the expected production output of crisis-relevant goods for the following 3 months, if available, the information request regarding production facilities located in the Union or in a third country in which the operator operates or contracts;

(b) ***any relevant disruptions or shortages of supply chains of crisis-relevant goods or services***.

3a. Any implementing act laying down an information request to economic operators pursuant to paragraph 2 shall:

(a) specify the crisis-relevant goods and services as defined in the list according to Article 14(3) that are relevant for the information request;

(b) specify the relevant economic operators concerned by the information request;

(c) specify the information that is sought, including providing where necessary a template with the questions that may be addressed to the individual relevant economic operators;

(d) demonstrate the existence of the exceptional need referred to in paragraph 1 point b for which the information are requested;

(e) explain the purpose of the request, the intended use of the information requested, and the duration of that use;

(f) specify the timeline by which the economic operator may ask the Commission to modify the request;

(g) be expressed in a clear, concise and understandable language;

(h) take into account the protection of trade secrets; and

(i) take into account the economic operator's effort required to make the information available on a voluntary basis, especially if it is an SME.

4. Following the activation of the information requests to economic operators by means of an implementing act ***pursuant to paragraph 2***, the Commission shall address a ▌ decision to each of those ***relevant*** economic operators in ***supply chains of*** crisis-relevant ***goods or services*** that have been identified in the implementing act ***pursuant to paragraph 2***, requesting them to ***either*** provide the information specified in the implementing act ***pursuant to paragraph 2 or to explain why they cannot provide such information***. The Commission shall rely, where possible, on the relevant and available contact lists of the economic operators active in the selected supply chains of crisis-relevant goods and services, compiled by the Member States ***in accordance with Article 11***. The Commission may ***also where relevant*** obtain the necessary information on the relevant economic operators from the Member States.

4a. When the processing of an information request by a relevant economic operator has the potential to significantly disrupt its operations, the said economic operator may refuse to supply the requested information. The relevant economic operator shall provide to the Commission the reasons for any refusal to supply requested information. The Commission shall not forward or publish an economic operator's refusal to supply the requested information or their reasoning for doing so.

4b. The Commission shall without delay forward a copy of any request for information referred to in paragraphs 1 and 2 to the competent authority of the Member State in whose territory the economic operator is situated. If the competent authority of the Member States so requires, the Commission shall transmit the information acquired from the respective economic operator in accordance with Union law.

4c. The Commission receiving information pursuant to a request for information referred to in paragraphs 1 and 2 shall:

(a) not use the information in a manner incompatible with the purpose for which the information was requested;

(b) ensure, insofar as the processing of personal data is necessary, the implementation of technical and organisational measures that preserve the confidentiality and integrity of the requested information, including in particular personal data, as well as safeguard the rights and freedoms of data subjects;

(c) erase the information as soon as it is no longer necessary for the stated purpose and inform the economic operator and the relevant competent authority of the Member State without undue delay that the information has been erased unless archiving of the information is required for transparency purposes in accordance with national law.

5. The Commission decisions containing individual information requests ***adopted pursuant to paragraph 4*** shall contain a reference to the implementing act referred to in paragraph 2 on which they are based and to the situations of severe crisis-related shortages or an immediate threat thereof which has given rise to them. Any information request shall be duly justified and proportionate in terms of the volume, nature and granularity of the data, as well as the frequency of access to the data requested, and shall be necessary for the management of the emergency ▌ . A request shall set out a reasonable time limit ***not exceeding 20 working days*** within which the information ***or the justification for the refusal to supply such information are*** to be provided. ***The operator may request a one-time extension to the time limit until two days prior to its expiration in the event that the gravity of the situation requires such extension. The Commission shall respond, within one working day, to any such request for an extension to the time limit***. ***When setting this time limit the Commission shall in particular take into consideration the size of the undertaking concerned in terms of employees and its effort to collect and make information available. The*** decision shall also contain safeguards for protection of data in accordance with Article ***40*** of this Regulation, safeguards for non-disclosure of sensitive business information ***and safeguards for non-disclosure of trade secrets and intellectual property*** contained in the reply in accordance with Article ***40a***, and information on the possibility of contesting it before the Court of Justice of the European Union in line with relevant Union law and the ▌ timeline for a reply.

6. ***Relevant*** economic operators or ***anyone duly*** authorised to represent ***the economic operator*** may supply the information requested on behalf of the economic operator ▌ concerned. Each ***relevant*** economic operator ▌ shall provide the requested information on an individual basis in line with the Union rules on competition governing the exchange of information. ▌

▌

8. The implementing acts referred to in paragraph 2 shall be adopted in accordance with the ***examination*** procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the ***internal*** market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

8a. The information requests shall not entail the supply of information the disclosure of which would be contrary to the essential interests of Member States' national security.

Article 26

Activation of emergency procedures in relevant Union **product legislation**

When the ***internal*** market emergency mode has been activated by means of a Council implementing act adopted pursuant to Article 14, and there is a shortage of ***crisis-relevant*** goods the Commission may activate by means of implementing acts the emergency procedures included in the Union legal frameworks amended by Regulation ***(EU) .../...*** of the European Parliament and of the Council[+26] ***[IMERA Omnibus*** Regulation***] and Directive (EU) .../...*** of the European Parliament and of the Council[++27] ***[IMERA Omnibus***

[+] ***OJ: please insert in the text the number of the Regulation contained in document PE-CONS No ... (2022/0279(COD)) and insert the number, date title and OJ reference and ELI reference of that Regulation in the footnote.***

[26] ***Regulation (EU) .../... of the European Parliament and of the Council (...) amending Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 and (EU) 2023/1230 as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency (OJ ...).***

[++] ***OJ: please insert in the text the number of the Directive contained in document PE-CONS No ... (2022/0280(COD)) and insert the number, date title and OJ reference and ELI reference of that Directive in the footnote.***

Directive] as regards crisis-relevant goods, indicating which crisis-relevant goods and emergency procedures are subject to the activation, providing reasons for such activation and its proportionality and indicating the duration of such activation ▌. ***That measure shall apply only during the duration of the internal market emergency mode.***

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the ***internal*** market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

---

[27] ***Directive .../... of the European Parliament and of the Council (...) amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency (OJ ...).***

Article 27

Priority-rated requests

1. The Commission may***, in exceptional situations, after consulting the Member State(s) in which the*** economic operators ***are established, and taking utmost account of its/their view(s), address a request to one or more economic operators*** established in the Union to accept and prioritise certain ***requests*** for the ***production or supply*** of crisis-relevant goods ***('priority-rated requests') when: (a) there is a severe and persistent shortage of the crisis-relevant goods subject to the request; and (b) the production or supply of such goods could not be achieved by other measures provided for in this Regulation, including those referred to in Article 33 or in Part V***.

1a. The Commission must demonstrate that the choice of the recipients and beneficiaries of the requests is non-discriminatory and complies with competition rules.

2. ***The Commission shall base its request on objective, factual, measurable and substantiated data, showing that such prioritisation is indispensable to ensure the maintenance of vital societal economic activities in the internal market,*** as well as ***having regard to the legitimate interests*** of the ▌ economic operator ***and the cost and effort required for any change in production sequence the supply chain***. The Commission's ***request*** shall ***explicitly indicate that the economic operator remains free to refuse the request.***

3. Where the economic operator to which the ***request*** referred to in paragraph ***1*** is addressed ***has expressly accepted the request to prioritise the requests, the Commission shall adopt an implementing act providing for:***

   (a) the legal basis of the priority-rated requests which has to be complied with by the economic operator;

   (b) the goods subject to the priority-rated requests and quantity in which they are to be supplied;

   (c) the time limits within which the priority-rated request is to be completed; and

   (d) the beneficiaries of the priority-rated requests; and

(e) the waiver of contractual liability under the conditions laid down in paragraph 3b.

3a. ***The priority-rated requests shall be placed at a fair and reasonable price adequately taking into account the economic operator's opportunity costs when fulfilling the priority-rated requests vis-à-vis existing contractual obligations. The priority-rated requests*** shall take precedence over any ***prior private or public contractual*** obligation ***related to the goods subject to the priority-rated request*** under private or public law.

3b. ***The economic operator subject to that priority-rated requests shall not be liable for any breach of contractual obligation that is governed by the law of a Member State, only to the extent that:***

(a) ***the breach of contractual obligations is necessary for compliance with the required prioritisation;***

(b) ***the implementing act referred to in paragraph 3 has been complied with; and***

(c) ***the acceptance of the priority-rated request was not solely made with a view to unduly avoiding a prior performance obligation.***

4. ***The priority-rated requests*** shall ***not include goods the production or supply of which would be contrary to the essential interests of Member States' national security or defence***.

▌

5. ***The Commission shall adopt the implementing act referred to in paragraph 3 in accordance with applicable Union law, including the principles of necessity and proportionality, and the Union's obligations under international law***.

6. The ***implementing act*** referred to in paragraph ***3*** shall ***be adopted in accordance with the examination procedure referred to*** in Article ***42(2)***.

7. Where an economic operator***, after having expressly accepted to prioritise the orders requested by the Commission, intentionally or through gross negligence, does not comply with the obligation to prioritise those orders, the Commission may by means of a decision, where deemed necessary and proportionate, impose a fine on the economic operator concerned. That fine*** shall ***not exceed 100 000 EUR. Fines imposed on***

economic operators that are SMEs, as defined in Recommendation 2003/361/EC, shall not exceed 25 000 EUR.

Article 28

Fines to *economic* operators for failure to comply with *an accepted priority-rated request*

1. In fixing the amount of the fine ***in Article 27(7)***, regard shall be had to the size and economic resources of the economic operator concerned, to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness.

2. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine ***in Article 27(7)***. It may cancel, reduce or increase the fine imposed.

Article 29

Limitation period for the imposition of fines

1. The Commission power to impose fines in accordance with Article ***27(7) and Article 28*** shall be subject to ***a two-year*** limitation periods**.**

2. The time shall begin to run on the day on which the Commission becomes aware of the infringement. However, in case of continuous or repeated infringements, time shall begin to run on the day on which the infringement ceases.

3. Any action taken by the Commission or the competent authorities of the Member States for the purposes of ensuring compliance with the provisions of this Regulation shall interrupt the limitation period.

4. The interruption of the limitation period shall apply for all the parties which are held responsible for the participation in the infringement.

5. Each interruption shall start the time running afresh. However, the limitation period shall expire at the latest on the day in which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine. That period shall be extended by the time during which the limitation period is suspended because the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.

Article 30

Limitation periods for enforcement of fines

1. The power of the Commission to enforce decisions taken pursuant to Article ***27(7)*** shall be subject to a limitation period of five years.

2. Time shall begin to run on the day on which the decision becomes final.

3. The limitation period for the enforcement of fines shall be interrupted:

   (a) by notification of a decision varying the original amount of the fine or refusing an application for variation;

   (b) by any action of the Commission or of a Member State, acting at the request of the Commission, designed to enforce payment of the fine.

4. Each interruption shall start time running afresh.

5. The limitation period for the enforcement of fines shall be suspended for so long as:

   (a) time to pay is allowed;

   (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union.

Article 31

Right to be heard for the imposition of fines

1. Before adopting a decision pursuant to Article ***27(7)***, the Commission shall give the economic operator concerned the opportunity of being heard on:

   (a) preliminary findings of the Commission, including any matter to which the Commission has taken objections;

   (b) measures that the Commission may intend to take in view of the preliminary findings pursuant to point (a) of this paragraph.

2. ***The*** economic operators concerned may submit their observations to the Commission's preliminary findings within a time limit which shall be fixed by the Commission in its preliminary findings and which may not be less than 21 days.

3. The Commission shall base its decisions only on objections on which economic operators ▌ concerned have been able to comment.

4. The rights of defence of the economic operator ▌ concerned shall be fully respected in any proceedings. The economic operator ▌ concerned shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of economic operators in the protection of their business secrets. The right of access to the file shall not extend to confidential information and internal documents of the Commission or the authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and the authorities of the Member States. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

Chapter II

Other measures for ensuring availability of crisis-relevant goods and services

Article 32

Solidarity and **coordinated distribution of** ***crisis-relevant goods and services***

1. In the event of a shortage of crisis-relevant goods and services affecting one or more Member States, the Member States concerned may notify the Commission thereof and indicate the quantities needed and any other relevant information. The Commission shall transmit the information to all competent authorities and streamline the coordination of Member States' responses.

2. Where***, pursuant to paragraph 1, the Commission is informed that crisis-relevant goods and services are*** insufficient ***in a Member State*** to meet the needs related to the ***internal*** market emergency, the Commission, taking into consideration the opinion provided by the ***Board and the information collected under this Regulation***, may recommend to ***other*** Member States to distribute ***these crisis-relevant goods or services*** in a targeted way,

where possible, having regard to the need not to further aggravate disruptions on the ***internal*** market, including in geographical areas particularly affected by such disruptions and in accordance with the principles of necessity, proportionality and solidarity and establishing the most efficient use of ***crisis-relevant goods and services*** with a view to ending the ***internal*** market emergency.

Article 33

▌Measures to ensure the availability and supply of crisis-relevant goods ***or*** services

1. ***Where, pursuant to Article 32(1), the Commission is informed*** that there is a risk of a shortage of crisis-relevant goods ***and services in a Member State to meet the needs related to the internal market emergency, it may, taking into consideration the opinion by the Board***, recommend that Member States ***take*** specific measures***. Those measures shall*** ensure the efficient re-organisation of supply chains and production lines and ***the use of*** existing stocks to increase the availability and supply of crisis-relevant goods and services, as quickly as possible.

2. In particular, the measures referred to in paragraph 1 may include measures:

   (a) facilitating the expansion or repurposing of existing or the establishment of new production capacities for crisis-relevant goods;

   (b) facilitating the expansion of existing or the establishment of new capacities related to service activities;

   (c) aiming at accelerating ***relevant approval and authorisation procedures, including environmental permits, regarding or affecting the production and distribution*** of crisis-relevant goods***;***

   (ca) aiming at accelerating authorisation and registration requirements of crisis-relevant services;

   (d) aiming at accelerating relevant product approval procedures in view of placing on the market crisis-relevant goods that are not subject to any Union legislation harmonising the conditions for the marketing of products.

Part V

Public procurement

CHAPTER I

Public procurement of goods and services of *critical* importance and crisis-relevant goods *and services* by the Commission on behalf *of or in the name* of Member States during vigilance and emergency modes

Article 34

Request of Member States to the Commission to procure goods and services on their behalf *or in their name*

1. Two or more Member ▌ may request that the Commission launch a procurement on behalf ***of or in the name*** of the Member States that wish to be represented by the Commission (‘participating Member ***States'***), for the ***provision*** of goods and services of ***critical*** importance listed in an implementing act ▌ pursuant to Article 9(1) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article ***14(3)***.

2. The Commission ***in consultation with the Board, shall assess without delay the*** necessity and proportionality of the request ***referred to in paragraph 1***. Where the Commission intends not to follow ***that*** request, it shall inform the Member States concerned and the ***Board*** and give reasons for its refusal.

3. Where the Commission agrees to procure on behalf of ***or in the name of the participating*** Member States, it shall***:***

   (a) inform all Member States and the Board of its intention to carry out the procurement procedure and invite the interested Member States to participate;

(b) draw up a proposal for ***an*** agreement to be concluded with the participating Member States allowing the Commission to procure ***in their name*** on their behalf. This agreement shall lay down the detailed conditions for the procurement***, including practical arrangements and the proposed maximum quantities, the conditions*** of the ***common purchasing or renting, including prices, and delivery timeframes on behalf of or in the name of the participating Member States***.

3a. ***Where the Commission cancels the procurement procedure in accordance with Article 171 of Regulation (EU, Euratom) 2018/1046, it shall immediately inform the participating Member States thereof, so that the participating Member States can initiate their own procurement procedures without delay.***

Article 35

Establishment and implementation of the negotiating mandate of the Commission

1. The agreement ▌ referred to in Article 34(3)***, point (b)*** shall establish a negotiating mandate for the Commission to ***procure on behalf of or in the name of the participating Member States*** for relevant goods and services of ***critical*** importance or crisis-relevant goods and services ***through the conclusion of new contracts. The negotiating mandate shall include the award criteria***.

2. ***Under this*** agreement, the Commission ***shall*** be entitled, ***when procuring*** on behalf of ***or in the name of*** the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of ***critical*** importance or crisis-relevant goods and services, concerning the ***provision*** of such goods or services.

▌

▌

4. ***Without prejudice to Article 171 of the Financial Regulation,*** the Commission shall carry out the procurement procedures***. When awarding on behalf of or in the name*** of the participating Member States***, the Commission shall conclude the resulting contracts with the economic operators***.

4a. ***The Commission shall invite participating Member States to nominate representatives to take part in the negotiation of the agreement referred to in Article 34 (3)(b) as well as in the preparation of the public procurement procedure.***

▌

4c. The Commission shall ensure that participating Member States are treated in a non-discriminatory manner when carrying out the procurement procedures and when implementing the resulting agreements.

Article 36

Modalities of procurement by the Commission on behalf of *or in the name of* the Member States

1. Procurement under this Regulation shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 ▌ for its own procurement.

2. ***When duly justified by the extreme urgency or when strictly necessary in order to adapt to unforeseen circumstances*** in the ***evolution of the internal market emergency, and provided the modification does not substantially alter the subject matter of the contract or agreement, the Commission may in agreement with the contractor:***

   (a) allow to modify the contract which has been signed, beyond the threshold of 50% and up to 100% of the initial contract value, provided that this is justified as strictly necessary to respond to the evolution of the internal market emergency; and/or

   (b) in common agreement with the simple majority of the participating Member States, allow other Member States to join a signed contract for procurement by the Commission on behalf of or in the name of Member States, or to sign an additional contract in the name of new participating Member State; provided that this is justified as strictly necessary to respond to the evolution of the internal market emergency.

2a. A modification shall be considered to be substantially altering the subject matter of the contract or agreement, where it renders the contract or agreement materially different in substance from the one initially concluded. A modification shall be considered to be substantially altering the subject matter of the contract or agreement where one or more of the following conditions are met:

   (a) the modification introduces or supresses significant conditions which, had they been part of the initial procurement procedure, would have allowed for the admission of other tenderers than those initially selected or for the acceptance of a tender other than that originally accepted, or would have attracted additional participants in the procurement procedure, or would not have led to the selection of the winning tenderer;

(b) the modification significantly changes the economic balance of the contract or the agreement in favour of the contractor in a manner which was not provided for in the initial contract or agreement;

(c) the modification significantly extends the scope of the contract or agreement.

CHAPTER II

Joint Procurement during vigilance and emergency modes

Article 37

Joint procurement procedure

1. ▌The Commission and one or more contracting authorities from ***the participating*** Member States ***may carry out a joint procurement procedure*** in accordance with the rules set out in Article 165(2) of Regulation (EU, Euratom) 2018/1046 ***with a view to the provision of crisis-relevant goods or services or goods and services of critical importance.*** The Member States may acquire, rent or lease fully the capacities jointly procured.

1a. The participation in the joint procurement procedure shall be open to all Member States, as well as to the European Free Trade Association States and Union candidate countries as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State.

1b. The joint procurement procedure shall be preceded by a joint procurement agreement between the participating Member States and third countries in order to determine the practical arrangements governing the procurement and the criteria for awarding the contract, in accordance with the relevant Union law.

▌

▌

The Commission shall inform the European Parliament about the joint procurement procedures conducted in accordance with this Article and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate

protection of commercially sensitive information, including business secrets, commercial relations and the interests of the Union.

Chapter III

Procurement by the Member States during the emergency mode

Article 38

Consultation and coordination regarding individual procurement by the Member States

When the ***internal*** market emergency mode has been activated pursuant to Article 14, Member States***,*** shall ***make best efforts to inform*** each other and the Commission ***about the ongoing procurement procedures of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(3).***

Prior to launching any new procurement procedures in accordance with Directive 2014/24/EU, Member States ***shall:***

(a) ***inform each other about the intention to launch*** procurement of ***such*** crisis-relevant goods and services ***by any of their contracting authorities or contracting entities;***

(b) ***consult the other Member States and the Commission about the most appropriate manner of procurement; and***

(c) ***coordinate their procurement actions at the time of internal market emergency in the spirit of solidarity between the Member States***.

Article 39

Exclusivity clause

1. ***During an internal*** market emergency mode***, the agreement governing the Commission's procurement on behalf or in the name of one or more participating Member States or joint procurement between the Commission and one or more Member States shall, where appropriate, provide for an exclusivity clause, under which participating countries commit to not procuring the crisis-relevant goods or services in question through other channels and to not running parallel negotiation processes.***

Where such clause is provided for, it shall stipulate that the participating Member States are allowed to launch their own procurement procedure for acquisition of additional quantities of crisis-relevant goods or services that are subject to the ongoing joint procurement or procurement by the Commission on behalf of ***or in the name of the*** Member States ***in a manner that does not undermine the ongoing procurement***, ***upon the agreement*** of the ***Commission, after consulting all other*** participating Member States***.*** ***The request for agreement*** shall ***be addressed to the Commission who shall forward it to the*** other ***participating Member States for their observations***.

2. The exclusivity clause shall apply to any new contracts, including specific contracts in framework contracts, that the contracting authorities or contracting entities of the participating Member States would consider concluding during the activation of the internal market emergency mode.

Article 40

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) ***2018/1725***, when fulfilling their responsibilities.

2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of this Regulation. In such cases, the conditions of Regulation (EU) ***2016/679*** and Regulation (EU) ***2018/1725*** shall apply as appropriate.

3. Where processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

Article 40a

Confidentiality and security rules on the protection of the received information

1. Information received as a result of the application of this Regulation shall be used only for the purpose for which it was requested.

2. Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive and confidential information acquired and generated in application of this Regulation, including recommendations and measures to be taken, in accordance with Union and the respective national law.

3. The Commission shall not share any information that it has received under this Regulation in a way that can lead to the identification of an individual operator when the sharing of the information results in potential commercial or reputational damage to this operator or in divulging any trade secrets.

4. The Board shall be bound by the Commission's security rules for protecting European Union classified information (EUCI) and sensitive non-classified information.

5. Member States and the Commission shall ensure that classified information provided or exchanged under this Regulation is not downgraded or declassified without the prior written consent of the originator.

I

Article 41

Digital tools

1. By ... [18 months after the date of entry into force of this Regulation], the Commission and the Member States ***shall, where there are no suitable existing tools or IT infrastructures,*** set up***, maintain and regularly update*** interoperable digital tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures

shall be developed outside the duration of ***an internal*** market emergency ***in order to respond to possible future emergencies in a timely and efficient manner. They shall include, inter alia, standardised, secure and effective digital tools for the secure collection and exchange of information, as well as a dedicated single digital portal or website where citizens and businesses can find and submit declaration, registration or authorisation forms***.

2. The Commission shall, by means of implementing acts, set out the technical aspects of such tools or infrastructures ***using, where possible, already existing IT tools or portals***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(2).

Part VI

Final provisions

Article 42

Committee

1. The Commission shall be assisted by ***the internal*** market emergency ***and resilience*** committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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.

Article 44

Report*, review and evaluation*

1. By ***... [***five years from the ***date of*** entry into force of this Regulation] and every five years thereafter ▌ the Commission shall ***carry out an evaluation of and submit*** a report to the European Parliament and the Council on the functioning ***and effectiveness of this Regulation.***

1a. ***In addition, by 4 months after the deactivation of the internal market vigilance mode or, as applicable, the internal*** market emergency ***mode, the Commission shall carry out an evaluation and submit a report to the European Parliament and the Council on the measures implemented under this Regulation in relation to the crisis that led to such an activation***, ***in particular on the effectiveness of those measures.***

1b. ***The reports referred to in paragraph 1 and 1a shall be*** accompanied, where appropriate, by relevant legislative proposals.

▌

2. ***The reports referred to in paragraphs 1 and 1a shall include, in particular, an evaluation of the following:***

   (a) the contribution of this Regulation to the smooth and efficient functioning of the internal market, in particular as regards the free movement of goods, services and persons and the avoidance of divergent national measures which would create cross-border restrictions;

   (b) all the measures implemented under this Regulation including an assessment of the principles of non-discrimination and proportionality, in particular: (i) the impact of the measures implemented under the contingency mode, in particular measures regarding stress tests, training and crisis protocols, digital tools, resilience and availability of goods; (ii) the impact of the measures implemented under the internal market vigilance mode; (iii) the impact of the measures implemented during the internal market emergency mode, and in particular on the

fundamental rights enshrined in the Charter of Fundamental Rights of the European Union, namely as regards the freedom to conduct business, the freedom to seek employment and to work, and on the right to collective bargaining and action, including the right to strike;

(c) the work of the Board, including its work in relation to the work of other relevant Union-level crisis management bodies, in particular the IPCR, HERA and UCPM;
(ca) the appropriateness of the criteria for the activation of the internal market vigilance mode or the internal market emergency mode, as appropriate.

▌

2a. For the purpose of paragraphs 1 and 1a, the competent authorities of the Member States and the Board shall provide the Commission with information upon its request.
Where necessary, the Commission may also ask and obtain from relevant Union bodies, offices and agencies any relevant specialised or scientific knowledge.

Article 45

Amendments to Regulation (EC) No 2679/98

Council Regulation (EC) ***No 2679/98 is amended as follows:***

(1) Article 2 is replaced by the following:

'This Regulation shall not in any way affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relation systems in Member States, in accordance with national law or practice. Nor does it affect the right to negotiate and conclude collective agreements and, in cases of conflicts of interest, to take collective action to defend their interests, including strike action in accordance with national law or practice.';

(2) The following Article is added:

'Article 5a

1. Where the internal market emergency mode referred to in Article 14 of Regulation …/2023 [IMERA] has been activated, Articles 3, 4 and 5 of this Regulation shall cease to apply in respect to the crisis-relevant goods listed in an implementing act adopted pursuant to Article 14(3) of Regulation (EU) .../... (IMERA)] for the duration of that mode.

2. Paragraph 1 is without prejudice to any obligation arising from this Regulation prior to the activation of the emergency mode in accordance with the [***IMERA Regulation***]***.'***

Article 46

Entry into force *and application*

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

▌

▌

It shall apply from ... [18 months after the date of entry into force of this 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*

▌

▌REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL▐

amending Regulations *(EU) No 305/2011,* **(EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU)** *2023/988 and (EU) 2023/1230* **as regards emergency procedures for the conformity assessment,** *presumption of conformity,* **adoption of common specifications and market surveillance due to** *an internal* **market emergency**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[24],

Acting in accordance with the ordinary legislative procedure[25],

---

[24] OJ C , , p. .

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

Whereas:

(1) [insert reference to ***IMERA*** Regulation] aims to ensure the normal functioning of the ***internal*** market, including the free movement of goods, services and persons and ***ensure*** 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 ***IMERA*** 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 ***internal*** market that a crisis may cause.

(3) [insert reference to ***IMERA*** Regulation] lays down a multi-layered mechanism consisting of contingency planning, ***and internal*** market ***vigilance and*** emergency ***modes***.

(4) [insert reference to ***IMERA*** Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the ***internal*** market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to ***IMERA*** 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 ***crisis-relevant goods*** referred to in [insert reference to ***IMERA*** 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[26], (EU) 2016/425[27], (EU) 2016/426[28],[29] ***(EU) No 305/2011[30] and (EU) No 2023/1230[31]*** 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) ***No***

---

[26] OJ L 81, 31.3.2016, p. 1.
[27] OJ L 81, 31.3.2016, p. 51.
[28] OJ L 81, 31.3.2016, p. 99.
[29] ***OJ L 170, 25.6.2019, p. 1.***
[30] ***OJ L 88, 4.4.2011, p. 5.***
[31] ***OJ L 165, 29.6.2023, p 1.***

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[32]**.**

[32] ***OJ L 218, 13.8.2008, p. 82.***

(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral ***Union*** 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 ***internal*** 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 ***IMERA*** Regulation].

(8a) Non-harmonised products can also be crisis-relevant goods. Therefore, some of the relevant mechanisms under this Regulation, notably the presumption of safety based on national requirements, national or international standards, could provide an additional avenue to establish the presumption of safety of non-harmonised crisis-relevant goods during the crisis. This would facilitate the placing on the market of non-harmonised crisis-relevant goods in times of crisis.

(9) In order to overcome the potential effects of disruptions on the ***internal*** market and in order to ensure that ***harmonised*** 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, no additional disproportionate costs may be charged by the conformity assessment body to the manufacturer. All additional costs charged by a conformity assessment body to the manufacturer should be strictly proportionate to the actual additional efforts deployed by the conformity assessment body to implement the prioritisation and should be limited to the period of application of the internal market emergency. The transfer of certain additional and proportionate costs by the conformity assessment bodies to the manufacturers should remain exceptional and should reflect a fair distribution of the costs among all the stakeholders involved in the efforts to contain the disruptions to the functioning of the internal market. The costs associated with conformity assessment should not become a barrier to the entry on the market of prospective new manufacturers, in particular SMEs and should not restrict the emergence***

of innovative products. Furthermore, 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) ***No 305/2011, (EU) 2023/988 and (EU) 2023/1230***. Those procedures should be available only following the activation of the ***internal*** market emergency mode in accordance with [***insert reference to IMERA 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 ***Union*** sectoral ***harmonisation*** legislation.

(12) As regards products falling within the scope of those ***harmonisation*** Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing ***internal*** market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, ▌ where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they ***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. By providing an additional, parallel avenue for exceptionally placing crisis-relevant goods on the market in the context of an internal market emergency, the derogatory rules enable new manufacturers to swiftly place their products on the market without the need to wait for the finalisation of the normal conformity assessment procedures. Such an accelerated and exceptional placing on the market contributes to the swift increase in the supply of crisis-relevant goods and at the same time provides the manufacturers with a facilitation as it allows them to place initial batches or series of products on the market before the conclusion of the conformity assessment procedures.

Once the conformity assessment procedures have been successfully completed, subsequent batches or series of products should be fully compliant with the relevant, applicable rules and thus benefit from free movement. The co-existence during an internal market emergency of an exceptional, derogatory set of rules alongside the existing rules thus makes it possible to transition towards the existing rules, enabling the manufacturers to continue placing their products on the market after the expiry or deactivation of the internal market emergency mode.

(12b) 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. That implementing act can provide that the benefit of the free movement is also granted to goods already placed on the market on the basis of pre-existing authorisation. 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.

(12c) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active internal market emergency mode, as referred to in the IMERA Regulation, should automatically expire on the date of expiry or deactivation of the internal market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once 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, (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.

(12d) 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 due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.

(12e) All authorisations for the placing on the market of crisis-relevant goods issued by Member States should contain at least certain elements which substantiate the assessment of the compliance of the good in question with the applicable essential requirements and which allow to ensure traceability. The relevant elements concerning the traceability include specific requirements regarding the labelling, accompanying documents or any additional means of ensuring the identification of the goods concerned and allowing to trace them along the supply chain. In order to ensure uniform and coherent implementation of the traceability requirements across the Union, Commission implementing acts extending the validity of authorisations issued by a Member State should also specify the common traceability requirements. These include the specific arrangements regarding the indication that the product concerned is a 'crisis-relevant good'. On expiry of the internal market emergency mode, the Commission should be empowered to adopt via implementing acts any necessary adjustments to the traceability requirements for crisis-relevant products that have already been placed on the market on the basis of an authorisation issued by a Member State.

(13) Where ***an internal*** 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. ***The Union general product safety framework established by Regulation (EU) 2023/988 also establishes under certain conditions a mechanism of presumption of conformity with the general safety requirement where a product complies with relevant European standards, the references of which have been published in the Official Journal of the European Union.*** However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative ***crisis-response*** mechanisms.

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

(15a) With respect to Regulation (EU) 2023/988, under the competent national authorities should be able to presume that products manufactured in accordance with European or national standards of the Member States, or with relevant international standards developed by a recognised international standardisation body comply with the general safety requirement. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the internal market emergency mode. Where there is evidence that the crisis-relevant non-harmonised product placed on the market during an internal market emergency on the basis of the presumption of conformity established via these emergency procedures is dangerous, the market surveillance authorities should be allowed to take all appropriate measures under Regulation (EU) 2023/988. After the expiry or deactivation of the internal market emergency mode a demonstration of compliance with the said European, relevant and

applicable international, or national standards of the Member States should no longer provide a presumption of conformity with the general safety requirement.

(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 ***and (EU) 2023/1230***, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers 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 ***internal*** market emergency. ***Products placed on the market on the basis of the presumption of conformity established via the demonstration of compliance with these common specifications should not be withdrawn automatically simply as a result of the expiry or withdrawal of the implementing act laying down the said common specifications. In cases where there are concerns regarding the compliance of a crisis-relevant product placed on the market during an internal market emergency on the basis of the presumption of conformity established via the demonstration of compliance with common specifications, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act laying down the common specifications a demonstration of compliance with the said common specifications should no longer provide a presumption of conformity with the relevant and applicable essential requirements.***

I

(18) In order to ensure that the level of safety provided by the harmonised ***and non-harmonised*** products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.

(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) ***No 305/2011, (EU) 2023/988 and (EU) 2023/1230*** should therefore be amended accordingly**.**

(21) In order for this Regulation to apply from the same date as ***IMERA*** 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) …/…. [IMERA Regulation];***

(29) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(2) The following Chapter Va is inserted after Chapter V:

‘Chapter Va

▌EMERGENCY PROCEDURES

Article 43a

▌Application of emergency procedures

1. Articles 43b to 43g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of ***the IMERA*** 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(3) of the IMERA Regulation***.

3. Articles 43b to 43g, except as regards ***the power*** of the Commission ***in Article 43e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

However, Article 43 ▌ c(5) shall apply during the ***internal*** 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 subsystems and safety components placed on the market in accordance with Articles 43c to ***43e***. 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 ***make best efforts to*** 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***.

▌

4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or the incorporation into a cableway installation within the territory of 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 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 ▌ competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation***. 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 ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the subsystem or safety component ***placed on the market***.

▌

5. By way of derogation from Articles 7***, 20 and 21***, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and Article 7*** shall not ***apply***.

5a. 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 subsystems or safety components.

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

▌

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

▌

▌

▌

▌

▌

▌

I

Article 43e

Presumption of conformity based on standards and common specifications

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

   (a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** market, which led to the activation of the ***internal*** market emergency mode in accordance with Article 14 of ***the IMERA*** Regulation ▌ , significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 44(3) and they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 17, subsystems and safety components 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 II covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 43a(3), ▌ 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 ▌ present a risk to the health or safety of persons, the subsystems or safety components ***which are in conformity 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 II*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** 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 II, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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

▌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) …/…. [IMERA Regulation];***

(20) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(2) The following Chapter VIa is inserted after Chapter VI:

‘Chapter VIa

▌EMERGENCY PROCEDURES

Article 41a

▌Application of emergency procedures

1. Articles 41b to 41g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of ***the IMERA*** Regulation.

2. Articles 41b to 41g apply exclusively to PPE, which has been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

3. Articles 41b to 41g, except as regards ***the power*** of the Commission ***in Article 41e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

   However, Article 41▌ c(5) shall apply during the ***internal*** 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 PPE placed on the market in accordance with Articles 41c to ***41e. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). ▌

Article 41b

▌ Prioritisation of the conformity assessment of crisis-relevant PPE

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

2. The notified bodies shall ***make best efforts to*** process all applications for conformity assessment of PPE designated as ***a*** crisis-relevant ***good*** 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***.

▌

4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for PPE 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 19, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, 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 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 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*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market***. 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 ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the PPE ***placed on the market***.

▌

▌

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

5a. 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 PPE.

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

▌

8. ▌The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned.▌

▌

▌

▌

▌

▌

Article 41e

Presumption of conformity based on standards and common specifications

1. Where PPE ***has*** been designated as ***a*** crisis-relevant ***good***, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications for such PPE to cover the ***applicable*** essential health and safety requirements set out in Annex II in either of the following cases:

   (a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   ▌

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation ***of the internal*** Market emergency mode ***in accordance with Article 14 of [the IMERA Regulation],*** 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 ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph ***1 shall*** be adopted ▌ in accordance with the examination procedure referred to in Article 44(3) ***and*** they shall ***apply*** until the last day of the period for which the ***internal*** 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 groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 14, PPE which ***is*** 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 ***applicable*** 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, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer***

be relied upon from the day the internal market emergency mode expires or is deactivated.

4. By way of derogation from Article 41a(3), ▌ unless there is sufficient reason to believe that the PPE covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the PPE ***which is in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market shall be deemed compliant with ***the applicable essential health and safety requirements set out in Annex II*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** 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 ▌ set out in Annex II, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

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 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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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 components*** designated as crisis-relevant goods.'

Article 3

Amendments to Regulation (EU) 2016/426

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

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

‘ ***(32) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(33) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation];’

(2) The following Chapter Va is inserted after Chapter V:

‘Chapter Va

▌ EMERGENCY PROCEDURES

Article 40a

Application of emergency procedures

1. Articles 40b to 40g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of ***the IMERA*** Regulation.

2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which ***have*** been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

3. Articles 40b to 40g, except as regards ***the power*** of the Commission ***in Article 40e(3)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

However, Article 40▌c(5) shall apply during the ***internal*** 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 appliances and fittings placed on the market in accordance with Articles 40c to ***40e***. 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 ***make best efforts to*** 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***.

▌

4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect ***of*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or ***the*** 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 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.

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).

1b. 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 ***an*** appliance or ***a*** fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ▌competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market***. 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 ***appliance or fitting*** concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of the IMERA Regulation***;

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

(e) measures to be taken ▌ upon expiry of the ***internal market emergency with respect to*** the appliance or fitting ***placed on the market***.

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 ▌ shall not ***bear the CE marking and Article 6*** shall not ***apply***.

5a. 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 appliances or fittings.

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

▌

8. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned. ▌

▌

▌

▌

▌

▌

Article 40e

Presumption of conformity based on standards and common specifications

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

   (a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   ▌

   ▌

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** market emergency mode in accordance with Article ***14 of the IMERA*** Regulation ▌ , significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential requirements set out in Annex I ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 42(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 13, appliances or fittings 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 ***applicable*** essential requirements set out in Annex I covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 40a(3), ▌ unless there is sufficient reason to believe that the appliances or fittings covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the appliances or fittings ***which are in conformity*** with those ***standards or*** common specifications ***and*** which have been placed on the market shall be deemed compliant with ***the applicable essential requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with ***the IMERA*** Regulation ▌ .

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential requirements ▌ set out in Annex I, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

Article 40g

▌ Prioritisation of market surveillance activities and mutual assistance among authorities

1. ▌ Member States shall prioritise the market surveillance activities for ***appliance*** 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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***an internal*** 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 4a

Amendments to Regulation (EU) 2023/988

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

(1) In Article 2(1), point (b) is replaced by the following:

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

(2) The following chapter is inserted:

‘Chapter IIa
EMERGENCY PROCEDURES

Article 8a

Activation of the emergency procedures, relationship with other provisions of this Regulation and deactivation

1. Articles 8b to 8d shall only apply if the Commission has adopted an implementing act pursuant to Article 14(3) of the IMERA Regulation.

2. Articles 8b to 8d shall only apply to products covered by this Regulation which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Articles 8b to 8d shall apply during the internal market emergency mode activated by a measure adopted in line with Article 14(3) of IMERA Regulation, except with respect to provisions concerning the powers of the Commission.

Article 8b

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

1. ***In addition to the presumption of conformity laid down in Article 7 of this Regulation, where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibility for manufacturers to make use of the relevant European standards already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, it shall be considered, for the purpose of placing products on the market, that the presumption of conformity with the general safety requirement laid down in Article 5 may also be established if the product conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law.***

2. ***In addition to the cases where the presumption of conformity with the general safety requirement laid down in Article 5 applies under paragraph 1 and Article 7(1), Member States shall take all appropriate measures to ensure that, for the purpose of placing or making available of products on the market, their competent authorities consider that the products which comply with the relevant European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012, the relevant international standards developed by a recognised international standardisation body as defined by Article 2(9) of Regulation (EU) 1025/2012, and relevant national standards developed by a national standardisation body as defined by Article 2(10) of Regulation (EU) 1025/2012, are presumed to meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those***

standards are concerned unless such standards are not adequate in view of the other elements of Articles 6 and 8 of this Regulation.

3. Article 7(3) applies in the presumption of conformity established in accordance with this Article.

Article 8d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. ***Member States shall prioritise market surveillance activities for products covered by this Regulation, which have been designated as crisis-relevant goods.***

2. ***The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency.'***

Article 5[33]

Amendments to Regulation (EU) No 305/2011

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

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

‘ ***(29) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(30) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(1) The following Chapter VIa is inserted ***after Chapter VI***:

‘Chapter VIa

▌EMERGENCY PROCEDURES

▌

Article 38a

Application of emergency procedures

1. Articles 38b to 38f ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of ***the IMERA*** Regulation.

2. Articles 38b to 38f shall apply exclusively to construction products, which have been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

[33] In order to ensure the continued application of the emergency provisions also to construction products covered by the new Construction Product Regulation, it is understood that corresponding provisions will also need to be inserted into the new Construction Product Regulation before its final adoption

3. Articles 38b to 38f, except as regards ***the power*** of the Commission ***in Article 38d(5)***, shall apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of the IMERA Regulation***.

However, Article 38▌c(5) shall apply during the ***internal*** 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 construction products placed on the market in accordance with Articles 38b to ***38d. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)**.**

▌

▌

Article 38b

Prioritisation of the assessment and verification of constancy of performance of 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 ***make best efforts to*** 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 38a***.

▌

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 ***2*** shall not give rise to ***additional disproportionate*** costs for the ***manufacturers, who*** have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods. ▌

Article 38d

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) ▌ 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 and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** market, which led to the activation of the ***internal*** market emergency mode ***in accordance with Article 14 of the IMERA Regulation,*** 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 ***Regulation (EU) No 1025/2012***.

1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 64(2a) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Regulation and shall duly consult all relevant stakeholders.

3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the ***standards or*** common specifications ***referred to in*** paragraph 1***, 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 internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 38a(3), ***unless there is sufficient reason to believe that construction products covered by the standards or*** common specifications referred to in paragraph 1 ***present a risk to the health or safety of persons or fail to achieve the declared performance, the 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 shall remain valid after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the internal market emergency mode in accordance with the IMERA Regulation***.

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*** a detailed explanation**.** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing ***act listing the standard or*** establishing the common specification in question**.**

▌

▌

▌

▌

Article 38f

▌ 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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during an ***internal*** 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) 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 are added:

‘***(37) ‘crisis-relevant goods’ means ‘crisis-relevant goods’ within the meaning of Article 3, point (6) of Regulation (EU) …/…. [IMERA Regulation];***

(38) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA 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 of this Regulation shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of the IMERA 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(3) of the IMERA Regulation.

3. ***Articles 25b to 25e, except as regards the power of the Commission in Article 25d(5), shall apply only during the internal market emergency mode activated in accordance with Article 14 of the IMERA Regulation.***

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

5. ***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 make best efforts to 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 additional disproportionate additional costs for the manufacturers, who have lodged those applications.***

4. ***The notified bodies shall make reasonable efforts to increase their testing capacities for machinery and related products designated as crisis-relevant goods in respect of which they have been notified.***

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 from an economic operator, the placing on the market or putting into service within the territory of the Member State concerned, of specific machinery or 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.***

2. ***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 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 internal market emergency mode has been activated in accordance with Article 14 of the IMERA 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 internal 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 applicable 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 II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period; or

(b) severe disruptions in the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant applicable 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

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 applicable 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 internal 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 applicable 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 internal market emergency mode in accordance with the IMERA Regulation.

5. When a Member State considers that a standard or common specification referred to in paragraph 1 does not entirely satisfy the applicable essential requirements set out in Annex 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 ensure that best efforts are made to provide assistance to other market surveillance authorities during an internal 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

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 IMERA 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*

▌

▌DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL▌

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

(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[34],

Having regard to the opinion of the Committee of the Regions[35],

Acting in accordance with the ordinary legislative procedure[36],

---

[34] OJ C , , p. .

[35] OJ C , , p. .

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

Whereas:

(1) [insert reference to ***IMERA*** Regulation] aims to ensure the normal functioning of the ***internal*** market, including the free movement of goods, services and persons and ***ensure*** 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 ***IMERA*** 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 ***internal*** market that a crisis may cause.

(3) [insert reference to ***IMERA*** Regulation] lays down a multi-layered mechanism consisting of contingency planning, ***and internal*** market ***vigilance and*** emergency ***modes***.

(4) [insert reference to ***IMERA*** Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the ***internal*** market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to ***IMERA*** 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 ***IMERA*** Regulation] may be swiftly placed on the ***internal*** market in order to contribute to addressing and mitigating the disruptions.

(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[37], 2006/42/EC[38], 2010/35/EU[39], , 2014/29/EU[40], 2014/30/EU[41], 2014/33/EU[11], 2014/34/EU[12], ▌ 2014/35/EU[13], 2014/53/EU[14] and 2014/68/EU[15] of the European Parliament 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[16].

---

37 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).

38 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).

39 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).

40 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).

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

11 Directive 2014/33/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).

12 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).

13 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).

14 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).

15 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).

16 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral ***Union*** 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 ***internal*** 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 ***IMERA*** Regulation].

(9) In order to overcome the potential effects of disruptions on the ***internal*** market and in order to ensure that ***harmonised*** 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, no additional disproportionate costs may be charged by the conformity assessment body to the manufacturer. All additional costs charged by a conformity assessment body to the manufacturer should be strictly proportionate to the actual additional efforts deployed by the conformity assessment body to implement the prioritisation and should be limited to the period of application of the internal market emergency. The transfer of certain additional and proportionate costs by the conformity assessment bodies to the manufacturers should remain exceptional and should reflect a fair distribution of the costs among all the stakeholders involved in the efforts to contain the disruptions to the functioning of the internal market. The costs associated with conformity assessment should not become a barrier to the entry on the market of prospective new manufacturers, in particular SMEs and should not restrict the emergence of innovative products. Furthermore, 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 Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, ▌ , 2014/29/EU, 2014/30/EU, ▌ 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and, 2014/68/EU. Those procedures should be available only following the activation of the ***internal*** market emergency ***mode*** and only when a specific good covered by those Directives is designated as ***a*** crisis-relevant ***good*** in accordance with [***insert reference to IMERA 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 ***Union*** sectoral ***harmonisation*** legislation.

(12) As regards products falling within the scope of those ***harmonisation*** Directives that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing ***Internal*** Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Directives, ▌ where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they ***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 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 the 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 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. By providing an additional, parallel avenue for exceptionally placing crisis-relevant goods on the market in the context of an internal market emergency, the derogatory rules enable new manufacturers to swiftly place their products on the market without the need to wait for the finalisation of the normal conformity assessment procedures. Such an accelerated and exceptional placing on the market contributes to the swift increase in the supply of crisis-relevant goods and at the same time provides the manufacturers with a facilitation as it allows them to place initial batches or series of products on the market before the conclusion of the conformity assessment procedures.

Once the conformity assessment procedures have been successfully completed, subsequent batches or series of products should be fully compliant with the relevant, applicable rules and thus benefit from free movement. The co-existence during an internal market emergency of an exceptional, derogatory set of rules alongside the existing rules thus makes it possible to transition towards the existing rules, enabling the manufacturers to continue placing their products on the market after the expiry or deactivation of the internal market emergency mode.

(12b) 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. That implementing act can provide that the benefit of the free movement is also granted to goods already placed on the market on the basis of pre-existing authorisation. 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.

(12c) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active internal market emergency mode, as referred to in the IMERA Regulation, should automatically expire on the date of expiry or deactivation of the internal market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once 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. 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.

(12d) 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 due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.

(12e) All authorisations for the placing on the market of crisis-relevant goods issued by Member States should contain at least certain elements which substantiate the assessment of the compliance of the good in question with the applicable essential requirements and which allow to ensure traceability. The relevant elements concerning the traceability include specific requirements regarding the labelling, accompanying documents or any additional means of ensuring the identification of the goods concerned and allowing to trace them along the supply chain. In order to ensure uniform and coherent implementation of the traceability requirements across the Union, Commission implementing acts extending the validity of authorisations issued by a Member State should also specify the common traceability requirements. These include the specific arrangements regarding the indication that the product concerned is a 'crisis-relevant good'. On expiry of the internal market emergency mode, the Commission should be empowered to adopt via implementing acts any necessary adjustments to the traceability requirements for crisis-relevant products that have already been placed on the market on the basis of an authorisation issued by a Member State.

(13) Where ***an internal*** 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 ***crisis-response*** mechanisms.

(15) With respect to ***Directives*** 2006/42/EC, ▌ 2014/29/EU, 2014/30/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 ***European or*** national ***standards of the Member States, or with relevant*** international standards ***developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and*** ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant ***and applicable*** essential ***requirements. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the implementing act listing the European, relevant and applicable international or the national standards of the Member States. In cases where there are concerns regarding the compliance of a harmonised crisis-relevant product placed on the market during an internal market emergency on the basis of a presumption of conformity established via such an implementing act, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act, compliance with the European, relevant and applicable international or the national standards of the Member States should no longer provide a presumption of conformity with the relevant and applicable essential*** requirements.

(16) Furthermore, with respect to Directives 2006/42/EC, ▌ 2014/29/EU, 2014/30/EU, ▌ 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers 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 ***internal market emergency. Products placed on the market on the basis of the presumption of conformity established via the demonstration of compliance with these common specifications should not be withdrawn automatically simply as a result of the expiry or withdrawal of the implementing act laying down the said common specifications. In cases where there are concerns regarding the compliance of a crisis-relevant product placed on the market during an internal*** market emergency ***on the basis of the presumption of conformity established via the demonstration of compliance with common specifications, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act laying down the common specifications a demonstration of compliance with the said common specifications should no longer provide a presumption of conformity with the relevant and applicable essential requirements***.

▌

(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, ▌, 2014/29/EU, 2014/30/EU, ▌ 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU should therefore be amended accordingly**,**

HAVE ADOPTED THIS DIRECTIVE:

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) …/…. [IMERA Regulation];

(h) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA 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, 17d shall*** only apply if ***the*** Commission has adopted an implementing act pursuant to Article ***26 of the IMERA*** Regulation ▌ .

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 ***pursuant to Article 14(3) of the IMERA Regulation***.

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

   However, Article 17 ▌ c(5) shall apply during the ***internal*** 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 equipment placed on the market in accordance with ***Articles 17c to 17e***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ***18(2)***.

Article 17b

▌ Prioritisation of the conformity assessment of 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 ***make best efforts to*** 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 43a***.

▌

4. The prioritisation of applications for conformity assessment of ▌ equipment pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or putting into service within the territory of 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 ▌ 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 the conformity with the applicable requirements concerning the noise emission in the environment , the Commission shall without delay adopt an implementing act extending 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 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 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 ***emissions*** in the environment ▌ and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ***competent national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the equipment may be placed on the market or put into service***. The authorisations shall at least set out the following***:

(a) a description of the procedures, by means of which ▌ compliance with the applicable requirements concerning the noise emission in the environment ▌ was successfully demonstrated;

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

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of [the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the equipment concerned ***placed on the market***.

▌

5. By way of derogation ***from Articles 6,*** and 11, equipment, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not bear the CE marking ***and Article 6 shall not apply***.

5a 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 Directive with respect to such equipment.

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

▌

8. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** 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 ***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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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.'

(3) Article 18 ***is replaced by the following***:

▌

'Article 18

Committee procedure

1. The Commission shall be assisted by a Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council.

▌

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

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) …/…. IMERA Regulation;

o 'internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… IMERA Regulation].;’

(2) the following Articles are inserted:

‘Article 21b

▌ Application of emergency procedures ▌

1. Member States shall ensure that measures taken to transpose Articles 21c to 21h of this directive only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of [the ***IMERA*** Regulation] ▌ .

2. Member States shall ensure that measures taken to transpose Articles 21c to 21h ▌ apply exclusively to machinery, which has been designated as crisis-relevant goods ***pursuant to Article 14 of [the IMERA Regulation]***.

3. Member States shall ensure that measures taken to transpose Articles 21c to 21h ***shall*** apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of [the IMERA Regulation]***.

   However, Article 21 ▌ d(5) shall apply during the ***internal*** 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 placed on the market 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 ***make the best efforts to*** 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.***▌

▌

4. The prioritisation of applications for conformity assessment of machinery pursuant to paragraph 2 ▌ shall not give rise to ▌ additional ***disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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 ***the*** conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article 12, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or putting into service within the territory of the Member State concerned, of ***a*** specific machinery 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 12 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 applicable essential health and safety requirements laid down in this Directive, the Commission shall without delay adopt an implementing act extending 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 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 ***competent*** national ▌ authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery may be placed on the market or put into service***. 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 ***internal*** market emergency mode has been activated ***in accordance with Article 14 of [the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to the*** machinery ***placed on the market or put into service***

▌

5. By way of derogation from Articles 6 and 16, machinery, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and Article 6*** shall not ***apply.***▌

5a. 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 Directive ▌ with respect to such machinery.

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

▌

8. 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 12 on the territory of the Member State concerned.

▌

▌

▌

▌

▌

Article 21f

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 ***applicable*** essential health and safety requirements set out in Annex I, in either of the following cases:

   (a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** market***,*** which led to the activation ***of the internal*** market emergency mode in accordance with Article ***14 of [the IMERA*** Regulation]***,*** 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 I ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 22(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 7, machinery which is 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 ***applicable*** 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 internal 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 ▌ presents a risk to the health or safety of persons, the machinery ***which is in conformity with the standards or*** common specifications ***and*** which has been placed on the market ***or put into service*** shall be deemed compliant with ***the applicable essential health and safety requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation].

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

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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:

‘ ***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) …/…. IMERA Regulation;

(28) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… IMERA Regulation.;'

(2) ***the following chapter is inserted:***

'Chapter 5a

▌EMERGENCY PROCEDURES

Article 33a

▌Application of emergency procedures▌

1. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d of this Directive only apply if the Commission has adopted an implementing act pursuant to Article ***26 of the IMERA*** 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 ***pursuant to Article 14 of [the IMERA Regulation].***▌

3. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d ***shall*** apply ***only during the internal market emergency mode activated in accordance with Article 14 of [the IMERA Regulation].***▌

4. However, ▌ Article 33c(5) shall apply during the ***internal*** market emergency mode and after its deactivation or expiry.

5. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to transportable pressure equipment placed on the market in accordance with Article 33c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38a(2). ▌

Article 33b

▌ Prioritisation of the conformity assessment of 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 ***make best efforts to*** 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***.

▌

4. The prioritisation of applications for conformity assessment of transportable pressure equipment pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, 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 specific transportable pressure equipment may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. 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 ***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 transportable pressure equipment may be placed on the market or put into service***. 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 set out in the Annexes to Directive 2008/68/EC and in this Directive was successfully demonstrated;

(b) ***any*** specific requirements regarding the traceability of the transportable pressure equipment concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the transportable pressure equipment ***placed on the market***.

▌

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 ▌ shall not ***bear the Pi marking and Article 16 shall not apply***.

5a. 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 transportable pressure equipment. 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 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.

▌

8. ▌The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article ***18*** 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 ***ensure that best efforts are made to provide assistance to other market surveillance authorities during a internal 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 designated as crisis-relevant goods. The market surveillance authorities of the Member States shall ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) 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 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) …/…. IMERA Regulation;

(19) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(2) ▌ the following chapter▌ is inserted:

‘Chapter 5a

▌ EMERGENCY PROCEDURES

Article 38a

▌ Application of emergency procedures ▌

1. Member States shall ensure that measures taken to transpose Articles 38b to 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to ▌ Article 26 of [the ***IMERA*** Regulation]**.**

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 ***pursuant to Article 14 of [the IMERA Regulation]***.

3. Member States shall ensure that measures taken to transpose Articles 38b to 38g ***shall*** apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of [the IMERA Regulation].***▌

However, Article 38▌ c(5) shall apply during the ***internal*** 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 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 ***make best efforts to*** 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.***▌

▌

4. The prioritisation of applications for conformity assessment of vessels ***components*** pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate costs for the manufacturers, who have lodged those applications.***
The prioritisation of applications for conformity assessment of vessels pursuant to paragraph 2 shall not give rise to additional ***disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or putting into service within the territory of 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 specific 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 ***competent*** national ▌ authority.

▌

3. Any authorisation issued ▌ 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***. 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 ***internal*** market emergency mode has been activated ***in accordance with Article 14 of [the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the vessel ***placed on the market***.

▌

5. By way of derogation from Articles 5***, 15*** and 16, vessels, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and inscriptions and Article 5*** shall not ***apply***.

5a. 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 Directive with respect to such vessels.

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

▌

8. ▌The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned.▌

▌

▌

▌

▌

▌

Article 38e

Presumption of conformity based on standards and common specifications

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

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode in accordance with Article ***14 of [the IMERA*** Regulation]***,*** significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential safety requirements set out in Annex I ***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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 shall be adopted ▌ in accordance with the examination procedure referred to in Article 39(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 12, vessels 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 ***applicable*** essential safety requirements set out in Annex I covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 38a(3), ▌ unless there is sufficient reason to believe that the vessels covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the vessels ***which are in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market shall be deemed compliant with ***the applicable essential safety requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation].

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential safety requirements ▌ set out in Annex I, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) …/…. [IMERA Regulation];

(27) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].’

(2) the following chapter ▌ 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 26 of [the ***IMERA*** 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 ***pursuant to Article 14 of [the IMERA Regulation].***▌

3. Member States shall ensure that measures taken to transpose Articles 40b to 40g ***shall*** apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of [the IMERA Regulation].***▌

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific labelling and traceability requirements*** with respect to apparatus placed on the market in accordance with 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 ***make best efforts to*** 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***.

▌

4. The prioritisation of applications for conformity assessment of apparatus pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for apparatus designated as crisis-relevant goods in respect ***of*** which they have been notified. ▌

▌

▌

▌

▌ ▌

▌

▌ ▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

▌

Article 40e

Presumption of conformity based on standards and common specifications

1. Where apparatus ▌ has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts***, listing appropriate standards or*** establishing common specifications ***for such apparatus*** to cover the ***applicable essential*** requirements set out in Annex I ▌ in either of the following cases:

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode ***in accordance with Article 14 of [the IMERA Regulation],*** significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential requirements set out in Annex I ***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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article ***41(2) and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 13, apparatus 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 ***applicable*** essential requirements set out in Annex I covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 40a(3), ▌ unless there is sufficient reason to believe that the apparatus covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the apparatus ***which are in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market shall be deemed compliant with ***the applicable essential requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation].

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential ▌ requirements ▌ set out in Annex I, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) in Article 41, the following paragraph ▌ is inserted:

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

▌

▌

▌

▌

▌

▌

▌

▌

▌

I

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) …/…. [IMERA Regulation];***

(23) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation]. ’

(2) the following chapter is inserted:

‘Chapter Va

▌EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures ▌

1. Member States shall ensure that measures taken to transpose Articles 41b to 41g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article ***26 of [the IMERA*** 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 ***pursuant to Article 14 of [the IMERA Regulation].***▌

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

However, ▌ Article 41c(6) shall apply during the ***internal*** 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 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 ***make the best efforts to*** 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.***▌

▌

4. The prioritisation of applications for conformity assessment of lifts and safety components for lifts ▌ pursuant to paragraph ***2*** shall not give rise to ▌ additional ***disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for lifts and safety components for lifts 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator, the placing on the market*** 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 ***the*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market ▌ within the territory of the Member State concerned, of a specific lift 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 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***.

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 specific lift or the safety component for lifts may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. 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 ▌ safety component for lifts subject to the authorisation ***procedure*** referred to in ***paragraph 1*** shall declare on his sole responsibility that the ***lifts or*** 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 ▌ competent ***national*** authority.

▌

4. Any authorisation issued ▌ pursuant to ***paragraph 1or*** 2 shall set out the conditions and requirements under which the lift or ▌ safety component for lifts may be placed on the market***. 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 ***internal*** market emergency mode has been activated ***in accordance with Article 14 of IMERA Regulation***;

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the ***lifts*** or safety component for lifts concerned;

(e) measures to be taken with respect to the lift or safety component for lifts ***placed on the market upon expiry of the internal market emergency***.

▌

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 ▌ shall not ***bear the CE marking and Article 3*** shall not ***apply. parked***

6a. The market surveillance authorities of ***a*** Member State, ***where*** an authorisation pursuant to ***paragraphs 1, 2, 2a and 2c 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 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.

▌

9. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 15 ***and*** 16 on the territory of the Member State concerned ▌

▌

▌

▌

▌

▌

Article 41e

Presumption of conformity based on standards and common specifications

1. Where lifts and safety components for lifts ▌ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts ***listing appropriate standards or*** establishing common specifications for such lifts and safety components for lifts to cover the ***applicable*** essential health and safety requirements set out in Annex I in either of the following cases:

   (a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

   ▌

   ▌

   ▌

   ▌

   (b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode in accordance with Article ***14 of [the IMERA*** Regulation], 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 I ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 42(3). They shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 14, lifts and safety components for lifts 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 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 internal 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 ▌ present a risk to the health or safety of persons, the lifts and safety components for lifts ***which are in conformity with the standards or*** common specifications ***and*** which have been placed on the market shall be deemed compliant with ***the applicable essential health and safety requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** Market Emergency mode in accordance with [the ***IMERA*** Regulation].

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

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) …/…. [IMERA Regulation];***

(28) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation]. '

(2) the following chapter is inserted:

'Chapter 5a

▌EMERGENCY PROCEDURES

Article 38a

▌Application of emergency procedures▌

1. Member States shall ensure that measures taken to transpose Articles 38b to 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article▌ 26 of [the ***IMERA*** Regulation]▌ .

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 ***pursuant to Article 14 (5) of [the IMERA Regulation]***.

3. Member States shall ensure that measures taken to transpose Articles 38b to 38g ***shall*** apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of [the IMERA Regulation]***.

   However, Article 38▌ c(5) shall apply during the ***internal*** 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 products placed on the market in accordance with Articles 38c to ***38e***. 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 ***make best efforts to*** 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***.

▌

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

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for ▌ products 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or putting into service within the territory of 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 ▌ 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 specific 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 ▌ competent ***national*** authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the product may be placed on the market or put into service***. 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 product concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of [the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the product ***placed on the market***.

▌

5. By way of derogation from Articles 5***, 15*** and 16, products, for which an authorisation has been granted in accordance with paragraph 1 ▌ shall not ***bear the CE marking and Article 5*** shall not ***apply***.

5a. 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 Directive with respect to such products.

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

▌

8. ▌ 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 13 on the territory of the Member State concerned. ▌

▌

▌

▌

▌

▌

▌

Article 38e

Presumption of conformity based on standards and common specifications

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

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode in accordance with Article ***14 of [the IMERA*** Regulation], 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 ***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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 39(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article ***17***, 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 ***applicable*** 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, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 38a(3), ▌ unless there is sufficient reason to believe that the ▌ products ▌ covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the products ***which are in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market shall be deemed compliant with ***the applicable essential health and safety requirements set out in Annex II*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation].

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential health and safety ▌ requirements ▌ set out in Annex II, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or

repeal the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) …/…. [IMERA Regulation];***

(16) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;’

(2) the following chapter is inserted:

‘Chapter 4a

▌ EMERGENCY PROCEDURES

Article 22a

▌ Application of emergency procedures ▌

1. Member States shall ensure that measures taken to transpose Articles 22b to 22c and 22d of this Directive ▌ only apply if the Commission has adopted an implementing act pursuant to Article ▌ 26 of [the ***IMERA*** Regulation] ▌ .

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 ***pursuant to Article 14 of [the IMERA Regulation]***.

3. Member States shall ensure that measures taken to transpose Articles 22b, 22c and 22d ***shall*** apply ***only*** during the ***internal*** market emergency mode ***activated in accordance with Article 14 of [the IMERA Regulation]***.

4. The Commission ***may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures*** to be ***followed and the specific***

labelling and traceability requirements with respect to electrical equipment placed on the market in accordance with Articles ***22c to 22e***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ***23(3)***. ▌

Article 22b

Presumption of conformity based on standards and common specifications

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

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode in accordance with Article ***14 of [the IMERA*** 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▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 23(2). They shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Articles 12, 13 and 14, electrical equipment which is 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 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 internal Market Emergency mode expires or is deactivated.

4. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that ▌ electrical equipment ***components*** covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ present a risk to the health or safety of persons, the electrical equipment ***which are in conformity*** with those ***standards or*** common specifications ***and*** which ***have*** been placed on the market ▌ shall be deemed compliant with ***the safety objectives referred to in Article 3 and set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** 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 ***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 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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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) …/…. [IMERA Regulation];

(28) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].; ’

(2) the following chapter is inserted:

‘Chapter Va

▌ EMERGENCY PROCEDURES

Article 43a

▌ Application of emergency procedures ▌

1. Member States shall ensure that measures taken to transpose Articles 43b to 43g ***shall apply only*** if the Commission has adopted an implementing act pursuant to Article ▌ 26 of [the ***IMERA*** Regulation] ▌ .

2. Member States shall ensure that measures taken to transpose Articles 43b to 43g ***shall*** apply exclusively to radio equipment, which has been designated as crisis-relevant goods ***pursuant to Article 14(3) of the IMERA Regulation***.

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

   However, Article 43 ▌ c(5) shall apply during the ***internal*** 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 radio equipment placed on the market in accordance with Articles 43c to ***43e***. 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 ***make best efforts to*** process all applications for conformity assessment ▌ 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***.

▌

4. The prioritisation of applications for conformity assessment of radio equipment pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** efforts to increase their testing capacities for radio equipment 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 17, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market within the territory of the Member State concerned, of ***a*** specific radio equipment 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 17*** 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 applicable essential requirements laid down in this Directive, the Commission shall without delay adopt an implementing act extending 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 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 44(3).

The specific 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 ***competent*** national ▌ authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the radio equipment may be placed on the market***. 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 radio equipment concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the radio equipment ***placed on the market***.

▌

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 ▌ shall not ***bear the CE marking and Article 9*** 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 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.

▌

7. ▌ The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned. ▌

▌

▌

▌

▌

▌

▌

Article 43e

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 ***applicable*** essential requirements set out in Article 3 in either of the following cases:

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode in accordance with Article ***14 of [the IMERA*** Regulation], ▌ significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential requirements set out in Article 3 ▌ 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 45(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 16, radio equipment which is 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 ***applicable*** essential requirements set out in Article 3 covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 43a(3), ***unless*** there is sufficient reason to believe that the radio equipment covered by the ***standards or*** common specifications referred to in paragraph 1 ▌ presents a risk to the health or safety of persons, the radio equipment ***which is in conformity*** with those ***standards or*** common specifications ***and*** which has been placed on the market shall be deemed compliant with ***the applicable essential requirements set out in Article 3*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation]**.**

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential requirements ▌ set out in Article 3, it shall inform the Commission thereof ***by submitting*** a detailed explanation**.** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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

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) …/…. [IMERA Regulation];***

(34) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [IMERA Regulation].;'

(2) the following chapter is inserted:

'Chapter 5a

▌EMERGENCY PROCEDURES

Article 43a

▌Application of emergency procedures▌

1. Member States shall ensure that measures taken to transpose Articles 43b to 43g of this Directive ***shall*** only apply if the Commission has adopted an implementing act pursuant to Article▌ 26 of [the ***IMERA*** Regulation]▌ .

2. Member States shall ensure that measures taken to transpose Articles 43b to 43g ***shall*** apply exclusively to pressure equipment and assemblies, which have been designated as crisis-relevant goods ***pursuant to Article [14(3) of the IMERA Regulation]***.

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

   However, Article 43▌ c(5) shall apply during the ***internal*** 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 pressure equipment and assemblies placed on the market in accordance with Articles 43c to ***43e***. 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 ***make best efforts to*** 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***.

▌

4. The prioritisation of applications for conformity assessment of pressure equipment and assemblies pursuant to paragraph ***2*** shall not give rise to ***additional disproportionate*** costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall ***make reasonable*** 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, ***the Member State*** may authorise, on a duly justified request ***from an economic operator***, the placing on the market or putting into service within the territory of the Member State concerned, of ***a*** specific pressure equipment or assembly ***which has been*** designated as crisis-relevant good and for which the conformity assessment procedures ***requiring the mandatory involvement of a notified body,*** referred to in▌ Article ***14*** have not been carried out by a notified body but for which the compliance with all the applicable essential safety requirements has been demonstrated ***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 safety requirements laid down in this Directive, the Commission shall without delay adopt an implementing act extending 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 pressure equipment or assemblies 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 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 ▌ 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 ***competent*** national ▌ authority.

▌

3. Any authorisation issued ▌ pursuant to paragraph 1 shall set out the conditions and requirements under which the pressure equipment or assembly may be placed on the market or put into service***. The authorisations shall at least set out the following***:

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

(b) ***any*** specific requirements regarding the traceability of the pressure equipment or assembly concerned;

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***internal*** market emergency mode has been activated ***in accordance with Article 14 of [the IMERA 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 ▌ upon expiry of the ***internal market emergency with respect to*** the pressure equipment or assembly ***placed on the market***.

▌

▌

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 ▌ shall not ***bear the CE marking and Article 5*** shall not ***apply***.

5a. 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 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.

▌

8. ▌The use of the authorisation procedure set out in ***paragraphs 1 to 1c shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

▌

▌

▌

▌

▌

▌

Article 43e

Presumption of conformity based on standards and common specifications

1. Where pressure equipment and assemblies have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts***,*** ***listing appropriate standards or establishing common specifications*** for such pressure equipment and assemblies ▌ to cover the ***applicable*** essential safety requirements set out in Annex ***I*** in either of the following cases:

▌

(a) ▌ 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***and no such reference is expected to be published within a reasonable period***; ***or***

▌

▌

▌

▌

(b) ▌ severe disruptions in the functioning of the ***internal*** Market, which led to the activation of the ***internal*** Market emergency mode ***in accordance with Article 14 of [the IMERA Regulation],*** significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant ***applicable*** essential safety requirements set out in Annex ***I 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 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.

▌

▌

▌

▌

2. The implementing acts referred to in paragraph 1 ▌ shall be adopted ▌ in accordance with the examination procedure referred to in Article 44(3) ***and*** they shall apply ▌ until the last day of the period for which the ***internal*** 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 groups established under this Directive and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 12, pressure equipment or assemblies 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 ***applicable*** essential safety requirements set out in Annex ***I*** covered by those ***standards,*** common specifications or parts thereof. ***The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.***

4. By way of derogation from Article 43a(3), ***unless*** there is sufficient reason to believe that the pressure equipment and assemblies covered by the ***standards or*** common specifications referred to in paragraph 1 ***present*** a risk to the health or safety of persons, the pressure equipment and assemblies ***which are in conformity*** with those ***standards or*** common specifications ***and*** which have been placed on the market shall be deemed compliant with ***the applicable essential safety requirements set out in Annex I*** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ▌ and after the expiry or deactivation of the ***internal*** market emergency mode in accordance with [the ***IMERA*** Regulation].

5. When a Member State considers that a ***standard or*** common specification referred to in paragraph 1 does not entirely satisfy the ***applicable*** essential safety requirements ▌ set out in Annex I, it shall inform the Commission thereof ***by submitting*** a detailed explanation***.*** The Commission shall assess that ***detailed explanation and, may, where*** appropriate, amend or ***repeal*** the implementing act ***listing the standard or*** establishing the common specification in question. ▌

▌

▌

▌

▌

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 ***ensure that*** best efforts ***are made*** to provide assistance to other market surveillance authorities during a ***internal*** 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 IMERA Regulation] Member States shall adopt and publish the measures*** necessary to comply with this Directive. They shall ***immediately inform*** the Commission ***thereof***.

2. They shall apply those ***measures*** from […***] [OP:*** please ***insert*** the date of ***the*** entry into ***application of the IMERA Regulation + 1 day***].

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

3. ***As soon as this Directive has entered into force,*** Member States shall ***ensure that*** the Commission ***is informed, in sufficient time for it to submit its comments, of any draft laws, regulations or administrative provisions*** which they ***intend to*** adopt in the field covered by this Directive.

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*