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Remiss: Europeiska kommissionens förslag till ett krisinstrument för den inre marknaden

Remissinstanser

1 ABB
2 AB SKF
3 AI Sweden
4 AB Volvo
5 Akavia
6 Alfa laval AB
7 Almega
8 Arbetsdomstolen
9 Arbetsgivarverket
10 Arbetsmiljöverket
11 Boverket
12 Business Sweden
13 Chalmers tekniska högskolan AB
14 Domstolsverket
15 Elsäkerhetsverket
16 Energiföretagen Sverige
17 Ericsson AB
18 Epiluvac
19 Folkhälsomyndigheten
20 Företagarna
21 Försvarsmakten
22 Försvarets materielverk
23 Försvarets radioanstalt
24 Förvaltningsrätten i Stockholm
25 Industrifacket Metall
26 Innovationsföretagen
27 IKEM - Innovations- och kemiindustrierna
28 Industriarbetsgivarna
29 Inspektionen för strategiska produkter
30 Inspektionen för vård och omsorg
31 Investor AB
32 Justitiekanslern (JK)
33 Kemikalieinspektionen
34 Knut och Alice Wallenbergs stiftelse
35 Kommerskollegium

36 Konkurrensverket
37 Konsumentverket
38 Kronofogdemyndigheten
39 Kungliga Tekniska högskolan
40 Kustbevakningen
41 Landsorganisationen i Sverige (LO)
42 Lantbrukarnas riksförbund
43 Lif – de forskande läkemedelsföretagen
44 Livsmedelsverket
45 Luleå tekniska universitet
46 Läkemedelsverket
47 Länsstyrelsen i Hallands län
48 Länsstyrelsen i Skåne län
49 Länsstyrelsen i Västmanlands län
50 Mobility Sweden
51 Myndigheten för samhällsskydd och beredskap
52 Mölnlycke Healthcare
53 Nacka tingsrätt (Mark- och miljödomstolen)
54 Naturskyddsföreningen
55 Northvolt
56 Näringslivets Regelnämnd
57 Polismyndigheten
58 Post- och telestyrelsen
59 Research Institutes of Sweden AB
60 Regelrådet
61 Riksdagens ombudsmän – JO
62 Saab
63 Scania
64 SINF
65 Småföretagarnas Riksförbund
66 Socialstyrelsen
67 Statens energimyndighet
68 Statens jordbruksverk
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2022-09-26
UD2022/12161

Utrikesdepartementet
Enheten för internationell handelspolitik och EU:s inre marknad, Inre marknaden

Europeiska kommissionens förslag till förordning om ett krisinstrument för den inre marknaden inklusive förslag till omnibusdirektiv och omnibusförordning med uppdatering av vissa förordningar och direktiv

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I remissen ligger att regeringen vill ha synpunkter på samtliga tre delar i kommissionens förslag till ett krisinstrument för den inre marknaden (förordning om ett krisinstrument, omnibusförordning och omnibusdirektiv). Krisinstrumentet gäller krisåtgärder och omnibusrättsakterna innehåller uppdateringar av 19 befintliga rättsakter om reglering av olika produktkategorier.

Myndigheter under regeringen är skyldiga att svara på remissen. En myndighet avgör dock på eget ansvar om den har några synpunkter att redovisa i ett svar. Om myndigheten inte har några synpunkter, räcker det att svaret ger besked om detta.

För **andra remissinstanser** innebär remissen en inbjudan att lämna synpunkter.

Råd om hur remissyttranden utformas finns i Statsrådsberedningens promemoria Svara på remiss (SB PM 2021:1). Den kan laddas ned från Regeringskansliets webbplats www.regeringen.se.

Charlotte Sammelin
Departementsråd

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EUROPEAN
COMMISSION

Brussels, 19.9.2022
COM(2022) 459 final

2022/0278 (COD)

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

(Text with EEA relevance)

{SEC(2022) 323 final} - {SWD(2022) 288 final} - {SWD(2022) 289 final} - {SWD(2022) 290 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The Single Market is one of the EU's greatest assets and provides the backbone for the EU's economic growth and wellbeing. Recent crises, such as the COVID-19 pandemic or Russia's invasion of Ukraine, have demonstrated some vulnerability of the Single Market and its supply chains in case of unforeseen disruptions and, at the same time, how much the European economy and all its stakeholders rely on a well-functioning Single Market. In the future, in addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. For this reason, the functioning of the Single Market needs to be guaranteed in times of emergency.

The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to the appearance of obstacles to free movement within the Single Market, thus disrupting its functioning. On the other hand, a crisis can amplify the shortages of crisis-relevant goods and services if the Single Market is fragmented and is not functioning. As a result, supply chains can swiftly become interrupted, companies face difficulties in sourcing, supplying or selling goods and services. Consumer access to key products and services becomes disrupted. Lack of information and legal clarity further exacerbate the impact of these disruptions. In addition to direct societal risks caused by the crisis, citizens, and in particular vulnerable groups, are confronted with strong negative economic impacts. The proposal therefore aims to address two separate but interrelated problems: obstacles to free movement of goods, services and persons in times of crisis and shortages of crisis-relevant goods and services.

In close cooperation with all Member States and other existing EU crisis instruments, the Single Market Emergency Instrument (SMEI) will provide a strong agile governance structure as well as a targeted toolbox to ensure the smooth functioning of the Single Market in any type of future crisis. It is likely that not all of the tools included in this proposal will be needed simultaneously. The purpose is rather to brace the EU for the future and equip it with what may prove to be necessary in a given crisis situation severely affecting the Single Market.

The European Council in its Conclusions of 1-2 October 2020[1] stated that the EU will draw the lessons from the COVID-19 pandemic and address remaining fragmentation, barriers and weaknesses of the Single Market in facing emergency situations. In the Update of the Industrial Strategy Communication[2], the Commission announced an instrument to ensure the free movement of persons, goods and services, as well as greater transparency and coordination in times of crisis. The initiative forms part of the Commission Work Programme for 2022[3]. The European Parliament welcomed the Commission's plan to present a Single Market Emergency Instrument and called on the Commission to develop it as a legally binding structural tool to ensure the free movement of persons, goods and services in case of future crises[4].

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1 https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf.

2 COM(2021)350 final.

3 https://ec.europa.eu/info/publications/2022-commission-work-programme-key-documents_en.

4 European Parliament resolution of 17 February 2022 on tackling non-tariff and non-tax barriers in the single market (2021/2043(INI).

- **Consistency with existing policy provisions in the policy area**

A number of EU legal instruments lay down provisions which are relevant for the management of crises in general. On the other hand, certain EU frameworks and recently adopted Commission proposals lay down more targeted measures which focus on certain aspects of crisis management or are relevant for specific sectors. The Single Market Emergency Instrument will apply without prejudice to the provisions put forward by these targeted crisis management instruments, which are to be considered as *lex specialis*. Financial services, medicinal products, medical devices or other medical counter-measures and food safety products in particular are excluded from the scope of the initiative due to the existence of a dedicated crisis-relevant framework in these areas.

Interplay with horizontal crisis response mechanisms

The integrated political crisis response mechanism (IPCR)[5] is among the horizontal crisis response mechanisms[6]. The Presidency of the Council of the EU uses the IPCR to facilitate information sharing and political coordination among the Member States in responding to complex crises. The IPCR scrutinised for the first time in October 2015 the refugee and migration crisis and it has been instrumental in monitoring and supporting the response to the crisis, reporting to Coreper, the Council and the European Council. The IPCR operated the Union response to major crises caused by cyber-attacks, natural disasters, or hybrid threats. More recently, the IPCR has also operated after the outbreak of the COVID-19 pandemic and the Russian brutal aggression on Ukraine.

Another EU mechanism for general crisis response is the Union Civil Protection Mechanism and its Emergency Response Coordination Centre (ERCC)[7]. The ERCC is the Commission's central operational 24/7 hub for first emergency response, the establishment of strategic stockpiles at the EU level for emergency response ("rescEU"), disaster risk assessments, scenario building, disaster resilience goals, EU wide overview of natural and man-made disaster risks, other prevention and preparedness measures, such as training and exercises.

Interplay with horizontal Single Market mechanisms

When appropriate and necessary, coordination should be ensured between the Single Market Emergency Instrument and the activities of the Single Market Enforcement Task-Force (SMET). In particular, the Commission shall refer notified obstacles that significantly disrupt the free movement of goods and services of strategic goods and services for discussion/review to the Single Market Enforcement Task Force (SMET).

- **Consistency with other Union policies**

Interplay with measures targeting specific aspects of crisis management

The above-mentioned horizontal crisis response mechanisms are supplemented by other more targeted measures, focusing on specific aspects of the Single Market such as the free movement of goods, common rules on exports or public procurement.

One such framework is the Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to

5 https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/.

6 It was formally set up by Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response, on the basis of previously existing arrangements.

7 Laid down by the Decision (EU) 1313/2013 governing the functioning of the Union Civil Protection Mechanism.

serious disruptions and requiring immediate action ('The Strawberry Regulation')[8]. This Regulation provides for a mechanism of notification as well as a system of information exchange between the Member States and the Commission. (See sections 8.1 and 8.2 for more details.)

The Regulation on common rules for exports[9] allows the Commission to subject certain categories of products to an extra-EU export surveillance or to an extra-EU export authorisation. The Commission was subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance[10] on this basis.

Other economic measures include negotiated procedure and occasional joint procurement by the Commission on behalf of the Member States[11].

Interplay with sector-specific crisis measures

Certain EU frameworks lay down more targeted measures which focus only on certain specific aspects of crisis management or only concern certain specific sectors.

The Commission communication "Contingency plan for ensuring food supply and food security"[12] draws lessons learnt during the COVID-19 pandemic and previous crises with the objective to step up coordination and crisis management including preparedness. To this end, the contingency plan puts forward key principles to be followed to ensure food supply and food security in the event of future crises. To ensure the implementation of the contingency plan and the key principles therein, the Commission in parallel established the European Food Security Crisis preparedness and response Mechanism (EFSCM), a group composed of Member States and non-EU countries representatives as well as of food supply chain stakeholders chaired by the Commission to strengthen coordination, exchange data and practices. The EFSCM was convened for the first time in March 2022 to discuss the impacts of the energy and input price increases and the consequences of Russia's invasion of Ukraine for food security and supply. The market observatories and the civil dialogue groups are other fora that ensure transparency and the flow of information in the food sector.

The Commission communication "Contingency plan for transport"[13] has the objective to ensure crisis preparedness and business continuity in the transport sector. The plan establishes a "crisis manual" that includes a toolbox consisting of 10 actions aimed at mitigating any negative impact on the transport sector, passengers and the internal market in the event of a crisis. These include among others measures rendering EU transport laws fit for crisis situations, ensuring adequate support for the transport sector, ensuring free movement of goods, services and people, sharing of transport information, testing transport contingency in real-life situations etc.[14]

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8 Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, *OJ L 337, 12.12.1998, p. 8.*

9 Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015.

10 Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021.

11 They can be adopted on the basis of 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.

12 COM(2021)689 final.

13 COM(2022)211 final.

14 Additional measures include: managing refugee flows and repatriating stranded passengers and transport workers, ensuring minimum connectivity and passenger protection, strengthening transport policy coordination through the Network of National Transport Contact Points, strengthening cybersecurity and cooperation with international partners.

Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products[15] (CMO Regulation) as well as the sister CMO Regulation for fisheries[16] provide the legal basis for collecting relevant information from Member States to improve market transparency[17].

Regulation (EU) No 2021/1139 1308/2013 establishing the European Maritime, Fisheries and Aquaculture Fund[18] (EMFAF Regulation) provides the legal basis for supporting the fisheries and aquaculture sector in case of exceptional events causing a significant disruption of markets.

Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate[19] sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Furthermore, based on Commission proposals, the Council adopted specific recommendations on the coordinated approach to the restriction of free movement in response to COVID-19 pandemic[20]. The Commission also announced in the 2020 citizenship report[21] that it intends to review the 2009 guidelines on free movement in order to improve legal certainty for EU citizens exercising their free movement rights, and to ensure a more effective and uniform application of the free movement legislation across the EU. The reviewed guidelines should address among others the application of restrictive measures on free movement, specifically those that are due to public health concerns.

Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices provides a framework to monitor and mitigate potential and actual shortages of centrally and nationally

[15] 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, *OJ L 347, 20.12.2013, p. 671.*

[16] Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000. *OJ L 354, 28.12.2013, p. 1.*

[17] Following Russia's invasion of Ukraine, the obligation for Member States to provide monthly notifications of cereal stocks has been included in an amendment to Commission Implementing Regulation (EU) 2017/1185 of 20 April 2017 laying down rules for the application of Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards notifications to the Commission of information and documents and amending and repealing several Commission Regulations, *OJ L 171, 4.7.2017, p. 113.*

[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[19] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, *OJ L 211, 15.6.2021, p. 1.*

[20] Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, *OJ L 337, 14.10.2020, p. 3 and its subsequent updates.*

[21] COM(2020)730 final.

authorised medicinal products for human use considered as critical to address a given 'public health emergency' or 'major event' [22].

Finally, the Commission Decision of 16 September 2021 established the Health Emergency Preparedness and Response Authority[23] for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.

Interplay with ongoing initiatives

In parallel, a number of initiatives, which have been recently proposed and are currently being discussed, concern aspects relevant for the crisis response and preparedness. These initiatives however have a limited scope covering specific types of crisis scenarios and are not intended to set up a general horizontal crisis-management framework. To the extent these initiatives include a sectoral crisis response and preparedness framework, that framework will take precedence over the Single Market Emergency Instrument as *lex specialis*.

The Commission proposal for a Regulation on serious cross-border threats to health, repealing Decision No 1082/2013/EU (the 'Cross-border Health Threats Decision')[24] aims at strengthening the EU's health security framework, and reinforcing the crisis preparedness and response role of key EU agencies with respect to serious cross-border health threats[25]. When adopted, it will strengthen the preparedness and response planning and reinforce epidemiological surveillance and monitoring, improve data reporting, strengthen EU interventions.

The Commission proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 established a European Centre for disease prevention and control[26].

The Commission proposal for a Council Regulation 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[27] provides for crisis response tools such as joint procurement, mandatory information requests for businesses about their production capacities, and repurposing production lines in case of public health crises once a public health emergency would be declared. The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis-relevant products. The proposal covers medical countermeasures defined as medicinal products for human use, medical devices and other goods or services that are necessary for the purpose of preparedness and response to serious cross-border threats to health.

The Commission proposal for the European Chips Act[28] aims to strengthen Europe's semiconductor ecosystem. One important pillar of this strategy is to set up a mechanism for coordinated monitoring and response to shortages in the supply of semiconductors, aiming to anticipate and swiftly respond to any future supply chain disruptions, through a dedicated

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22 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*

23 C(2021)6712 final.

24 COM(2020)727 final.

25 The term of "cross-border" is understood as covering both any situation affecting more than one Member State ("across borders") as well as more specifically a situation affecting regions in two or more Member States sharing a common border ("border regions").

26 COM/2020/726 final

27 COM(2021)577 final.

28 COM(2022)46 final.

emergency toolbox, together with Member States and international partners. The planned mechanism is specific to a possible semiconductor crisis and will apply in an exclusive way if the crisis mode is activated.

The Commission proposal for a Data Act[29] will allow public sector bodies to access data held by the private sector that is necessary for exceptional circumstances, particularly to implement a legal mandate if data are not otherwise available or in case of a public emergency (i.e. exceptional situation negatively affecting the population of the Union, a Member State or part of it, with a risk of serious and lasting repercussions on living conditions or economic stability, or the substantial degradation of economic assets in the Union or the relevant Member State(s)).

The Commission proposal to amend the Schengen Borders Code[30] aims to provide a common response at the internal borders in situations of threats affecting a majority of Member States. The proposed amendment will also put in place procedural safeguards in case of unilateral reintroductions of internal border controls and provide for the application of mitigating measures and specific safeguards for cross-border regions in cases where internal border controls are reintroduced. Such controls affect in particular people crossing the border for their daily life (work, education, health care, family visits) as evidenced during the COVID-19 pandemic. The proposal promotes increased use of effective alternative measures to address the identified threats to internal security or public policy instead of internal border controls, for instance increased checks by police or other authorities in border regions, subject to certain conditions. The proposal also includes the possibility for the Council to quickly adopt binding rules setting out temporary travel restrictions for third country nationals at the external borders in case of a threat to public health. It also clarifies which measures Member States can take to manage the EU's external borders effectively in a situation where migrants are instrumentalised by third countries for political purposes.

The proposal for a Directive on the resilience of critical entities adopted by the Commission in December 2020[31] has the objective to enhance the resilience of entities providing services that are essential for the maintenance of vital societal functions or important economic activities the EU. With this initiative, the aim is to create a comprehensive framework to support Member States in ensuring that critical entities providing essential services are able to prevent, protect against, respond to, resist, mitigate, absorb, accommodate and recover from significant disruptive incidents such as natural hazards, accidents or terrorism. The Directive will cover eleven key sectors, including energy, transport, banking and health.

The Joint communication of 18 May 2022 on the Defence Investment Gaps Analysis and Way Forward, identified several issues including the ability of the EU's Defence Technological and Industrial Base (as well as the global Defence Technological and Industrial Base) to address upcoming defence Member State procurement needs, and putting forward several measures.

In the context of the General Product Safety Directive 2001/95/EC revision, the Commission intends to examine the questions whether and to what extent, or by what modalities, the production issues that are addressed by the Omnibus rules as regards goods covered by various harmonised regimes could be addressed in the distinct context of non-harmonised goods.

Consistency with the EU's external action

29 COM (2022)68 final.
30 COM (2021)891 final.
31 COM(2020)829 final.

The European External Action Service will support the High Representative in her/his function, as Vice-President of the Commission, to coordinate the Union's external action within the Commission. Union delegations under the authority of the High Representative will exercise their functions as external representatives of the Union and assist, as relevant, in external dialogues.

Interplay with other instruments

The Commission can support Member States in designing and implementing reforms to anticipate, prepare and respond to impacts of natural or man-made crises on the Single Market through the Technical Support Instrument (TSI)[32].

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 114, 21 and 45 TFEU.

Within the context of a crisis, the Single Market can be impacted both by the appearance of the specific disruptions and shortages inherent to the said crisis, as well as by the possible intra-EU restrictions to the free movement of goods, services and persons, which may emerge in an attempt to address the said crisis. The general objective of the initiative is to lay down the mechanisms and procedures, which would allow to prepare for and to address potential crises and disruptions to the proper functioning of the Single Market. Such measures are also aimed to minimise the intra-EU obstacles to the free movement in times of crisis. Whereas the measures concerning free movement of goods and freedom to provide services are covered by the internal market legal basis, the free movement of persons' provisions require the Regulation to rely additionally on Articles 21 and 45 TFEU. In the case of a crisis that affects the supply chains of the Single Market, measures have to be taken to address any identified shortages and to safeguard the availability of crisis-critical goods and services across the entire EU.

A number of measures in this proposal derogate from or complement existing EU harmonisation legislation, based on the general internal market legal basis. Measures such as facilitating the ramping up of production capacities for crisis relevant goods and service activities, accelerating the permitting procedures, prioritising orders and the building-up and distributing strategic reserves are of exceptional nature and aim at ensuring a coherent response to future crises and to avoid the fragmentation of the Single Market. In cases where there are substantial risks to the functioning of the Single Market or in cases of severe shortages or an exceptionally high demand of goods of strategic importance, measures at EU level aimed to ensure the availability of crisis-relevant products, such as strategic reserves or priority rated orders, may prove to be indispensable for the return to the normal functioning of the Single Market. Such measures have a gradual, stepped approach, whereby the resort to more binding measures follows inaction of economic operators to tackle the crisis at stake.

• Subsidiarity (for non-exclusive competence)

The economic activities across the Single Market are deeply integrated. Interaction between companies, service providers, clients, consumers and workers located in different Member States that rely on their free movement rights, is increasingly common. The experience of past crises has shown that often the distribution of production capacities across the EU is uneven.

[32] Regulation (EU) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support Instrument https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32021R0240.

In parallel, in the case of a crisis, the demand for crisis-relevant goods or services across the EU territory may also be uneven as some EU regions are disproportionally vulnerable and exposed to supply chain disruptions, in particular the EU outermost regions[33] located thousands of kilometres away from mainland Europe The objective of ensuring the smooth and undisrupted functioning of the Single Market cannot be achieved by means of unilateral national measures. Moreover, even if measures adopted by the Member States individually may be able to address to a certain extent the deficiencies resulting from a crisis at the national level, they are in fact more likely to further exacerbate the said crisis across the EU by adding further obstacles to the free movement and/or additional strain on products already impacted by shortages.

The introduction of rules which govern the functioning of the Single Market is a competence shared between the EU and the Member States. A significant number of EU frameworks governing various aspects are already in place and they contribute to the smooth operation of the Single Market by laying down coherent sets of rules which apply across all the territories of the Member States. However, the existing EU frameworks generally lay down rules concerning the day-to-day functioning of the Single Market, outside of any specific crisis scenarios. There is currently no horizontal set of rules and mechanisms which address aspects such as the contingency planning, the crisis anticipation and monitoring and the crisis response measures, which would apply in a coherent manner across economic sectors and the entire Single Market.

The emergency instrument has the objective of ensuring a coordinated approach to anticipate, prepare for and respond to crises that have important effects across borders or specifically in border regions or both and threaten the functioning of the Single Market, and where no EU instrument already exists or where the existing instruments do not lay down crisis-relevant provisions. Putting in place contingency and vigilance measures across the Single Market can facilitate the coordination of the response measures in the case of a crisis. Furthermore, such measures can be complemented by effective and efficient coordination and cooperation between the Commission and Member States during the crisis in order to ensure that the most appropriate measures to address the crisis are taken.

The Single Market Emergency Instrument is not intended to lay down a detailed set of EU level provisions which should be exclusively relied upon in the case of crisis. Instead, the instrument is intended to lay down and ensure the coherent application of possible combinations between provisions taken at EU level together with rules on the coordination of the measures taken at the level of the Member States. In this respect, the measures which may be taken at EU level on the basis of the Single Market Emergency Instrument would be coordinated with and complement the response measures adopted by the Member States. In order to allow for such coordination and complementarity, the Single Market Emergency Instrument sets out specific measures which the Member States should refrain from imposing once a Single Market emergency has been activated at EU level.

In this context, the EU added value of this instrument would be to lay down the mechanisms for a swift and structured way of communication between the Commission and Member States, coordination and information exchange when the Single Market is put under strain,

[33] The EU outermost regions - Guadeloupe, French Guiana, Martinique, Mayotte, Réunion and Saint-Martin (France), the Azores and Madeira (Portugal) and the Canary Islands (Spain) - are located in the Atlantic and Indian Oceans, in the Caribbean basin and in South America. In accordance with Article 349 TFEU these regions can benefit from specific measures and tailored EU legislation to help address the major challenges they face due to their location, remoteness, insularity, small size, vulnerability to climate change and extreme weather events.

and to be able to take necessary measures in a transparent and inclusive way – accelerating existing mechanisms as well as adding new targeted tools for crisis situations. It would also ensure transparency across the internal market, ensuring that businesses and citizens that rely on their free movement rights have at their disposal appropriate information about the applicable measures in all the Member States. This will increase legal certainty allowing them to take informed decisions.

A further advantage of action in this domain would be to equip the EU with the resilience tools needed to sustain the competitiveness of the EU industry in a geopolitical context in which our international partners and competitors can already rely on legal instruments allowing for a structured monitoring of supply chain disruptions and for the adoption of possible response measures such as strategic reserves.

- **Proportionality**

The measures contained in this Regulation are carefully tailored in order to ensure that they do not go beyond what is necessary for the achievement of its objective of ensuring the smooth and undisrupted functioning of the Single Market. The measures complement Member States' action where the aims of the Regulation cannot be achieved by means of unilateral action by the Member States. They take into account the need for the economic operators to be able to manage the normal business risks, to have their own contingency plans and to come up with initiatives for resolving supply chain issues. This is catered for in particular by means of obligations of the Commission to consult the economic operators before resorting to mandatory Single Market emergency measures such as mandatory information requests and priority rated orders.

- **Choice of the instrument**

The Single Market Emergency Instrument initiative takes the form of a Proposal for a Regulation of the European Parliament and of the Council. Considering that in the case of provisions laid down in a Regulation, there is no need for the Member States to transpose them into their respective national legislation, this specific legal instrument would allow to ensure that the provisions are applied in a consistent manner.

The proposed Regulation will introduce procedures which are complementary to the Single Market Transparency Directive or the Services Directive and are to be applied in the emergency mode. The Regulation clarifies the relationship between the relevant legal frameworks but without amending the respective legal frameworks.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation') will be repealed. According to its evaluation finalised in October 2019 and supported by an external study, this mechanism is rarely used and its information exchange system is insufficient as it is too slow and outdated[34].

[34] As assessed in the evaluation supporting study and the evaluation Commission Staff Working Document SWD(2019)371 final of 8 October 2019.

- **Stakeholder consultations**

As outlined in Annex 2 to the Impact Assessment accompanying this proposal, **stakeholder consultation** activities were conducted between October 2021 and May 2022. The consultation activities included: a **call for evidence** published on the "Have your say" portal and open from 13 April to 11 May 2022, a **public consultation** conducted via a questionnaire published on the same portal in the same period, a **stakeholder workshop** on 6 May 2022, a **Member State survey** in May 2022 and **targeted consultations** conducted by means of meetings with Member States and specific stakeholders.

Stakeholders largely agree with the need to ensure free movement as well as greater transparency and coordination in times of crisis. Most experiences described by stakeholders came from the COVID-19 crisis. When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance. A number of Member States have voiced concern about including broad crisis preparedness measures when no crisis is looming on the horizon, without specifying targeted supply chains. While some business stakeholders voiced concerns about mandatory measures targeting economic operators, others have expressed support for a greater coordination and transparency, measures to ensure free movement of workers, fast-track notifications of national measures, fast track procedures for development and publishing of European standards, EU and national single points of information, emergency simulations for experts.

- **Collection and use of expertise**

Evidence and data that were used for the development of the Impact Assessment included:

– "The impact of COVID-19 on the Internal Market", study at the request of the EP IMCO Committee;

– Evaluation of the "Strawberry Regulation" (EC) No 2679/98 and its supporting external study;

– Evaluation of the New Legislative Framework;

– Relevant information and/or evidence collected in the context of preparation of existing or proposed EU crisis response initiatives and mechanisms, including through consultation activities or impact assessment studies (e.g. the Data Act, Single Market Information Tool (SMIT), the EU Health Security Framework, Schengen Borders Code, Contingency plan for ensuring food supply and food security, the integrated political crisis response mechanism (IPCR), Contingency plan for transport, EU Digital COVID Certificate Regulation, Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic and its adaptations);

– Academic studies and literature on the effect of previous crises on the functioning of the Single Market, as well as existing position papers and other documents drawn up by relevant stakeholders;

– Newspaper articles and press materials.

The Impact Assessment further relied on the information received from consultation activities as detailed in the synopsis report contained in Annex 2 of the Impact Assessment.

The evidence base of the report is strongly limited due to the relatively low number of responses to the call for evidence and the public consultation, and the lack of a supporting study. To remedy this situation, on 6 May 2022 the Commission conducted a stakeholder

workshop attended by a large number of stakeholders and conducted a series of targeted consultations, especially with Member States and stakeholders.

- **Impact assessment**

In line with its 'Better Regulation' policy, the Commission conducted an Impact Assessment[35]. The Impact Assessment evaluated three policy options establishing a governance body and a framework for contingency planning, vigilance and emergency modes. Both Single Market vigilance mode and Single Market emergency mode would be activated according to specific criteria and triggering mechanisms. Certain measures in the toolbox would need additional activation.

On the basis of analysis of problem drivers and gaps in the relevant sector-specific legislation, eight building blocks of measures were defined by grouping measures into blocks applying at different times (at all times, in vigilance mode and in emergency mode). For each building block, three policy approaches were analysed ranging from non-legislative measures (approach 1) to a hybrid approach (approach 2) to a more comprehensive legislative framework (approach 3). On the basis of this analysis, some or all approaches were retained for each building block and were combined into three realistic policy options reflecting different levels of political ambition and stakeholder support:

Mode	**Building blocks**	**Policy Option 1** **TRANSPARENCY**	**Policy Option 2** **COOPERATION**	**Policy Option 3** **SOLIDARITY**
All times	1. governance, coordination and cooperation	*Approach 2* Formal Advisory Group as the technical-level forum and obligation of the MS to share information within the group in anticipation and during the crisis		
All times	2. crisis contingency planning	*Approach 2* Recommendation to the MS for risk assessment, training and drills & compendium of crisis response measures	*Approach 3* - Recommendation to MS for risk assessment & compendium of crisis response measures and - Obligation of the Commission for Union level risk assessment - Obligation of MS to train their relevant crisis management staff regularly	
Vigilance	3. Single Market vigilance	*Approach 2* - Recommendation to the Member States on information gathering concerning identified strategic supply chains - Recommendations to the Member States for building up strategic reserves of goods of strategic importance		*Approach 3* - Obligation to MS to gather information concerning identified strategic supply chains - Obligation of the Commission to draw up and regularly update list with targets for strategic reserves - Obligations to MS[36] to build up strategic

35 See the accompanying Staff Working Document SWD(2022)289.

36 Subject to additional trigger

				reserves for selected goods of strategic importance if the MS strategic reserves fall significantly short of the targets
Emergency	4. key principles and supportive measures for facilitating free movement during emergency	*Approach 2* Reinforcing key principles of free movement of crisis-relevant goods and services in binding rules where appropriate for effective crisis management		
Emergency	5. transparency and administrative assistance during emergency	*Approach 3* Binding full-fledged fast-track notification mechanism, flash peer review and possibility to declare the notified measures incompatible with EU law; contact points and electronic platform		
Emergency	6. speeding up the placing of crisis-relevant products on the market during emergency	*Approach 2* Targeted amendments of existing Single Market harmonisation legislation: faster placing of crisis-relevant products on the market; Commission can adopt technical specifications; MS prioritise market surveillance for crisis-relevant products		
Emergency	7. public procurement during emergency	*Approach 2* New provision on joint procurement/common purchasing by the Commission for some or all Member States		
Emergency	8. measures impacting crisis-relevant supply chains during emergency mode	*Approach 1* Guidance on ramping up production capacity; speeding up permitting procedures; accepting and prioritising orders of crisis relevant goods Recommendations to businesses to share crisis-relevant information	*Approach 2* Recommendations to MS for the distribution of stockpiled products; speeding up permitting procedures; encouraging economic operators to accept and prioritise orders Empowering MS[37] to oblige economic operators to ramp up production capacity and to address binding information requests to economic operators	*Approach 3* Obligations of MS[38] to distribute products previously stockpiled; speeding up permitting procedures, Obligations of businesses to accept and prioritise orders; ramp up production capacity and provide crisis-relevant information

The Impact Assessment did not present a preferred option, instead leaving the choice of options for political decision. The measures chosen in the legal proposal correspond to Policy

37 Subject to additional trigger

38 Subject to additional trigger

Option 3 for all building blocks with the exception of building block 8. For building block 8, a combination of Policy Option 1 (for ramping up production), Policy Option 2 (for distribution of stockpiled products and for speeding up permitting procedures), and Policy Option 3 (for obligations of businesses to accept and prioritise orders and to provide crisis-relevant information) has been chosen.

On 15 June 2022, the Commission submitted the Impact Assessment to the Regulatory Scrutiny Board (RSB). The RSB gave a negative opinion, noting in particular (1) the need to provide clear and detailed information related to the foreseen Single Market emergency including a definition, the criteria and decision-mechanisms for establishing and terminating it and the measures which would be implemented during it; (2) the need to provide a thorough assessment of the impacts of the policy options; and (3) the need to present alternative combinations of relevant policy options, in addition to the policy approaches, and to link the comparison to the analysis of impacts. To address these findings, the Commission provided a clear definition of a Single Market emergency, specified the criteria and decision making mechanisms, explained the three modes of functioning of SMEI and specified which building block of SMEI would be activated under which mode. It further elaborated the assessment of impacts to cover more types of impacts i.e. economic impacts for key stakeholders (businesses, Member States and Commission), impacts on SMEs, impacts on competitiveness, competition, international trade, and differentiated which impact would occur with the immediate effects and which could be expected under the vigilance and emergency modes. Further, the Impact Assessment defined three alternative policy options based on a combination of different approaches to some of the building blocks, provided an assessment of impacts of these options and extended the comparison of options to cover proportionality and subsidiarity.

On 29 July 2022, the Commission submitted the revised Impact Assessment to the RSB. The RSB then gave a positive opinion with comments. These comments related to the need to further explore the different types of crisis that may impact the functioning of the Single Market, to more clearly set out the interplay with possible measures taken on the basis of Article 4(2) TFEU and to sufficiently justify some of the measures proposed from the subsidiarity and proportionality point of view. To address these comments, indications on effects of potential future crises were added, interplay with potential measures under Article 4(2) TFEU was better explained and further details were added on the obligatory measures foreseen under emergency mode.

Further information on how the RSB recommendations are reflected in the Impact Assessment report can be found in Annex 1, point 3, of the Impact Assessment.

- **Regulatory fitness and simplification**

According to the Commission's Regulatory Fitness and Performance Programme (REFIT), all initiatives with the objective to change existing EU legislation should aim to simplify and deliver stated policy objectives more efficiently (i.e. reducing unnecessary regulatory costs).

The proposal provides a toolbox of measures to address Single Market emergency, consisting a set of measures applicable at all times as well as certain measures only applicable in vigilance or emergency modes, to be separately activated. There are **no administrative costs for businesses and citizens** that would apply with immediate effect and during the normal functioning of the Single Market.

For measures likely to lead to strong impacts and potential costs for SMEs, in particular measures such as mandatory information requests, requests to ramp up production and to accept priority-rated orders, during the additional activation of such measures specific

analysis and assessment will be done as to their impact and proportionality, in particular their impact on SMEs, by the Commission. This assessment will be part of the process of additional activation of these specific measures by a Commission implementing act (additional to the overall activation of the emergency mode). Depending on the nature of the crisis and the concerned strategic supply chains and crisis-relevant products, specific accommodations will be provided for SMEs. While it is not possible to except microenterprises completely from the scope of measures such as mandatory information requests, as these enterprises may have specific unique know-how or patents of critical importance in a crisis, specific accommodations will include simplified survey designs, less onerous reporting requirements, and longer deadlines for responses, to the extent possible in view of the need for urgency in the context of a specific crisis.

The Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation') will be repealed. This will lead to the simplification of the legal framework.

- **Fundamental rights**

This Regulation and in particular the priority rated orders and the measures facilitating the repurposing of production lines as well as the measures facilitating the expansion of production capacity affect the freedom to conduct business set out in Article 16 of the EU Charter of Fundamental Rights of the economic operators active on the Single Market during the Single Market emergency. Such restrictions have been carefully tailored and are balanced against the vital interests of the society. The provisions on priority rated orders provide for a number of safeguards for the economic operators subject to such orders, in order to balance the intensity of the restriction.

The mandatory information requests to economic operators may also affect the protection of business secrets and other sensitive information of economic operators. However, the Regulation provides for safeguards and guarantees that such information requests will be only made in case the relevant information is indispensable for resolving the Single Market emergency and is not available on a voluntary basis or from publicly accessible sources, and the obtained information is handled carefully, ensuring secrecy and non-disclosure of sensitive business information, such restrictions are proportionate and justified.

Finally the sanctions which are foreseen for breaches of the mandatory information requests to economic operators and the priority rated orders constitute restrictions to the right to property set out in Article 17 of the EU Charter of Fundamental Rights. Given the fact that the amounts of fines have been set at appropriately dissuasive, but not excessive levels, and the period of their application is limited in time, with a possibility to contest them before the CJEU, they amount to proportionate and justified restrictions of the right to property.

The Regulation respects the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter. It reiterates the right of economic operators subject to information requests and priority rated orders to defend their rights before the CJEU and provides for possibilities of contesting such requests of the Commission in administrative procedures before that.

4. BUDGETARY IMPLICATIONS

The budgetary implications of the proposals would relate to three expenditure categories. The recurrent costs of staff within the Commission would be in principle covered under the heading "Administrative expenditure" while costs for the foreseen training activities and the

necessary extension of the IT tool used for the notification system would be covered under the Single Market Programme. Under the current set-up, the costs related to the emergency mode, namely building up of strategic reserves, the secure supply, such as those related to procurement of goods and services of strategic importance and crisis-relevant goods, or to priority rated orders would be borne exclusively by the Member States and there would be no impact on Union resources. The additional management costs in the Commission deriving from the occurrence of a crisis, which are unpredictable by nature, would be covered in principle via internal redeployment of Union resources under the heading 1 "Single market, innovation and digital" and/or heading 7 "Administrative expenditure".

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will carry out an evaluation of the effectiveness, efficiency, coherence, relevance and EU added value of this legislative initiative and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions five years after the date of application of the legislative acts. The Commission may propose based on the evaluation report how to improve the Single Market Emergency Instrument.

The European Anti-Fraud Office (OLAF) shall be consulted for all the contracts and financing agreements issued on the basis of this Regulation, to ensure that antifraud clauses are appropriately integrated.

- **Detailed explanation of the specific provisions of the proposal**

The SMEI aims to establish a comprehensive preparedness and crisis-response architecture composed of the following main components:

– an advisory group;

– a framework for contingency planning;

– a framework for Single Market vigilance and

– a framework for Single Market emergencies.

1. The advisory group

   The role of this group will be to *advise* the Commission on the appropriate measures for preventing or addressing the impact of the crisis on the Single Market. It can be involved in the activation and in determining the scope of the Single Market vigilance and emergency modes and analyse the relevant information gathered by voluntary or mandatory means, including from the economic operators. This central body will be composed of one representative of each Member State with expertise in Single Market matters as permanent members, and observers representing other crisis relevant bodies such as the Integrated Political Crisis Response group of the Council, the Health Crisis Board, the Health Security Committee, European Semiconductor Board, European Food Security Crisis preparedness and response Expert Group, etc. The Commission will organise and chair the meetings.

2. The framework for contingency planning

   In normal times where no sudden event is likely to have or is already having severe disruptive effects on the Single Market, market forces ensure the functioning of the businesses and the Single Market. The framework of contingency planning does not require an activation step and consists of:

(a) Arrangements for crisis protocols and crisis communication and training and emergency simulations in view of ensuring timely cooperation and exchange of information between the Commission, Member States and relevant Union level bodies and organising trainings and rehearsals on potential scenarios of Single Market emergencies.

(b) Ad hoc alerts for early warning system for any incidents that significantly/ seriously disrupt or have the potential to significantly/seriously disrupt the functioning of the Single Market and in its supply chains of goods and services. In determining the significance or the seriousness of the disruption, pre-determined parameters will be taken into account such as the number of economic operators affected, geographical area or duration of the disruption.

3. The framework for Single Market vigilance

This will be the framework for impacts of significant incidents that have not yet escalated into a full-blown Single Market emergency. It requires activation when an incident that has occurred has the potential to significantly disrupt the supply chains of goods and services of strategic importance that are dependent on non-diversifiable and non-substitutable inputs or which causes firsts signs of severe shortages of such goods and services. This framework includes a set of measures such as:

(a) Monitoring of the supply chains of goods and services of strategic importance that have been identified in the Union level risk assessment referred in the framework for contingency planning and whose supply could be significantly disrupted due to the occurrence of an incident. Such monitoring will be carried out by the Member States on the basis of voluntary requests for information about factors impacting the availability of the selected goods and services of strategic importance (such as production capacity, stocks, suppliers limitations, possibilities for diversification and substitution, demand conditions, bottlenecks) 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.

(b) Building-up of strategic reserves, which is a measure subject to additional activation by means of additional Commission implementing acts. The Commission may draw up lists of individual and non-binding targets for the strategic reserves that the Member States should maintain. The Member States, acting jointly in a spirit of solidarity, shall deploy their best efforts to build up strategic reserves of the goods identified as being of strategic importance. The Commission might, in exceptional circumstances, on its own initiative or if asked by 14 Member States, assess the need to take further measures to build up strategic reserves of such goods. Following such assessment supported by objective data, the Commission may adopt an implementing act to render the individual target for one or more Member States mandatory;

(c) Public procurement: i) procurement of goods and services of strategic importance by the Commission on behalf of Member States and ii) procurement of goods and services of strategic importance by the Member States

4. The framework for Single Market emergencies

The activation of the Single Market emergency will immediately activate the application of a number of emergency-response measures, which include:

(a) Measures to improve transparency: Member States obligations to notify any draft measures relating to crisis-relevant goods and services and goods and services of strategic importance as well as crisis-relevant restrictions of free movement of persons, together with the reasons for those measures;

(b) Actions for re-establishing and facilitating free movement: general requirements for free movement restrictions during a Single Market emergency (list of key principles) as well as provisions on prohibited restrictions.

(c) The banning of restrictions to free movement rights during a Single Market emergency requiring Member States to refrain from, for example, introducing intra-EU export bans of crisis-relevant goods or services and any export restriction of products or services that

– hamper their free movement;

– disrupt their supply chains and

– create or increase shortages in the Single Market;

(d) Public procurement: i) procurement of crisis-relevant goods by the Commission on behalf of Member States and ii) procurement of crisis-relevant goods by the Member States

(e) Actions to ensure the availability and supply of crisis-relevant goods

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

– facilitating the expansion of existing or the establishment of new capacities related to activities;

– the introduction of measures ensuring regulatory flexibility, including on permitting, aimed at facilitating the production and placing on the market of crisis-relevant goods

(f) Targeted and coordinated distribution of strategic reserves

The Commission may recommend the Member States to distribute Union strategic reserves and, where those are not available or sufficient, Member States strategic reserves in a targeted way, where there is concrete and reliable evidence of serious disruptions in the supply chain of crisis-relevant goods leading to dire shortages of goods of strategic importance, including in geographical areas particularly vulnerable to such disruptions such as the EU outermost regions

(g) Emergency measures of exceptional nature requiring additional activation:

– information requests to economic operators

The Commission shall, if necessary in case of severe shortages of crisis-relevant goods or services or an immediate threat thereof and after consulting the designated Advisory Group, request representative organisations of economic operators or, if necessary individual economic operators in crisis-relevant supply chains to provide targeted information to the Commission in relation to their production capacities and current supply chain disruptions.

The Commission shall present aggregate information based on any targeted information requests to economic operators or representative organisations of economic operators to the designated Advisory Group.

– priority rated orders

In the first stage, the Commission may invite economic operators to accept and prioritise an order of inputs for production of crisis-relevant goods or orders for the production or supply of crisis-relevant goods as final products.

In the second stage, the Commission may, in exceptional circumstances, on its own initiative or if asked by 14 Member States, assess the necessity and proportionality of resorting to priority rated orders of such goods, taking into account the position of the economic operator and potential affected parties. Following such assessment, the Commission may address an implementing act requiring an economic operator to accept and prioritise orders of inputs for the production or supply of crisis-relevant goods or orders of crisis-relevant goods as final products. Economic operators may, within 10 working days, decline to accept such obligation, and provide an explanation of duly justified reasons for doing so. The Commission may make such reasoned explanation or parts thereof public. The obligation, if accepted, shall take precedence over any performance obligation under private or public law.

– The Commission shall have regard to the circumstances of the case, including the principles of necessity and proportionality. The priority rated order shall be placed at fair and reasonable price;targeted amendments of harmonised product legislation

(b) This measure will allow an accelerating placing on the market of the identified crisis-relevant goods by introducing emergency procedures for conformity assessment, adoption of common technical specifications and market surveillance in the context of a Single Market emergency.

2022/0278 (COD)

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

(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 114, 21 and 45 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[39],

Having regard to the opinion of the Committee of the Regions[40],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the internal market (also referred to as the Single Market and its supply chains can be severely affected by such crises, and appropriate crisis management tools and coordination mechanisms are either lacking, do not cover all aspects of the Single market or do not allow for a timely response to such impacts.

(2) The Union was not sufficiently prepared to ensure efficient manufacturing, procurement and distribution of crisis-relevant non-medical goods such as personal protective equipment, especially in the early phase of the COVID-19 pandemic and the ad-hoc measures taken by the Commission in order to re-establish the functioning of the Single Market and to ensure the availability of crisis-relevant non-medical goods during the COVID-19 pandemic were necessarily reactive The pandemic also revealed insufficient overview of manufacturing capacities across the Union as well as vulnerabilities related to the global supply chains.

(3) Actions by the Commission were delayed by several weeks due to the lack of any Union wide contingency planning measures and ofclarity as to which part of the national administration to contact to find rapid solutions to the impact on the Single Market being cause 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 Single 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.

39 OJ C , , p. .
40 OJ C , , p. .

(4) Representative organisations of economic operators have suggested that economic operators did not have sufficient information on the crisis response measures of the Member States during the pandemics, partly due to not knowing where to obtain such information, partly due to 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 may rely on 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 crisis response measures

(5) These recent events have also highlighted the need for the Union to be better prepared 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. Given the fact that it is not known which kind of crises could come up next and produce severe impacts on the Single 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 Single Market of a wide range of crises.

(6) The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to obstacles to free movement within the Single Market, thus disrupting its normal functioning. On the other hand, a crisis can amplify shortages of crisis-relevant goods and services on the Single Market. The Regulation should address both types of impacts on the Single Market.

(7) Since any specific aspects of future crises that would impact the Single Market and its supply chains are hard to predict, this Regulation should provide for a general framework for anticipating, preparing for, mitigating and minimising the negative impacts which any crisis may cause on the Single Market and its supply chains. .

(8) The framework of measures set out under 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, meaning including public security, safety, public order, or public health respecting, 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.

(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 Single Market and its strategic supply chains, including 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 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, building on on-going analysis concerning strategically important areas of the Single Market economy and the Union’s continuous foresight work.

(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) …/… on serious cross-border health threats [SCBTH Regulation (COM/2020/727)], Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical counter-measures [Emergency Framework Regulation (COM/2021/577)], Regulation (EU) …/… on the extended mandate of the ECDC [ECDC Regulation (COM/2020/726)] and Regulation (EU) 2022/123 on the extended mandate of the EMA [EMA Regulation].Therefore, medicinal products, medical devices or other medical counter-measures, when they have been placed on the list referred to in Article 6(1) of the Emergency Framework Regulation, shall be excluded from the scope of this Regulation, except in relation to the provisions relating to free movement during the Single Market emergency, and in particular those designed to re-establish and facilitate free movement as well as the notification mechanism.

(12) This Regulation should complement the Integrated Political Crisis Response mechanism operated by the Council under Council Implementing Decision (EU) 2018/1993 as regards its work on Single Market impacts of cross-sectoral crises that require political decision-making.

(13) This Regulation should be without prejudice to the Union Civil Protection Mechanism ('UCPM'). This Regulation should be in complementarity with the UCPM and should support it, where neessary, 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 Articles 55 to 57 of Regulation (EC) No 178/2002 on the general plan on crisis management in the area of food and feed, implemented by Commission Decision (EU) 2019/300.

(15) The Regulation should be without prejudice to the European Food Security Crisis preparedness and response Mechanism (EFSCM). Nevertheless, food products should be governed by the provisions of this Regulation, including those concerning the notification mechanism and concerning restrictions to free movement rights . The measures concerning food products notified under this Regulation may be also reviewed for their compliance with any other relevant provisions of EU law.

(16) In order to account for the exceptional nature of and potential far-reaching consequences for the fundamental operation of the Singe Market of a Single Market emergency, implementing powers should exceptionally be conferred on the Council for the activation of Single Market emergency mode pursuant to Article 281(2) of the Treaty on the Functioning of the European Union.

(17) 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. This 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 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.

(18) As regards the measures for re-establishing and 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 without affecting its application at the time of Single 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.

(19) 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. This Regulation contains provisions which complement the existing measures in order to reinforce free movement of persons, increase transparency and provide administrative assistance during Single 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 Single Market vigilance and emergency modes under this regulation.

(20) If Member States adopt measures affecting free movement of goods or persons, goods or the freedom to provide services in preparation for and during Single Market emergencies, they should limit such measures to what is necessary and remove them as soon as the situation allows it. Such measures should respect the principles of proportionality and non-discrimination and should take into consideration the particular situation of border regions.

(21) The activation of the Single Market emergency mode should trigger an obligation for the Member States to notify crisis-relevant free movement restrictions.

(22) When examining the compatibility of any notified draft or adopted measures with the principle of proportionality, the Commission should pay due regard to the evolving crisis situation and often limited information that is at the disposal of the Member States when they seek to reduce the emerging risks in the context of the crisis. Where justified and necessary in the circumstances, the Commission may consider based on any available information, including specialised or scientific information, the merits of Member State arguments relying on the precautionary principle as a reason for adoption of free movement of persons restrictions. It is the task of the Commission to ensure that such measures comply with Union law and do not create unjustified obstacles to the functioning of the Single Market. The Commission should react to the notifications of Member States as quickly as possible, taking into account the circumstances of the particular crisis, and at the latest within the time-limits set out by this Regulation.

(23) In order to ensure that the specific Single Market emergency measures provided for in this Regulation are used only where this is indispensable for responding to a particular Single Market emergency, such measures should require individual 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 activation of the Single 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.

(25) Information requests to economic operators should be used by the Commission only where the information which is necessary for responding adequately to the Single 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, cannot be obtained from publicly available sources or as a result of information provided voluntarily.

(26) The activation of the Single Market emergency mode, where needed, should also trigger 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. These crisis-response procedures should enable products, designated as crisis-relevant goods to be placed swiftly on the market in an emergency context. The conformity assessment bodies should prioritise the conformity assessment of crisis-relevant goods over any other ongoing applications for other products. On the other hand, in cases, where there are undue delays in the conformity assessment procedures, the national competent authorities should be able to issue authorisations for products, 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 shall be only valid on the territory of the issuing Member State and limited to the duration of the Single Market emergency. In addition, in order to facilitate the increase in supply of crisis-relevant products, certain flexibilities should be introduced with respect to the mechanism of presumption of conformity. In the context of a Single 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 harmonised European standards. In cases where the later do not exist or the compliance with them is rendered excessively difficult by the disruptions to the Single Market, the Commission should be able to issue common technical specifications of voluntary or of mandatory application 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 19 sectorial frameworks: Directive 2000/14/EC, Directive 2006/42/EU, Directive 2010/35/EU, Directive 2013/29/EU, Directive 2014/28/EU, Directive 2014/29/EU, Directive 2014/30/EU, Directive 2014/31/EU, Directive 2014/32/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) 2019/1009 and Regulation (EU) 305/2011. The activation of the emergency procedures should be conditional upon the activation of the Single Market emergency and should be limited to the products designated as crisis-relevant goods.

(28) In cases where there are substantial risks to the functioning of the Single Market or in cases of severe shortages or an exceptionally high demand of goods of strategic importance, measures at Union level aimed to ensure the availability of crisis-relevant products, such as priority rated orders, may prove to be indispensable for the return to the normal functioning of the Single Market.

(29) In order to leverage the purchasing power and negotiating position of the Commission during the Single Market vigilance mode and the Single Market emergency mode, Member States should be able to request the Commission to procure on their behalf.

(30) Where there is a severe shortage of crisis-relevant products or services on the Single market during a Single Market emergency, and it is clear that the economic operators that operate on the Single market do not produce any such goods, but would in principle be able to repurpose their production lines or would have insufficient capacity to provide the goods or services needed, the Commission should be able to recommend to the Member States as a last resort to take measures to facilitate or request the ramping up or repurposing of production capacity of manufacturers or the capacity of the service providers to provide crisis-relevant services. In doing so the Commission would inform the Member States as to the severity of the shortage and the type of the crisis-relevant goods or services that are needed and would provide support and advice in relation to the flexibilities in the EU acquis for such purposes.

(31) The measures ensuring regulatory flexibility would allow the Commission to recommend that Member States accelerate the procedures for granting permits that would be necessary for enhancement of the capacity to produce crisis-relevant goods or provide crisis-relevant services.

(32) Additionally, to ensure that crisis-relevant goods are available during the Single Market emergency, the Commission may invite the economic operators that operate in crisis-relevant supply chains to prioritise the orders of inputs necessary for the production of final goods that are crisis relevant, or the orders of such final goods themselves. Should an economic operator refuse to accept and prioritise such orders, following objective evidence that the availability of crisis-relevant goods is indispensable, the Commission may decide to invite the economic operators concerned to accept and prioritise certain orders, the fulfilment of which will then take precedence over any other private or public law obligations. In the event of failure to accept, the operator in question should explain its legitimate reasons for declining the request. The Commission may make such reasoned explanation or parts of it public, with due regard to business confidentiality.

(33) Furthermore, to ensure availability of crisis-relevant goods during the Single Market emergency, the Commission may recommend that Member States distribute strategic reserves, having with 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[41] and Regulation (EU) 2016/679 of the European Parliament and of the Council[42].

(35) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the possibility to adopt supportive measures for facilitating free movement of persons, for establishing a list of individual targets (quantities and deadlines) for those strategic reserves that the Member States should maintain, so that the objectives of the initiative are achieved. Furthermore, implementing powers should be conferred on the

[41] 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).

[42] 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).

Commission as regards activating the vigilance mode and vigilance measures in order to carefully monitor the strategic supply chains and coordinate the building up of strategic reserves for goods and services of strategic importance. Moreover, implementing powers should be conferred on the Commission as regards activation of specific emergency response measures at the time of a Single 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.

(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 26 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. Since the objective of this Regulation 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.

(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 shall include interregional elements to establish coherent, multi-sectoral, cross-border Single Market vigilance and emergency response measures, in particular considering the resources, capacities and vulnerabilities across neighbouring regions, specifically border regions.

(39) The Commission shall also where appropriate enter into consultations or cooperation, on behalf of the Union, with relevant third countries, with particular attention paid to developing countries, with a view to seeking cooperative solutions to address supply chain disruptions, in compliance with international obligations. This shall involve, where appropriate, coordination in relevant international fora.

(40) In order to put in place a framework of crisis protocols the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement the regulatory framework set out in this Regulation by further specifying the modalities of cooperation of the Member States and Union authorities during the Single Market vigilance and emergency modes, secure exchange of information and risk and crisis communication. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making . In particular, to ensure equal participation in the preparation of delegated acts, the

European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(41) Council Regulation (EC) 2679/98 which provides for a mechanism for bilateral discussions of obstacles to the functioning of the Single Market has been rarely used and is outdated. Its evaluation demonstrated that the solutions provided by that Regulation are not able to cater for the realities of complex crises, which are not limited to incidents happening at the borders of two neighbouring Member States. It should therefore be repealed.

HAVE ADOPTED THIS REGULATION:

Part I
General Provisions

TITLE I
SCOPE

Article 1
Subject matter

1. This Regulation establishes a framework of measures to anticipate, prepare for and respond to impacts of crises on the Single Market, with the purpose of safeguarding the free movement of goods, services and persons and of ensuring the availability of goods and services of strategic importance and crisis-relevant goods and services in the Single Market.

2. The measures referred to in paragraph 1 include:

   (a) an advisory group to advise the Commission on the appropriate measures for anticipating, preventing or responding to the impact of a crisis on the Single Market;

   (b) measures for obtaining, sharing and exchanging the relevant information;

   (c) contingency measures aiming at anticipation and planning;

   (d) measures for addressing Single Market impacts of significant incidents that have not yet resulted in a Single Market emergency (Single Market vigilance), including a set of vigilance measures and

   (e) measures for addressing Single Market emergencies, including a set of emergency response measures.

3. Member States shall regularly exchange information on all matters falling within the scope of this Regulation among themselves and with the Commission.

4. The Commission may obtain any relevant specialised and/or scientific knowledge, which is necessary for the application of this Regulation.

Article 2
Scope of application

1. The measures set out in this Regulation apply in relation to significant impacts of a crisis on the functioning of the Single Market and its supply chains.

2. This Regulation shall not apply to the following:

   (a) medicinal products as defined in Article 2, paragraph 2 of Directive 2001/83/EC[43];

   (b) medical devices as defined in Article 2, point (e), of Regulation (EU) 2022/123 of the European Parliament and of the Council[44];

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[44] 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.

(c) other medical countermeasures as defined in Article 3, point (8), of Regulation (EU) …/… on Serious Cross-Border Threats to Health [the SCBTH Regulation] [45] and included in the list established in accordance with Article 6(1) of the proposal for] Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures [46];

(d) semiconductors as defined in Article 2(1) of the Regulation of the Council and of the European Parliament establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)[47];

(e) energy products as defined in Article 2, paragraph 1, of Directive 2003/96/EC[48], 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, as well as settlement and clearing activities and advisory, intermediation and other auxiliary financial services.

3. By way of derogation from paragraph 2, points (a), (b) and (c), Articles 16 to 20 and Article 41 of this Regulation shall apply to the products referred to in those points.

4. This Regulation is without prejudice to the Union Civil Protection Mechanism set out in Decision 1313/13/EU and the general plan on crisis management in the area of food and feed in accordance with Regulation (EC) No 178/2002.

5. This Regulation is without prejudice to Union competition rules (Articles 101 to 109 TFEU and implementing regulations), including antitrust, merger and State aid rules.

6. This Regulation is without prejudice to the Commission:

(a) entering into consultations or cooperation, on behalf of the Union, with relevant third countries, 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; or

(b) assessing 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 [49].

7. Any actions under this Regulation shall be consistent with Union's obligations under international law

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.

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45 [reference to adopted Act to be inserted once available]
46 [reference to adopted Act to be inserted once available]
47 [reference to adopted Act to be inserted once available]
48 OJ L 283, 31.10.2003, p. 51.
49 OJ L 83, 27.3.2015, p. 34.

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;

(2) 'Single Market vigilance mode' means a framework for addressing a threat of significant disruption of the supply of goods and services of strategic importance and which has the potential to escalate into a Single Market emergency within the next six months;

(3) 'Single Market emergency' means a wide-ranging impact of a crisis on the Single Market that severely disrupts the free movement on the Single Market or the functioning of the supply chains that are indispensable in the maintenance of vital societal or economic activities in the Single Market;

(4) 'strategically 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 public security, public safety, public order or public health, and the disruption, failure, loss or destruction of which would have a significant impact on the functioning of the Single Market;

(5) 'goods and services of strategic importance' means goods and services that are indispensable for ensuring the functioning of the Single Market in strategically important areas and which cannot be substituted or diversified;

(6) 'crisis-relevant goods and services' means goods and services that are indispensable for responding to the crisis or for addressing the impacts of the crisis on the Single Market during a Single Market emergency ;

(7) 'strategic reserves' means a stock of goods of strategic importance for which building a reserve may be necessary to prepare for a Single Market emergency, under the control of a Member State.

TITLE II
GOVERNANCE

Article 4
Advisory group

1. An advisory group is established.

2. The advisory group shall be composed of one representative from each Member State. Each Member State shall nominate a representative and an alternate representative.

3. The Commission shall chair the advisory group and ensure its secretariat. The Commission may invite a representative of the European Parliament, representatives of EFTA States that are contracting parties to the Agreement on the European Economic Area[50], representatives of economic operators, stakeholder organisations, social partners and experts, to attend meetings of the advisory group as observers. It

[50] OJ L 1, 3.1.1994, p. 3.

shall invite the representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory group.

4. For the purpose of contingency planning under Articles 6 to 8, the advisory group shall assist and advise the Commission as regards the following tasks:

   (a) proposing arrangements for administrative cooperation between the Commission and the Member States at the time of the Single Market vigilance and emergency modes that would be contained in the crisis protocols;

   (b) assessingment of significant incidents that the Member States have alerted the Commission to.

5. For the purpose of of the Single Market vigilance mode as referred to in Article 9, the advisory group shall assist the Commission in the following tasks:

   (a) establishing whether the threat referred to in Article 3(2) is present, and the scope of such threat;

   (b) gathering foresight, data analysis and market intelligence;

   (c) consulting the representatives of economic operators, including SMEs, and industry to collect market intelligence;

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

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

   (f) maintaining a repository of national and Union crisis measures that have been used in previous crises that have had an impact on the Single Market and its supply chains

6. For the purposes of the Single Market emergency mode as referred to in Article 14, the advisory group shall assist 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 implementation of the measures chosen to respond to Single Market emergency at Union level;

   (d) performing a review of national crisis measures;

   (e) 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 developing countries, and international organisations.

7. The Commission shall ensure the participation of all bodies at Union level that are relevant to the respective crisis. The advisory group shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies at Union level. The Commission shall ensure coordination with the measures implemented through other Union mechanisms, such as the Union Civil Protection Mechanism (UCPM) or

the EU Health Security Framework. The advisory group shall ensure information exchange with the Emergency Response Coordination Centre under the UCPM.

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

9. The advisory group may adopt opinions, recommendations or reports in the context of its tasks set out in paragraphs 4 to 6.

Article 5
Central liaison offices

1. Member States shall designate central liaison offices responsible for contacts, coordination and information exchange with the central liaison offices of other Member States and Union level central liaison office under this Regulation. Such liaison offices shall coordinate and compile the inputs from relevant national competent authorities.

2. The Commission shall designate a Union level central liaison office for contacts with the central liaison offices of the Member States during the Single Market vigilance and emergency modes under this Regulation. The Union level central liaison office shall ensure the coordination and information exchange with the central liaison offices of the Member States for the management of the Single Market vigilance and emergency modes.

Part II
Single Market contingency planning

Article 6
Crisis protocols

1. The Commission taking into consideration the opinion of the advisory group and the input of relevant Union level bodies, is empowered after consulting the Member States, to adopt a delegated act to supplement this Regulation with a framework setting out crisis protocols regarding crisis cooperation, exchange of information and crisis communication for the Single Market vigilance and emergency modes, in particular:

   (a) cooperation between national and Union level competent authorities for the management of the Single Market vigilance and emergency modes in vigilance and emergency modes across the sectors of the Single Market;

   (b) general modalities for secure exchange of information;

   (c) a coordinated approach to risk and crisis communication also vis-à-vis the public with a coordinating role for the Commission;

   (d) the management of the framework.

2. The Commission and the Member States shall put in place detailed administrative arrangements for ensuring timely cooperation and secure exchange of information between the Commission, the relevant Union-level bodies and the Member States concerning:

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

   (b) consultation of the representatives of economic operators and social partners, including SMEs, on their initiatives and actions to mitigate and respond to potential supply chain disruptions and overcome potential shortages of goods and services in the Single Market;

   (c) technical level cooperation in the vigilance and emergency modes across the sectors of the Single Market;

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

3. In order to ensure the operation of the framework referred to in 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.

Article 7
Trainings and simulations

The Commission shall organise the training on crisis 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 Single Market emergencies.

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 incidents that significantly disrupt or have the potential to significantly disrupt the functioning of the Single Market and its supply chains (significant incidents).

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

3. In order to determine whether the disruption or potential disruption of the functioning of the Single Market and its supply chains of goods and services is significant and should be the object of an alert, the central liaison office of a Member State shall take the following into account:

   (a) the number of economic operators affected by the disruption or potential disruption;

   (b) the duration or anticipated duration of a disruption or potential disruption;

   (c) the geographical area; the proportion of the Single Market affected by the disruption or potential disruption; the impact on specific geographical areas particularly vulnerable or exposed to supply chain disruptions including the EU outermost regions;

   (d) the effect of the disruption or potential disruption on non-diversifiable and non-substitutable inputs.

Part III
Single Market Vigilance

TITLE I
VIGILANCE MODE

Article 9
Activation

1. Where the Commission, taking into consideration the opinion provided by the advisory group, considers that the threat referred to in Article 3(2) is present, it shall activate the vigilance mode for a maximum duration of six months by means of an implementing act. Such an implementing act shall contain the following:

   (a) an assessment of the potential impact of the crisis;

   (b) list of the goods and services of strategic importance concerned, and

   (c) the vigilance measures to be taken.

2. The implementing act referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 41(2).

Article 10
Extension and deactivation

1. The Commission, if it 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 advisory group, may extend the vigilance mode for a maximum duration of six months by means of an implementing act.

2. Where the Commission, taking into consideration the opinion provided by the advisory group, finds that the threat referred to in Article 3(2) is no longer present, with respect to some or all vigilance measures or for some or all of the goods and services, it shall deactivate the vigilance mode in full or in part by means of an implementing act.

3. Implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 42(2).

TITLE II
VIGILANCE MEASURES

Article 11
Monitoring

1. When the vigilance mode has been activated in accordance with Article 9, national competent authorities shall monitor the supply chains of goods and services of strategic importance that have been identified in the implementing act activating the vigilance mode.

2. The Commission shall provide for standardised and secure means for the collection and processing of information for the purpose of paragraph 1, using electronic means. Without prejudice to national legislation requiring collected information

including business secrets to be kept confidential, confidentiality with regard to the commercially sensitive informationand information affecting the security and public order of the Union or its Member States shall be ensured.

3. Member States shall set up and maintain an inventory of the most relevant economic operators established on their respective national territory that operate along the supply chains of goods and services of strategic importance that have been identified in the implementing act activating the vigilance mode.

4. On the basis of the inventory set up pursuant to Article 6, national competent authorities shall address requests for voluntary provision of information to the most relevant operators along the supply chains of goods and services identified in the implementing act adopted pursuant to Article 9 and other relevant stakeholders established in their respective national territory. Such requests shall in particular states which information about factors impacting the availability of the identified goods and services of strategic importance is requested. Each economic operator/stakeholder 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 national competent authorities shall transmit the relevant findings to the Commission and the advisory group without undue delay via the respective central liaison office.

5. National competent authorities 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 it is kept to a minimum.

6. The Commission may ask the advisory group to discuss the findings and prospects of evolution based on the monitoring of supply chains of goods and services of strategic importance.

7. On the basis of the information collected through the activities carried out in accordance with paragraph 1, the Commission may provide a report of the aggregated findings.

Article 12
Strategic reserves

1. The Commission may, among the goods of strategic importance listed in an implementing act adopted pursuant to Article 9(1),, identify those for which it may be necessary to build a reserve in order to prepare for a Single Market emergency, taking into account the probability and impact of shortages. The Commission shall inform the Member States thereof.

   Capacities which are a part of the rescEU reserve in accordance with Article 12 of Decision No 1313/2013/EU are excluded from the application of this Article.

2. The Commission may require, by means of implementing acts, that the Member States provide information on the goods listed in an implementing act adopted pursuant to Article 9(1), as regards all of the following:

   (a) the current stock in their territory;

   (b) any potential for further purchase;

   (c) any options for alternative supply;

   (d) further information that could ensure the availability of such goods.

The implementing act shall specify the goods for which information is to be given.

Member States shall report to the Commission the levels of strategic reserves of goods of strategic importance held by them, and the levels of other stocks of such goods held on their territory.

3. Taking due account of stocks held or being built up by economic operators on theirterritory, Member States shall deploy their best efforts to build up strategic reserves of the goods of strategic importance identified in accordance with paragraph 1. The Commission shall provide support to Member States to coordinate and streamline their efforts.

4. Where the building of strategic reserves of goods of strategic importance identified pursuant to paragraph 1 can be rendered more effective by streamlining among Member States, the Commission may draw up and regularly update, by means of implementing acts, a list of individual targets regarding the quantities and the deadlines for those strategic reserves that the Member States should maintain. When setting the individual targets for each Member State, the Commission shall take into account:

   (a) the probability and impact of shortages referred in paragraph 1;

   (b) the level of existing stocks of the economic operators and strategic reserves across the Union, and any information on economic operators' ongoing activities to increase their stocks;

   (c) the costs for building and maintaining such strategic reserves.

5. The Member States shall regularly inform the Commission about the current state of their strategic reserves. Where a Member State has reached the individual targets referred to in paragraph 4, it shall inform the Commission if it has at its disposal any stocks of the goods in question in excess of their target. The Member States whose reserves have not reached the individual targets shall explain to the Commission the reasons for this situation. The Commission shall facilitate cooperation between the Member States which have already reached their targets and the other Member States.

6. Where the strategic reserves of a Member State continuously fall significantly short of the individual targets referred to in paragraph 4 and economic operators on its territory are not able to compensate that shortfall, the Commission may, at its own initiative or at the request of 14 Member States, assess the need to take further measures to build up strategic reserves of goods of strategic importance identified pursuant to paragraph 1.

Following such an assessment, where the Commission establishes, supported by objective data, that

   (a) the needs for the good in question remain unchanged or have increased compared to the situation at the time the target referred to in paragraph 4 was first set or last amended pursuant to paragraph 4,

   (b) access to the concerned good is indispensable to ensure preparedness for a Single Market emergency

   (c) the Member State concerned has not provided sufficient evidence to explain the failure to meet the individual target, and

(d) exceptional circumstances exist, in that the failure by that Member State, considering its importance to the supply chain concerned, to build up such strategic reserves gravely imperils the Union's preparedness in the face of an impending threat of a Single Market emergency,

the Commission may adopt an implementing act, requiring the Member State in question to build up its strategic reserves of the goods concerned by a set deadline.

7. When acting under this Article, the Commission shall seek to ensure that the building up of strategic reserves does not create a disproportionate strain on the supply chains of the goods identified in accordance to paragraph 1, or on the fiscal capacity of the Member State concerned.

The Commission shall take fully into account any national security concerns raised by Member States.

8. The implementing acts referred to in this Article shall be adopted in accordance with the examination procedure referred to in Article 42(2).

Part IV
Single Market Emergency

TITLE I
EMERGENCY MODE

Article 13
Criteria for activation

1. When assessing the severity of a disruption for the purposes of ascertaining whether the impact of a crisis on the Single Market qualifies as a Single Market emergency, the Commission shall, based on concrete and reliable evidence, taking into account at least the following indicators:

   (a) the crisis has caused activation of any relevant Council crisis response mechanism, Union Civil Protection Mechanism or the mechanisms set up within the EU Health Security Framework, including [the proposal for] Regulation (EU) …/… on serious cross-border health threats and [the proposal for] Council Regulation (EU) …/… on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures;

   (b) an estimation of the number of economic operations or users relying on the disrupted sector or sectors of the Single Market for the provision of the goods or services concerned;

   (c) the importance of the goods or services concerned for other sectors;

   (d) the impacts in terms of degree and duration on economic and societal activities, the environment and public safety;

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

   (f) the market position of affected economic operators in the concerned sector or sectors;

   (g) the geographic area that is and could be affected, including any cross-border impacts on the functioning of supply chains that are indispensable in the maintenance of vital societal or economic activities in the Single Market;

   (h) the importance of the affected economic operator 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 of substitute goods, inputs or services.

Article 14
Activation

1. The Single Market Emergency mode may be activated without the Single 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 advisory group, considers there is a Single Market emergency, it shall propose to the Council to activate the Single Market emergency mode.

3. The Council may activate the Single Market emergency mode by means of a Council implementing act. The duration of the activation, hall be specified in the implementing act, and shall be a maximum of six months.

4. The activation of the Single 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 Articles 11 and 12 regarding the same goods and services.

5. As soon as the Single Market emergency mode is activated, the Commission shall, without delay, adopt a list of crisis-relevant goods and services by means of an implementing act. The list may be amended by means of implementing acts.

6. The Commission implementing act referred to in paragraph 5 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 Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

Article 15
Extension and deactivation

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

2. Where the advisory group has concrete and reliable evidence that the Single Market emergency 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 advisory group, considers a Single Market emergency no longer exists, it shall propose to the Council without delay the deactivation of the Single Market emergency mode.

3. The measures taken in accordance with Articles 24 to 33 and pursuant to the emergency procedures introduced in the respective Union legal frameworks by means of the amendments to sectorial product legislation set out in Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 and introducing emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of a Single Market emergency and 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, and2014/68/EU and introducingas regard emergency procedures for the conformity assessment,

adoption of common specifications and market surveillance in the context ofdue to a Single Market shall cease to apply upon deactivation of the duration of the Single Market emergency mode. The Commission shall submit to the Council an assessment on the effectiveness of the measures taken in addressing the Single Market emergency no later than three months after the expiry of the measures, on the basis of the information gathered via the monitoring mechanism foreseen by Article 11.

TITLE II
FREE MOVEMENT DURING THE SINGLE MARKET EMERGENCY

Chapter I
Measures for re-establishing and facilitating free movement

Article 16

General requirements for measures restricting free movement to address a Single Market emergency

1. When adopting and applying national measures in response to a Single Market emergency and the underlying crisis, Member States shall ensure that their actions fully comply with the Treaty and Union law and, in particular, with the requirements laid down in this Article.
2. Any restriction shall be limited in time and removed as soon as the situation allows it. Additionally, any restriction should take into account the situation of border regions.
3. Any requirement imposed on citizens and businesses shall not create an undue or unnecessary administrative burden.
4. Member States shall inform citizens, consumers, businesses, workers and their representatives about measures that affect their free movement rights in a clear and unambiguous manner.
5. Member States shall ensure that all affected stakeholders are informed of measures restricting 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 of free movement rights during a Single Market emergency

1. During the Single Market emergency mode and when responding to a Single Market emergency, Member States shall refrain from introducing any of the following:
   (a) intraUnion export bans or other measures having equivalent effect on crisis-relevant goods or services listed in an implementing act adopted pursuant to Article 14, paragraph 5;
   (b) restrictions on the intra-EU export of goods or provision or receipt of services, or measures having equivalent effect, where those restrictions do any of the following

(i) disrupt supply chains of crisis-relevant goods and services that are listed in an implementing act adopted pursuant to Article 14, paragraph 5, or

(ii) create or increase shortages of such goods and services in the single market;

(c) discrimination between Member States or between citizens, including in their role as service providers or workers, based directly on nationality or, in the case of companies, the location of the registered office, central administration or principal place of business;

(d) restrictions on the free movement of persons involved in the production of crisis-relevant goods that are listed in an implementing act adopted pursuant to Article 14, paragraph 5 and their parts or in provision of crisis-relevant services that are listed in an implementing act adopted pursuant to Article 14 paragraph 5, or other measures having equivalent effect, that:

(i) cause shortages of necessary workforce on the Single Market and thus disrupt supply chains of crisis-relevant goods and services or create or increase shortages of such goods and services in the Single market or

(ii) are directly discriminatory based on nationality of the person.

2. During the Single Market emergency mode and when responding to the Single Market emergency, Member States shall refrain from any of the following, unless to do so is inherent to the nature of the crisis:

(a) applying more generous rules to goods originating from a neighbouring Member State, any other Member State or a group of Member States, as compared to goods originating from other Member States;

(b) selectively refusing the entry of goods originating from specific other Member States to their territory;

(c) introducing prohibitions of the operation of freight transport;

3. During the Single Market emergency mode and when responding to a Single Market emergency, Member States shall refrain from any of the following unless to do so is inherent to the nature of the crisis/Single Market emergency:

(a) banning types of services or modes of service provision;

(b) blocking flows of passenger transport;

4. During the Single Market emergency mode and when responding to the Single Market emergency, Member States shall refrain from any of the following:

(a) applying of more generous rules to travel to or from one Member State to or from another Member State or group of Member States, as compared to travel to and from other Member States unless to do so is inherent to the nature of the crisis/Single Market emergency;

(b) denying, to beneficiaries of the right of free movement under Union law, of the right to enter the territory of their Member State of nationality or residence, the right to exit the territory of Member States to travel to the Member State of nationality or residence, or the right to transit through a Member State in order to reach the Member State of nationality or residence;

(c) prohibiting of business travel linked to the research and development, to production of crisis-related goods that are listed in an implementing act

adopted pursuant to Article 14, paragraph 5, or their placing on the market or to the related inspections;

(d) imposing prohibitions on travel, including travel for imperative family reasons, which are not appropriate for the achievement of any legitimate public interest purportedly pursued by such measures or which manifestly go beyond what is necessary to achieve that aim;

(e) imposing restrictions on workers and service providers and their representatives, unless to do so in inherent to the nature of the crisis/Single Market emergency and it does not manifestly go beyond what is necessary for that purpose.

5. When a Single Market emergency has been activated in accordance with Article 14 and the activities exercised by the service providers, business representatives and workers are not affected by the crisis in the Member State and safe travel is possible despite the crisis, that Member State shall not impose travel restrictions on such categories of persons from other Member States that would prevent them from having access to their place of activity or workplace.

6. When a Single Market emergency has been activated in accordance with Article 14 and exceptional circumstances resulting from the crisis do not allow all service providers, business representatives and workers from other Member States to travel and to have unhindered access to their place of activity or workplace, but travelling is still possible, Member States shall not impose travel restrictions, on:

(a) Those service providers that provide crisis-relevant services that are listed in an implementing act adopted pursuant to Article 14(5), or business representatives or workers that are involved in production of crisis-relevant goods or provision of crisis-relevant services that are listed in an implementing act adopted pursuant to Article 14(5) to allow them to have access to the place of their activities, if activities in the sector concerned are still allowed in the Member State;

(b) civil protection workers to allow them to have unhindered access to their place of activity with their equipment in any of the Member States.

7. When taking the measures referred to in this provision, the Member States shall ensure full compliance with the Treaties and Union law. Nothing in this provision shall be construed as authorising or justifying restrictions to free movement contrary to the Treaties or other provisions of Union law.

Article 18
Supportive measures

1. During the Single Market emergency mode, the Commission may provide for supportive measures to reinforce free movement of persons referred to in Article 17(6) and 17(7) by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 422(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

2. During the Single Market emergency mode, where the Commission establishes that Member States have put in place templates for attesting that the individual or

economic operator is a service provider that provides crisis-relevant services, a business representative or worker that is involved in production of crisis-relevant goods or provision of crisis-relevant services or a civil protection worker and it considers that the use of different templates by each Member States is an obstacle to the free movement at the time of a Single Market emergency, the Commission may issue, if it considers it necessary for supporting the free movement of such categories of persons and their equipment during the ongoing Single Market emergency, templates for attesting that they fulfil the relevant criteria for the application Article 17(6) in all Member States by means of implementing acts.

3. The implementing acts referred to in paragraphs 1 and 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 Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

Chapter II
Transparency and administrative assistance

Article 19
Notifications

1. During the Single Market emergency, Member States shall notify to the Commission any crisis-relevant draft measures restricting free movement of goods and the freedom to provide services as well as crisis-relevant restrictions of free movement of persons, including workers together with the reasons for those measures.

   Such notification shall not prevent Member States from adopting the measures in question in case immediate action is needed due to reasons occasioned by serious and unforeseeable circumstances. Member States shall notify the adopted measure immediately together with a justification for the need to immediately adopt the measure.

2. Member States shall provide to the Commission a statement of the reasons which make the enactment of such measure justified and proportionate, where those reasons have not already been made clear in the notified measure. Member States shall communicate to the Commission the full text of the national legislative or regulatory provisions which contain or are modified by the measure.

3. Member States shall use the information system set up for notifications under Directive (EU) 2015/1535 of the European Parliament and of the Council[51] for notifications under this Article.

4. The Commission shall communicate the notified measures to the other Member States without delay and shall share them at the same time with the advisory group.

5. If the advisory group chooses to deliver an opinion on a notified measure, it shall do so within four working days from the date of receipt by the Commission of the notification concerning that measure.

6. The Commission shall ensure that citizens and businesses are informed of the notified measures, unless Member States request that the measures remain confidential, or the Commission deems disclosure of those measures would affect the

[51] OJ L 241, 17.9.2015, p. 1.

security and public order of the European Union or its Member States, as well as of the decisions and Member States' comments adopted in accordance with this Article.

7. Member States shall postpone the adoption of a notified draft measure for 10 days from the date of receipt by the Commission of the notification referred to in this Article.

8. Within 10 days from the date of receipt of the notification, the Commission shall examine the compatibility of any draft or adopted measure with Union law, including Articles 16 and 17 of this Regulation as well as the principles of proportionality and non-discrimination, and may provide comments on the notified measure when there are immediately obvious and serious grounds to believe that it does not comply with Union law. Such comments shall be taken into account by the notifying Member State. In exceptional circumstances, in particular to receive scientific advice, evidence or technical expertise in the context of an evolving situation, the period of 10 days may be extended by the Commission. The Commission shall set out the reasons justifying any such extension, shall set a new deadline and shall inform the Member States about the new deadline and the reasons for the extension without delay.

9. Member States may also provide comments to the Member State which has notified a measure; that Member State shall take such comments into account.

10. The notifying Member State shall communicate the measures it intends to adopt in order to comply with the comments delivered in accordance with paragraph 8 to the Commission within 10 days after receiving them.

11. If the Commission finds that the measures communicated by the notifying Member State are still not in accordance with Union law, it may issue within 30 days of that communication, a decision requiring that Member State to refrain from adopting the notified draft measure. The notifying Member State shall communicate the adopted text of a notified draft measure to the Commission without delay.

12. If the Commission finds that an already adopted measure that has been notified to it, is not in accordance with Union law, it may issue within 30 days of that notification a decision requiring the Member State to abolish it. The notifying Member State shall communicate the text of a revised measure in case it modifies the notified adopted measure without delay.

13. The period of 30 days referred to in paragraphs 11 and 12 may be exceptionally extended by the Commission in order to take account of a change of circumstances, in particular to receive scientific advice, evidence or technical expertise in the context of an evolving situation. The Commission shall set out the reasons justifying any such extension and shall set a new deadline and shall inform the Member States about the new deadline and the reasons for the extension without delay.

14. The Commission decisions referred to in paragraphs 11 and 12 shall be based on available information and may be issued when there are immediately obvious and serious grounds to believe that the notified measures do not comply with Union law, including Article 16 or 17 of this Regulation, the principle of proportionality or the principle of non-discrimination. The adoption of those decisions shall be without prejudice to the possibility for the Commission to adopt measures at a later stage, including the launching of an infringement procedure on the basis of Article 258 TFEU.

15. Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall relate to draft measures and shall be justified.

16. The Commission shall publish the text of the measures adopted by the Member States in the context of the Single market emergency that restrict free movement of goods, services and the persons, including workers, which have been communicated by means of the notifications referred to in this Article as well as via other sources. The text of the measures shall be published within one working day of its receipt by means of an electronic platform managed by the Commission.

Article 20
Link to other notification mechanisms

1. Where a Member State is required to notify a measure under Article 19 of this Regulation and under Article 5(1) of Directive (EU) 2015/1535[52], a notification made under this Regulation shall be deemed to have satisfied also the notification obligation set out in Article 5(1) of Directive (EU) 2015/1535.

2. Where a Member State is required to notify a measure under Article 19 of this Regulation and under Articles 15(7) or 39(5) of Directive 2006/123/EC of the European Parliament and of the Council[53], a notification made under this Regulation shall be deemed to have satisfied also the notification obligations set out in Directive 2006/123/EC. Similarly the Commission Decisions referred to in Article 19(11) and 19(12) of this Regulation are deemed to be a Decision taken under Article 15(7) of Directive 2006/123/EC for the purposes of that Directive.

3. Where a Member State is required to notify a measure under Article 19 of this Regulation and to inform the Commission in accordance with Article 59(5) of Directive 2005/36/EC of the European Parliament and of the Council[54], that notification shall be deemed to have satisfied also the information obligation set out in Article 59(5) of Directive 2005/36/EC.

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 assistance:

   (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 Single Market emergency;

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

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

52 OJ L 241, 17.9.2015, p. 1
53 OJ L 376, 27.12.2006, p. 36.
54 OJ L 255, 30.9.2005, p. 22.

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.

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 assistance:

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

   (c) putting together a list with all national crisis measures and national contact points.

TITLE III
SINGLE MARKET EMERGENCY RESPONSE MEASURES

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

Article 23
Requirement of dual activation

1. Binding measures included in this Chapter may be adopted by the Commission by means of implementing acts in accordance with Articles 24(2), first subparagraph of Article 26 and Article 27(2) may be adopted only after a Single Market Emergency has been activated by means of a Council implementing act in accordance with Article 14.

2. An implementing act introducing a measure included in this Chapter shall clearly and specifically list the crisis-relevant goods and services to which such measure applies. That measure shall apply only for the duration of the emergency mode.

Article 24
Information requests to economic operators

1. Where there is a severe crisis-related shortages or an immediate threat thereof, the Commission may invite representative organisations or economic operators in crisis-relevant supply chains to transmit on a voluntary basis, within a set time limit, specific information to the Commission on the production capacities and possible

existing stocks of crisis-relevant goods and components thereof in Union production facilities and third country facilities which it operates, contracts or purchases supply from, as well as information on any relevant supply chain disruptions within a given deadline.

2. If the addressees do not transmit the information requested in accordance with paragraph 1 within the time-limit and do not provide a valid justification for not doing so, the Commission may, by means of an implementing act, require that they transmit the information, indicating in the implementing act why it is proportionate and necessary to do so, specifying the crisis-relevant goods and services and addressees concerned by the information request, and the information that is sought, providing where necessary a template with the questions that may be addressed to the economic operators.

3. The information requests referred to in paragraph 1 may concern the following:

   (a) targeted information to the Commission in relation to the production capacities and possible existing stocks of the crisis-relevant goods and components thereof in production facilities located in the Union and production facilities located in a third country which the organisation or the operator referred to in paragraph 1 operates, contracts or purchases supply from, while fully respecting trade and business secrets and requiring them to transmit to the Commission a schedule of the expected production output for the following 3 months for production facility located in the Union as well as any relevant supply chain disruptions;

   (b) other information necessary for assessing the nature or magnitude of a given supply chain disruption or shortage.

4. Following the activation of the mandatory information requests to economic operators by means of an implementing act, the Commission shall address a formal decision to each of those representative organisations or economic operators in crisis-relevant supply chains that have been identified in the implementing act, requesting them to provide the information specified in the implementing act. 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. The Commission may obtain the necessary information on the relevant economic operators from the Member States.

5. The Commission Decisions containing individual information requests 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 or for compiling relevant official statistics. A request shall set out a reasonable time limit within which the information is to be provided. It shall take into account the effort required to collect and make the data available by the economic operator or representative organisation. The formal decision shall also contain safeguards for protection of data in accordance with Article 39 of this Regulation, safeguards for non-disclosure of sensitive business information contained in the reply in accordance with Article 25, 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 fines provided for in Article 28 for failure to comply and the timeline for a reply.

6. The owners of the economic operators or their representatives and, in the case of legal persons, companies or firms, or associations having no legal personality, the persons authorised to represent them by law or by their constitution may supply the information requested on behalf of the economic operator or the association of economic operators concerned. Each economic operator or association of economic operators shall provide the requested information on an individual basis in line with the Union rules on competition governing the exchange of information. Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.

7. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed a mandatory information request to an economic operator.

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

Article 25
Confidentiality and processing of the 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. 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.

4. The Commission may present to the advisory group referred to in Article 4 aggregate information based on any information collected pursuant to Article 24.

5. The Commission shall not share any information 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.

Article 26
Targeted amendments to harmonised product legislation

When the Single 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 of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU)

2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 and introducing emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of a Single Market emergency and 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, and2014/68/EU and introducingas regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context ofdue to a Single Market] 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 .

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 Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

Article 27
Priority rated orders

1. The Commission may invite one or more economic operators in crisis-relevant supply chains established in the Union to accept and prioritise certain orders for the production or supply of crisis-relevant goods (‘priority rated order’).

2. If an economic operator does not accept and prioritise priority rated orders, the Commission may, at its own initiative or at the request of 14 Member States, assess the necessity and proportionality of resorting to priority rated orders in such cases, the Commission shall give the economic operator concerned as well as any parties demonstrably affected by the potential priority rated order, the opportunity to state their position within a reasonable time limit set by the Commission in light of the circumstances of the case. In exceptional circumstances, following such an assessment, the Commission may address an implementing act to the economic operator concerned, requiring it to either accept and prioritise the priority rated orders specified in the implementing act or explain why it is not possible or appropriate for that operator to do so. The Commission’s decision shall be based on objective data showing that such prioritisation is indispensable to ensure the maintenance of vital societal economic activities in the Single Market

3. Where the economic operator to which the decision referred to in paragraph 2 is addressed accepts the requirement to accept and prioritise the orders specified in the decision, that obligation shall take precedence over any performance obligation under private or public law.

4. Where the economic operator to which the decision referred to in paragraph 2 is addressed declines to accept the requirement to accept and prioritise the orders specified in the decision, it shall provide to the Commission, within 10 days from the notification of the decision, a reasoned explanation setting out duly justified reasons why it is not possible or appropriate, in light of the objectives of this provision, for it to comply with the requirement. Such reasons include the inability of the operator to perform the priority rated order on account of insufficient production capacity or a serious risk that accepting the order would entail particular hardship or economic burden for the operator, or other considerations of comparable gravity.

The Commission may make such reasoned explanation or parts of it public, with due regard to business confidentiality.

5. When an economic operator established in the Union is subject to a measure of a third country which entails a priority rated order, it shall inform the Commission thereof.

6. The Commission shall take the decision referred to in paragraph 2 in accordance with applicable Union law, including the principles of necessity and proportionality, and the Union's obligations under international law. The decision shall in particular take into account the legitimate interests of the economic operator concerned and any available information concerning the cost and effort required for any change in production sequence. It shall state the legal basis for its adoption, fix the time limits within which the priority rated order is to be performed and, where applicable, specify the product and quantity. It shall state the fines provided for in Article 28 for failure to comply with the decision. The priority rated order shall be placed at a fair and reasonable price.

7. Where an economic operator accepts and prioritises a priority rated order, it shall not be liable for any breach of contractual obligations governed by the law of a Member State that is required to comply with the priority rated order. Liability shall be excluded only to the extent the violation of contractual obligations is necessary for compliance with the required prioritisation.

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 Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

Article 28

Fines to operators for failure to comply with the obligation to reply to mandatory information requests or to comply with priority rated orders

1. The Commission may, by means of a decision, where deemed necessary and proportionate, impose fines:

   (a) where a representative organisation of economic operators or an economic operator, intentionally or through gross negligence, supplies incorrect, incomplete or misleading information in response to a request made pursuant to Article 24, or does not supply the information within the prescribed time limit;

   (b) where an economic operator, intentionally or through gross negligence, does not comply with the obligation to inform the Commission of a third country obligation pursuant to Article 27 or fails to explain why it has not accepted a priority rated order;

   (c) where an economic operator, intentionally or through gross negligence, does not comply with an obligation which it has accepted to prioritise certain orders of crisis-relevant goods ('priority rated order') pursuant to Article 27

2. Fines imposed in the cases referred to in paragraph 1 (a) and (b) shall not exceed 200 000 EUR.

3. Fines imposed in the cases referred to in paragraph 1 (c) shall not exceed 1 % of the average daily turnover in the preceding business year for each working day of non-compliance with the obligation pursuant to Article 27 (priority rated orders) calculated from the date established in the decision not exceeding 1% of total turnover in the preceding business year.

4. In fixing the amount of the fine, 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.

5. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine. 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 30 shall be subject to the following limitation periods:

   (a) two years in the case of infringements of provisions concerning requests of information pursuant to Article 24;

   (b) three years in the case infringements of provisions concerning the obligation to prioritise the production of crisis-relevant goods pursuant to Article 26(2).

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 28 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 28, the Commission shall give the economic operator or representative organisations of economic operators 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. Undertakings and representative organisations of 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 and representative organisations of economic operators concerned have been able to comment.

4. The rights of defence of the economic operator or representative organisations of economic operators concerned shall be fully respected in any proceedings. The economic operator or representative organisations of economic operators 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
Coordinated distribution of strategic reserves

Where the strategic reserves constituted by the Member States in accordance with Article 12 prove to be insufficient to meet the needs related to the Single Market emergency, the Commission, taking into consideration the opinion provided by the advisory group, may recommend to the Member States to distribute the strategic reserves in a targeted way, where possible, having regard to the need not to further aggravate disruptions on the Single 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 reserves with a view to ending the Single Market emergency.

Article 33

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

1. The Commission may, when it considers that there is a risk of a shortage of crisis-relevant goods, recommend that Member States implement specific measures to ensure the efficient re-organisation of supply chains and production lines and to use 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 permitting of crisis-relevant goods.

Part V
Procurement

CHAPTER I
PROCUREMENT OF GOODS AND SERVICES OF STRATEGIC IMPORTANCE AND CRISIS-RELEVANT GOODS BY THE COMMISSION ON BEHALF 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

1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission (‘participating Member States’), for the purchasing of goods and services of strategic importance listed in an implementing act adopted pursuant to Article 9(1) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).

2. The Commission shall assess the utility, necessity and proportionality of the request. Where the Commission intends not to follow the request, it shall inform the Member States concerned and the advisory group referred to in Article 4 and give reasons for its refusal.

3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a framework agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.

Article 35

Establishment and implementation of the negotiating mandate of the Commission

1. The agreement [referred to in Article 34(3) shall establish a negotiating mandate for the Commission to act as a central purchasing body for relevant goods and services of strategic importance or crisis-relevant goods and services on behalf of the participating Member States through the conclusion of new contracts.

2. In accordance with the agreement, the Commission may be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of strategic importance or crisis-relevant goods and services, concerning the purchase of such goods or services.

3. Representatives of the Commission or experts nominated by the Commission may carry out on-site visits at the locations of production facilities of relevant goods of strategic importance or crisis-relevant goods.

4. The Commission shall carry out the procurement procedures and conclude the resulting contracts with economic operators on behalf of the participating Member States.

Article 36

Modalities of procurement by the Commission on behalf 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 of the European Parliament and of the Council[55] for its own procurement.

2. The contracts may include a clause stating that a Member State which has not participated in the procurement procedure may become a party to the contract after it has been signed, laying out in detail the procedure for doing so and its effects.

CHAPTER II

JOINT PROCUREMENT DURING VIGILANCE AND EMERGENCY MODES

Article 37

Joint procurement procedure

Where it is necessary to carry out a joint procurement between the Commission and one or more contracting authorities from Member States in accordance with the rules set out in Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, the Member States may acquire, rent or lease fully the capacities jointly procured.

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 Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council[56].

Article 39

Ban of individual procurement action by participating Member States

Where the Single Market emergency mode has been activated pursuant to Article 16 and procurement by the Commission on behalf of Member States has been launched in accordance with Articles 34 to 36, the contracting authorities of the participating Member States shall not procure goods or services covered by such procurement by other means.

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55 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).*

56 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)*..

Part VI
Final provisions

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) No 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) No 2016/679 and Regulation (EU) No 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 41

Digital tools

The Commission and the Member States may set up interoperable digital tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures may be developed outside the duration of the Single Market Emergency.

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

Article 42
Committee

1. The Commission shall be assisted by a Single Market Emergency Instrument 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 43
Delegated acts

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.

3. The delegation of power referred to in Article 6 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

Article 4
Report and review

1. By [*OP: please insert date = five years from the entry into force of this Regulation*] and every five years thereafter, the Commission shall present a report to the European Parliament and the Council on the functioning of the contingency planning, vigilance and Single Market emergency response system suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.

2. This report shall include an evaluation of the work of the advisory group under the emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis management bodies.

Article 45
Repeal

Council Regulation (EC) 2679/98 is repealed with effect from [date].

Article 46
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*.

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*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council for a Single Market Emergency Instrument

1.2. Policy area(s) concerned

Internal Market; free movement of goods, services and persons

1.3. The proposal/initiative relates to:

X a new action

☐ a new action following a pilot project/preparatory action[57]

☐ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.4. Objective(s)

1.4.1. General objective(s)

The general objective of Single Market Emergency Instrument (SMEI) is to enhance the Single Market's vigilance for, response to and its smooth functioning in times of crisis. To this end, SMEI will equip the EU with a well-calibrated crisis toolbox that permits a rapid and effective response to any future crisis that threatens to hamper the functioning of the Single Market, complementing other existing EU mechanisms, including through better coordination, transparency and speed. The objective is to strengthen the functioning of the Single Market and provide quick and practical solutions to issues of free movement of goods, services and persons and of supply in times of crisis.

1.4.2. Specific objective(s)

Specific objective No 1

Minimise obstacles to free movement of goods, services and persons in times of crisis

The specific objective 1 is to minimise obstacles to free movement of goods, services and persons in times of crisis by providing a toolbox of solutions to ensure a well-coordinated EU-level vigilance and response to crises affecting the Single Market. To this end, it is expected to provide a toolbox of solutions consisting of vigilance, coordination and transparency measures assuring more aligned and targeted Member State responses and providing needed transparency when it comes to obstacles to free movement.

Specific objective No 2

Address shortages and safeguard availability of crisis-relevant goods and services

[57] As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

This specific objective aims at facilitating quick and practical solutions to issues of supply in times of crisis. To this end, it is expected to provide adequate vigilance, coordination and transparency mechanisms for a targeted policy response and for all Single Market players by enabling information exchange and close cooperation with industry/stakeholders for identifying crisis-relevant supply chain bottlenecks and capacity needs and taking further action when necessary to ensure the availability of crisis-relevant goods and services in an emergency.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The inititave will ensure access to the Single Market during times of crisis for citizens and businesses and will provide support for the identified supply chains ensuring the functioning of the Single Market and better overall EU-level crisis response thanks to the availability of crisis-relevant products needed in the crisis response, and will also generate indirect social benefits in terms of improving living conditions and quality of life of citizens and saving lives, depending on the type of crisis.

The initiative is expected to contribute to the achievement of the United Nations Sustainable Development Goals (SDGs), in particular SDG #1 No poverty, SDG #8 Decent work and economic growth, SDG #9 Industry, innovation and infrastructure, SDG #10 Reduced inequalities and SDG #16 Peace, justice and strong institutions.

Businesses will be positively affected, in particularly during an emergency, due to better EU-level crisis response leading to less obstacles to free movement and better availability of crisis-relevant products. Measures in the toolbox that would have a direct positive effect on businesses include key principles to ensure free movement and supporting measures, transparency and administrative assistance during emergency, public procurement during emergency and measures to place products faster on the market during emergency, and speeding up permitting during emergency. Businesses however could also face costs and their operations could be impacted, notably due to measures to support supply chains during emergency, in particular information requests to companies, obligations to ramp up production and to accept priority-rated orders.

Citizens would benefit from the overall better EU-level crisis response thanks to the presence of the coordination mechanisms as well as the toolbox to ensure less obstacles to free movement and better availability of crisis-relevant products. They would further directly benefit from key principles to ensure free movement, in particular as it concerns free movement of persons, in their capacity as workers and consumers. They could also directly benefit from distribution of previously stockpiled crisis-relevant products of strategic importance. There are no direct costs to citizens.

Member States would benefit from overall better EU-level crisis response and directly benefit from the existence of a dedicated governance body ensuring coordination during a crisis with impact on the Single Market. There would be administrative and compliance costs for Member States for a range of measures foreseen under the toolbox, including for contingency planning, gathering information on supply chains, participation in match-making and constitution of strategic reserves under vigilance mode, as well as in emergency mode for compliance with key principles for free movement, measures on transparency and

administrative assistance, compliance with measures on placing crisis-relevant products on the market, participation in public procurement during emergency and measures impacting crisis-relevant supply chains during emergency.

For the Commission, we consider that the activity of developing new guidance, recommendations and coordinating obligatory measures forms part of the normal activities. The Commission would nevertheless incur additional specific costs, in particular for the organisation of the SMEI Advisory Group meetings, organising trainings and emergency symulation for national experts, organising match-making between companies, analysis of notifications under transparency and administrative assistance.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

The Commission will carry out an evaluation of the effectiveness, efficiency, coherence, proportionality and subsidiarity of this legislative initiative and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions five years after the date of application of the legislative acts. The Commission may propose in that evaluation report how to improve the Single Market Emergency Instrument. This review mechanism is similar to the review mechanisms included with the Commission proposal for a Council Regulation 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 as well as with the Commission proposal for a Regulation of the European Parliament and of the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act) .

Member States and representative organisations of economic operators will be obliged to provide the Commission with the information necessary for the preparation of that report.

The Commission and Member States will regularly monitor the application of the legal acts, in particular the effectiveness of the measures facilitating the free movement of goods, persons and services during the crisis on the persons and businesses concerned as well as the functioning of the Single Market, and the impacts of the information requests and monitoring, building and distribution of the strategic reserves and other measures increasing the availability of products and services on the Single Market to economic operators and their representatives.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

N/A as the application of the instrument depends on the emergence of a crisis which by its nature cannot be foreseen.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at European level (ex-ante): the economic activities across the Single Market are deeply integrated. Interaction between companies, service providers, clients, consumers and workers located in different Member States that rely on their free movement rights, is increasingly common. The experience of the past crisis has shown that often the distribution of production capacities across the EU is uneven (e.g. with the production lines of certain products primarily located in a few Member States such as PPE). In parallel, in the case of a crisis, the demand for crisis-relevant goods or services across the EU territory may also be uneven. The objective of ensuring the smooth and undisrupted functioning of the Single Market cannot be achieved by means of unilateral national measures. Moreover, even if measures adopted by the Member States individually may be able to address to a certain extent the deficiencies resulting from a crisis at the national level, they are in fact more likely to further exacerbate the said crisis across the EU by adding further obstacles to the free movement and/or additional strain on products already impacted by shortages.

Expected generated Union added value (ex-post): the introduction of rules which govern the functioning of the Single Market is a competence shared between the EU and the Member States. A significant number of EU frameworks governing various aspects are already in place and they contribute to the smooth operation of the Single Market by laying down coherent sets of rules which apply across all the territories of the Member States.

However, the existing EU frameworks generally lay down rules concerning the day-to-day functioning of the Single Market, outside of any specific crisis scenarios. This being said, some proposals which have been recently adopted by the Commission contain certain crisis-relevant provisions. However, there is currently no horizontal set of rules and mechanisms which address aspects such as the contingency planning, the crisis monitoring and the crisis response measures, which would apply in a coherent manner across economic sectors and across the entire Single Market.

The emergency instrument would only be deployed with the objective of ensuring a coordinated approach to respond to crises that have important cross-border effects and threaten the functioning of the Single Market, and where no EU instrument already exists or where the existing instruments do not lay down crisis-relevant provisions. Putting in place contingency and vigilance measures across the Single Market can facilitate the coordination of the response measures in the case of a crisis. Furthermore, such measures can be complemented by effective and efficient coordination and cooperation amongst the Commission and Member States during the crisis in order to ensure that the most appropriate measures to address the crisis are taken.

The Single Market Emergency Instrument is not intended to lay down a detailed set of EU level provisions which should be exclusively relied upon in the case of crisis. Instead, the instrument is intended to lay down and ensure the coherent application of possible combinations between provisions taken at EU level together with rules on the coordination of the measures taken at the level of the Member States. In this

respect, the emergency measures which may be taken at EU level on the basis of the Single Market Emergency Instrument would be coordinated with and complement the emergency response measures adopted by the Member States. In order to allow for such coordination and complementarity, the Single Market Emergency Instrument would set out specific measures which the Member States should refrain from imposing once a Single Market emergency has been activated at EU level.

In this context, the EU added value of this instrument would be to lay down the mechanisms for a swift and structured way of communication between the Commission and Member States, coordination and information exchange when the Single Market is put under strain, and to be able to take necessary measures in a transparent way – speeding up existing mechanisms as well as adding new targeted tools for emergency situations. It would also ensure transparency across the internal market, ensuring that businesses and citizens that rely on their free movement rights have at their disposal appropriate information about the applicable measures across all the Member States. This will increase legal certainty allowing them to take informed decisions.

A further advantage of action in this domain would be to equip the EU with the resilience tools needed to sustain the competitiveness of the EU industry in a geopolitical context in which our international competitors can already rely on legal instruments allowing for a structured monitoring of supply chain disruptions and for the adoption of possible response measures such as strategic reserves.

1.5.3. Lessons learned from similar experiences in the past

In recent years, the world has been witnessing a sequence of crises from the COVID-19 pandemic to Russia's invasion of Ukraine. These will not be the last crises that the world will have to weather. In addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. Unfortunately, there is no crystal ball at hand to predict the exact time and form of the next crisis.

As recent crises have shown, a fully-operational Single Market and smooth cooperation of Member States on Single Market issues can considerably strengthen the EU's resilience and crisis response. Therefore, the Single Market Emergency Instrument, for which this Impact Assessment analyses different policy options, should provide a blueprint for an EU reaction on Single Market matters in a future crisis. It should take into account the lessons learned from past emergencies and extrapolate them to possible future emergencies.

The European Council in its Conclusions of 1-2 October 2020 stated that the EU will draw the lessons from the COVID-19 pandemic and address remaining fragmentation, barriers and weaknesses of the Single Market in facing emergency situations. In the Update of the Industrial Strategy Communication, the Commission announced an instrument to ensure the free movement of persons, goods and services, as well as greater transparency and coordination in times of crisis. The initiative forms part of the Commission Work Programme for 2022. The European Parliament welcomed the Commission's plan to present a Single Market Emergency Instrument and called on the Commission to develop it as a legally binding structural tool to ensure the free movement of persons, goods and services in case of future crises.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

The proposal is a political priority of the European Commission and delivers on the commitment to ensure the smooth functioning of the Single Market. The initiative presents synergies with various instruments, for instance with horizontal crisis response mechanisms (integrated political crisis response mechanism - IPCR); with measures targeting specific aspects of crisis management (Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports); with sector-specific crisis measures (the European Food Security Crisis preparedness and response Mechanism – EFSCM; Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate; Regulation (EU) 123/2022 reinforcing the role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices; Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority; Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products (CMO Regulation) as well as the sister CMO Regulation for fisheries; Commission communication "Contingency plan for transport").

In parallel, a number of initiatives, which have been recently proposed and are currently being discussed, concern aspects relevant for the crisis response and preparedness. These initiatives however have a limited scope covering specific types of crisis scenarios and are not intended to set up a general horizontal crisis-management framework. To the extent these initiatives include a sectoral crisis response and preparedness framework, that framework will take precedence over the Single Market Emergency Instrument as lex specialis:

- the Commission proposal for a Regulation on serious cross-border threats to health

- the Commission proposal amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control

- the Commission proposal for a Council Regulation 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

- the Commission proposal for the European Chips Act

- the Commission proposal for a Data Act

- the Commission proposal to amend the Schengen Borders Code

- the Commission proposal for a Directive on the resilience of critical entities

1.5.5. Assessment of the different available financing options, including scope for redeployment

For recurrent expenditures, which derive from staff costs within the Commission for the foreseen training activities and the necessary extension of the IT tool used for the notification system, the source of financing could be identified via redeployment of Union resources under the Single Market Programme.

1.6. Duration and financial impact of the proposal/initiative

Comment: considering the nature of the initiative, which is closely linked to the occurrence of a crisis of unpredictable nature and scale, the duration of the initiative cannot be indicated.

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☐ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Management mode(s) planned[58]

X Direct management by the Commission

– **X** by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐ the EIB and the European Investment Fund;

– ☐ bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

The standard rules for monitoring the Commission expenditures for the implementation of this Regulation apply.

[58] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The management mode for this initiative is direct management by the Commission and its responsibilities in implanting it will pertain to its departments.

Report by Commission to the Council in five years from the entry into force of this Regulation and every five years after that on the functioning of the contingency planning, vigilance and Single Market emergency response system suggesting any improvements if necessary.

This review shall include an evaluation of the work of the Advisory Board established under this Regulation under the emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis management bodies.

Member States shall be consulted and their views and recommendations on the implementation of the emergency framework reflected in the final report. The Commission shall, if appropriate, present proposals based on that report in order to amend this Regulation or make further proposals.

2.2. Management and control system(s)

2.2.1. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

The controls are part of the Commission's internal control system. These new activities will generate non-significant additional costs of control at DG level.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

The Commission shall ensure that, when actions financed under this Decision are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and by the recovery of the amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties.

The measures implemented by the Commission will be subject to the ex-ante and ex-post controls in accordance with the Financial Regulation. Contracts and agreements financing the implementation of this Regulation will expressly entitle the Commission, including OLAF and the Court of Auditors to conduct audits, and investigations in accordance with Regulation (EU, Euratom) No 883/2013, including on-the-spot checks and inspections.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

Direct management, as per article 62.1(a) of the Financial Regulation, is the preferable mode as the actions will be implemented by the European Commission, which will ensure the coordination with the Member States and the various stakeholders.Information concerning the risks identified and the internal control system(s) set up to mitigate them

3.2. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[59]	from EFTA countries [60]	from candidate countries[61]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
1	03.010101 - Support expenditure for the Single Market Programme	Non-diff.	YES	TBD[62]	TBD[60]	NO
1	03.020101 - Operation and development of the internal market of goods and services	diff.	YES	TBD[60]	TBD[60]	NO

59 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
60 EFTA: European Free Trade Association.
61 Candidate countries and, where applicable, potential candidates from the Western Balkans.
62 Association agreements in the Single Market Programme currently under finalisation

3.3. Estimated financial impact of the proposal on appropriations

3.3.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Heading of multiannual financial framework	1	Single Market, Innovation and Digital

EUR million (to three decimal places)

DG: GROW			Year 2024	Year 2025	Year 2026	Year 2027	Following years	**TOTAL**
• Operational appropriations								
Budget line 03.020101 - Operation and development of the internal market of goods and services	Commitments	(1a)	0,250	0,025	0,025	0,025		**0,325**
	Payments	(2a)	0,125	0,150	0,025	0,025		**0,325**
Appropriations of an administrative nature financed from the envelope of specific programmes[63]								
Budget line 03.010101 - Support expenditure for the Single Market Programme		(3)	0,038	0,028	0,028	0,028		**0,122**
TOTAL appropriations for DG GROW	Commitments	=1a+1b +3	0,288	0,053	0,053	0,053		**0,447**
	Payments	=2a+2b +3	0,163	0,178	0,053	0,053		**0,447**

• TOTAL operational appropriations	Commitments	(4)	0,250	0,025	0,025	0,025		**0,325**

[63] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

	Payments	(5)	0,125	0,150	0,025	0,025		**0,325**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,038	0,028	0,028	0,028		**0,122**
TOTAL appropriations under HEADING 1 of the multiannual financial framework	Commitments	=4+ 6	0,288	0,053	0,053	0,053		**0,447**
	Payments	=5+ 6	0,163	0,178	0,053	0,053		**0,447**

• TOTAL operational appropriations (all operational headings)	Commitments	(4)	0,250	0,025	0,025	0,025		**0,325**
	Payments	(5)	0,125	0,150	0,025	0,025		**0,325**
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)	0,038	0,028	0,028	0,028		**0,122**
TOTAL appropriations under HEADINGS 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6	0,288	0,053	0,053	0,053		**0,447**
	Payments	=5+ 6	0,163	0,178	0,053	0,053		**0,447**

Heading of multiannual financial framework	7	'Administrative expenditure'

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex V to the internal rules), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL**
DG: GROW						
• Human resources		0,628	0,628	0,628	0,628	**2,512**
• Other administrative expenditure		0,030	0,030	0,030	0,030	**0,120**
TOTAL DG GROW	Appropriations	0,658	0,658	0,658	0,658	**2,632**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	0,658	0,658	0,658	0,658	**2,632**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	Following years	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	0,946	0,711	0,711	0,711		**3,079**
	Payments	0,821	0,836	0,711	0,711		**3,079**

3.3.2. Estimated output funded with operational appropriations

Comment: considering the nature of the initiative and the inherent character of unexpected, unpredictable crisis, this estimation is not possible at the moment.

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **N**		Year **N+1**		Year **N+2**		Year **N+3**		Enter as many years as necessary to show the duration of the impact (see point 1.6)						**TOTAL**	
	OUTPUTS																	
	Type[64]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[65]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

64 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

65 As described in point 1.4.2. 'Specific objective(s)…'

3.3.3. Summary of estimated impact on administrative appropriations

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2023**	Year **2024**	Year **2025**	Year **2026**	**TOTAL**
HEADING 7 of the multiannual financial framework					
Human resources	0,628	0,628	0,628	0,628	**2,512**
Other administrative expenditure	0,030	0,030	0,030	0,030	**0,120**
Subtotal HEADING 7 of the multiannual financial framework	0,658	0,658	0,658	0,658	**2,632**

Outside HEADING 7[66] of the multiannual financial framework					
Human resources					
Other expenditure of an administrative nature	0,038	0,028	0,028	0,028	**0,122**
Subtotal outside HEADING 7 of the multiannual financial framework	0,038	0,028	0,028	0,028	**0,122**

TOTAL	**0,696**	**0,686**	**0,686**	**0,686**	**2,754**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

66 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.3.3.1. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

		Year 2024	**Year 2025**	**Year 2026**	**Year 2027**
20 01 02 01 (Headquarters and Commission's Representation Offices)		4	4	4	4
20 01 02 03 (Delegations)					
01 01 01 01 (Indirect research)					
01 01 01 11 (Direct research)					
Other budget lines (specify)					
20 02 01 (AC, END, INT from the 'global envelope')					
20 02 03 (AC, AL, END, INT and JPD in the delegations)					
XX 01 xx **yy zz** [67]	- at Headquarters				
	- in Delegations				
01 01 01 02 (AC, END, INT - Indirect research)					
01 01 01 12 (AC, END, INT - Direct research)					
Other budget lines (specify)					
TOTAL		4	4	4	4

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	1 FTE for the secretariat of the advisory board
External staff	

[67] Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.3.4. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

In case of activation of the Emergency mode, redeployment will be considered first within the Single Market Programme.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

Explain what is required, specifying the headings and budget lines concerned, the corresponding amounts, and the instruments proposed to be used.

– ☐ requires a revision of the MFF.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.3.5. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**[68]	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

[68] Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

3.4. Estimated impact on revenue

– ☐ The proposal/initiative has no financial impact on revenue.

– ☒ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☒ on other revenue

– please indicate, if the revenue is assigned to expenditure lines ☐

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[69]						
		Year **2024**	Year **2025**	Year **2026**	Year **2027**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article 4 2 9 - Other non-assigned fines and penalty payments		p.m.	p.m.	p.m.	p.m.			

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

The potential assigned revenues cannot be evaluated at this stage as there is not certainty that any fine will materialise.

[69] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.

EUROPEAN
COMMISSION

Brussels, 19.9.2022
COM(2022) 462 final

2022/0280 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

{SEC(2022) 323 final} - {SWD(2022) 288 final} - {SWD(2022) 289 final} - {SWD(2022) 290 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The Single Market is one of the EU's greatest assets and provides the backbone for the EU's economic growth and wellbeing. Recent crises, such as the COVID-19 pandemic or Russia's invasion of Ukraine, have demonstrated some vulnerability of the Single Market and its supply chains in case of unforeseen disruptions and, at the same time, how much the European economy and all its stakeholders rely on a well-functioning Single Market. In the future, in addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. For this reason, the functioning of the Single Market needs to be guaranteed in times of emergency.

The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to the appearance of obstacles to free movement within the Single Market, thus disrupting its functioning. On the other hand, a crisis can amplify the shortages of crisis-relevant goods and services if the Single Market is fragmented and is not functioning. As a result, supply chains can swiftly become interrupted, companies face difficulties in sourcing, supplying or selling goods and services. Consumer access to key products and services becomes disrupted. Lack of information and legal clarity further exacerbate the impact of these disruptions. In addition to direct societal risks caused by the crisis, citizens, and in particular vulnerable groups, are confronted with strong negative economic impacts. The proposal therefore aims to address two separate but interrelated problems: obstacles to free movement of goods, services and persons in times of crisis and shortages of crisis-relevant goods and services.

In close cooperation with all Member States and other existing EU crisis instruments, the Single Market Emergency Instrument (SMEI) package will provide a strong agile governance structure as well as a targeted toolbox to ensure the smooth functioning of the Single Market in any type of future crisis. It is likely that not all of the tools included in this proposal will be needed simultaneously. The purpose is rather to brace the EU for the future and equip it with what may prove to be necessary in a given crisis situation severely affecting the Single Market.

The European Council in its Conclusions of 1-2 October 2020[1] stated that the EU will draw the lessons from the COVID-19 pandemic and address remaining fragmentation, barriers and weaknesses of the Single Market in facing emergency situations. In the Update of the Industrial Strategy Communication[2], the Commission announced an instrument to ensure the free movement of persons, goods and services, as well as greater transparency and coordination in times of crisis. The initiative forms part of the Commission Work Programme for 2022[3]. The European Parliament welcomed the Commission's plan to present a Single Market Emergency Instrument and called on the Commission to develop it as a legally binding structural tool to ensure the free movement of persons, goods and services in case of future crises[4].

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1 https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf.

2 COM(2021)350 final.

3 https://ec.europa.eu/info/publications/2022-commission-work-programme-key-documents_en.

4 European Parliament resolution of 17 February 2022 on tackling non-tariff and non-tax barriers in the single market (2021/2043(INI).

- **Consistency with existing policy provisions in the policy area**

A number of EU legal instruments lay down provisions which are relevant for the management of crises in general. On the other hand, certain EU frameworks and recently adopted Commission proposals lay down more targeted measures which focus on certain aspects of crisis management or are relevant for specific sectors. The Single Market Emergency Instrument will apply without prejudice to the provisions put forward by these targeted crisis management instruments, which are to be considered as *lex specialis*. Financial services, medicinal products, medical devices or other medical counter-measures and food safety products in particular are excluded from the scope of the initiative due to the existence of a dedicated crisis-relevant framework in these areas.

Interplay with horizontal crisis response mechanisms

The integrated political crisis response mechanism (IPCR)[5] is among the horizontal crisis response mechanisms[6]. The Presidency of the Council of the EU uses the IPCR to facilitate information sharing and political coordination among the Member States in responding to complex crises. The IPCR scrutinised for the first time in October 2015 the refugee and migration crisis and it has been instrumental in monitoring and supporting the response to the crisis, reporting to Coreper, the Council and the European Council. The IPCR operated the Union response to major crises caused by cyber-attacks, natural disasters, or hybrid threats. More recently, the IPCR has also operated after the outbreak of the COVID-19 pandemic and the Russian brutal aggression on Ukraine.

Another EU mechanism for general crisis response is the Union Civil Protection Mechanism and its Emergency Response Coordination Centre (ERCC)[7]. The ERCC is the Commission's central operational 24/7 hub for first emergency response, the establishment of strategic stockpiles at the EU level for emergency response ("rescEU"), disaster risk assessments, scenario building, disaster resilience goals, EU wide overview of natural and man-made disaster risks, other prevention and preparedness measures, such as training and exercises.

Interplay with horizontal Single Market mechanisms

When appropriate and necessary, coordination should be ensured between the Single Market Emergency Instrument and the activities of the Single Market Enforcement Task-Force (SMET). In particular, the Commission shall refer notified obstacles that significantly disrupt the free movement of goods and services of strategic goods and services for discussion/review to the Single Market Enforcement Task Force (SMET).

- **Consistency with other Union policies**

Interplay with measures targeting specific aspects of crisis management

The above-mentioned horizontal crisis response mechanisms are supplemented by other more targeted measures, focusing on specific aspects of the Single Market such as the free movement of goods, common rules on exports or public procurement.

One such framework is the Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to

5 https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/.

6 It was formally set up by Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response, on the basis of previously existing arrangements.

7 Laid down by the Decision (EU) 1313/2013 governing the functioning of the Union Civil Protection Mechanism.

serious disruptions and requiring immediate action ('The Strawberry Regulation')[8]. This Regulation provides for a mechanism of notification as well as a system of information exchange between the Member States and the Commission. (See sections 8.1 and 8.2 for more details.)

The Regulation on common rules for exports[9] allows the Commission to subject certain categories of products to an extra-EU export surveillance or to an extra-EU export authorisation. The Commission was subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance[10] on this basis.

Other economic measures include negotiated procedure and occasional joint procurement by the Commission on behalf of the Member States[11].

Interplay with sector-specific crisis measures

Certain EU frameworks lay down more targeted measures which focus only on certain specific aspects of crisis management or only concern certain specific sectors.

The Commission communication "Contingency plan for ensuring food supply and food security"[12] draws lessons learnt during the COVID-19 pandemic and previous crises with the objective to step up coordination and crisis management including preparedness. To this end, the contingency plan puts forward key principles to be followed to ensure food supply and food security in the event of future crises. To ensure the implementation of the contingency plan and the key principles therein, the Commission in parallel established the European Food Security Crisis preparedness and response Mechanism (EFSCM), a group composed of Member States and non-EU countries representatives as well as of food supply chain stakeholders chaired by the Commission to strengthen coordination, exchange data and practices. The EFSCM was convened for the first time in March 2022 to discuss the impacts of the energy and input price increases and the consequences of Russia's invasion of Ukraine for food security and supply. The market observatories and the civil dialogue groups are other fora that ensure transparency and the flow of information in the food sector.

The Commission communication "Contingency plan for transport"[13] has the objective to ensure crisis preparedness and business continuity in the transport sector. The plan establishes a "crisis manual" that includes a toolbox consisting of 10 actions aimed at mitigating any negative impact on the transport sector, passengers and the internal market in the event of a crisis. These include among others measures rendering EU transport laws fit for crisis situations, ensuring adequate support for the transport sector, ensuring free movement of goods, services and people, sharing of transport information, testing transport contingency in real-life situations etc.[14]

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8 Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, *OJ L 337, 12.12.1998, p. 8.*

9 Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015.

10 Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021.

11 They can be adopted on the basis of 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.

12 COM(2021)689 final.

13 COM(2022)211 final.

14 Additional measures include: managing refugee flows and repatriating stranded passengers and transport workers, ensuring minimum connectivity and passenger protection, strengthening transport policy coordination through the Network of National Transport Contact Points, strengthening cybersecurity and cooperation with international partners.

Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products[15] (CMO Regulation) as well as the sister CMO Regulation for fisheries[16] provide the legal basis for collecting relevant information from Member States to improve market transparency[17].

Regulation (EU) No 2021/1139 1308/2013 establishing the European Maritime, Fisheries and Aquaculture Fund[18] (EMFAF Regulation) provides the legal basis for supporting the fisheries and aquaculture sector in case of exceptional events causing a significant disruption of markets.

Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate[19] sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Furthermore, based on Commission proposals, the Council adopted specific recommendations on the coordinated approach to the restriction of free movement in response to COVID-19 pandemic[20]. The Commission also announced in the 2020 citizenship report[21] that it intends to review the 2009 guidelines on free movement in order to improve legal certainty for EU citizens exercising their free movement rights, and to ensure a more effective and uniform application of the free movement legislation across the EU. The reviewed guidelines should address among others the application of restrictive measures on free movement, specifically those that are due to public health concerns.

Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices provides a framework to monitor and mitigate potential and actual shortages of centrally and nationally authorised medicinal products for human use considered as critical to address a given 'public health emergency' or 'major event' [22].

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[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[19] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, *OJ L 211, 15.6.2021, p. 1.*

[20] Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, *OJ L 337, 14.10.2020, p. 3 and its subsequent updates.*

[21] COM(2020)730 final.

[22] 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*

Finally, the Commission Decision of 16 September 2021 established the Health Emergency Preparedness and Response Authority[23] for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.

Interplay with ongoing initiatives

In parallel, a number of initiatives, which have been recently proposed and are currently being discussed, concern aspects relevant for the crisis response and preparedness. These initiatives however have a limited scope covering specific types of crisis scenarios and are not intended to set up a general horizontal crisis-management framework, nor to introduce emergency procedures in the relevant sectoral Union framework regulating the design, conformity assessment, placing on the market and market surveillance of goods. To the extent these initiatives include a sectoral crisis response and preparedness framework, that the sectoral frameworks considered in the context of this initiative, which lay down the harmonised Union level rules for the design, conformity assessment, placing on the market and market surveillance of goods are maximum harmonisation frameworks, the will be no overlap with any of the ongoing initiatives.

None of the relevant ongoing intiatives lay down any sectoral emergency procedures, which are to be incorporated in the relevant sectoral harmonised frameworks regulating the free movement of goods.

The Commission proposal for a Regulation on serious cross-border threats to health, repealing Decision No 1082/2013/EU (the 'Cross-border Health Threats Decision')[24] aims at strengthening the EU's health security framework, and reinforcing the crisis preparedness and response role of key EU agencies with respect to serious cross-border health threats[25]. When adopted, it will strengthen the preparedness and response planning and reinforce epidemiological surveillance and monitoring, improve data reporting, strengthen EU interventions.

The Commission proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control[26].

The Commission proposal for a Council Regulation 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[27] provides for crisis response tools such as joint procurement, mandatory information requests for businesses about their production capacities, and repurposing production lines in case of public health crises once a public health emergency would be declared. The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis-relevant products. The proposal covers medical countermeasures defined as medicinal products for human use, medical devices and other goods or services that are necessary for the purpose of preparedness and response to serious cross-border threats to health.

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23 C(2021)6712 final.

24 COM(2020)727 final.

25 The term of “cross-border” is understood as covering both any situation affecting more than one Member State (“across borders”) as well as more specifically a situation affecting regions in two or more Member States sharing a common border (“border regions”).

26 COM/2020/726 final

27 COM(2021)577 final.

The Commission proposal for the European Chips Act[28] aims to strengthen Europe's semiconductor ecosystem. One important pillar of this strategy is to set up a mechanism for coordinated monitoring and response to shortages in the supply of semiconductors, aiming to anticipate and swiftly respond to any future supply chain disruptions, through a dedicated emergency toolbox, together with Member States and international partners. The planned mechanism is specific to a possible semiconductor crisis and will apply in an exclusive way if the crisis stage is triggered.

The Commission proposal for a Data Act[29] will allow public sector bodies to access data held by the private sector that is necessary for exceptional circumstances, particularly to implement a legal mandate if data are not otherwise available or in case of a public emergency (i.e. exceptional situation negatively affecting the population of the Union, a Member State or part of it, with a risk of serious and lasting repercussions on living conditions or economic stability, or the substantial degradation of economic assets in the Union or the relevant Member State(s)).

The Commission proposal to amend the Schengen Borders Code[30] aims to provide a common response at the internal borders in situations of threats affecting a majority of Member States. The proposed amendment will also put in place procedural safeguards in case of unilateral reintroductions of internal border controls and provide for the application of mitigating measures and specific safeguards for cross-border regions in cases where internal border controls are reintroduced. Such controls affect in particular people crossing the border for their daily life (work, education, health care, family visits) as evidenced during the COVID-19 pandemic. The proposal promotes increased use of effective alternative measures to address the identified threats to internal security or public policy instead of internal border controls, for instance increased checks by police or other authorities in border regions, subject to certain conditions. The proposal also includes the possibility for the Council to quickly adopt binding rules setting out temporary travel restrictions for third country nationals at the external borders in case of a threat to public health. It also clarifies which measures Member States can take to manage the EU's external borders effectively in a situation where migrants are instrumentalised by third countries for political purposes.

The proposal for a Directive on the resilience of critical entities adopted by the Commission in December 2020[31] has the objective to enhance the resilience of entities providing services that are essential for the maintenance of vital societal functions or important economic activities the EU. With this initiative, the aim is to create a comprehensive framework to support Member States in ensuring that critical entities providing essential services are able to prevent, protect against, respond to, resist, mitigate, absorb, accommodate and recover from significant disruptive incidents such as natural hazards, accidents or terrorism. The Directive will cover eleven key sectors, including energy, transport, banking and health.

The Joint communication of 18 May 2022 on the Defence Investment Gaps Analysis and Way Forward, identified several issues including the ability of the EU's Defence Technological and Industrial Base (as well as the global Defence Technological and Industrial Base) to address upcoming defence Member State procurement needs, and putting forward several measures.

In the context of the General Product Safety Directive 2001/95/EC revision, the Commission intends to examine the questions whether and to what extent, or by what modalities, the production issues that are addressed by the Omnibus rules as regards goods covered by

28 COM(2022)46 final.
29 COM (2022)68 final.
30 COM (2021)891 final.
31 COM(2020)829 final.

various harmonised regimes could be addressed in the distinct context of non-harmonised goods.

Consistency with the EU's external action

The European External Action Service will support the High Representative in her/his function, as Vice-President of the Commission, to coordinate the Union's external action within the Commission. Union delegations under the authority of the High Representative will exercise their functions as external representatives of the Union and assist, as relevant, in external dialogues.

Interplay with other instruments

The Commission can support Member States in designing and implementing reforms to anticipate, prepare and respond to impacts of natural or man-made crises on the Single Market through the Technical Support Instrument (TSI) laid down by Regulation (EU) 2021/240 of the European Parliament and of the Council.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 91 and 114 TFEU, with Article 91 being the original legal basis for the adoption of Directive 2010/35/EU on transportable pressure equipment and Article 114 being the original legal basis for the remaining 13 sectoral frameworks. These 13 sectoral frameworks are: Directive 2000/14/EC on noise emissions in the environment by equipment for use outdoors; Directive 2006/42/EU on machinery; Directive 2013/29/EU on pyrotechnic articles; Directive 2014/28/EU on civil explosives; Directive 2014/29/EU on simple pressure vessels; Directive 2014/30/EU on electromagnetic compatibility; Directive 2014/31/EU on non-automatic weighing instruments; Directive 2014/32/EU on measuring instruments; Directive 2014/33/EU on lifts; Directive 2014/34/EU on equipment for potentially explosive atmospheres (ATEX); Directive 2014/35/EU on low voltage equipment; Directive 2014/53/EU on radio equipment and Directive 2014/68/EU pressure equipment.

The EU sectoral frameworks, which are considered in the context of this proposal are the ones, which are among the so-called "harmonised products". What is common among these sectoral frameworks is that they lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of such products. Essentially, these sectoral frameworks introduce for each respective sector/product category the essential safety requirements which the products should meet and the procedures how to assess the compliance with these requirements. These rules lay down full harmonisation and therefore the Member States cannot derogate from these rules, even in a case of emergency, unless the respective framework provides for such a possibility.

Another common feature of these frameworks is that they are more or less closely aligned to the general principles laid down in 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[32], which lays down reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products.

Other EU harmonised frameworks, which follow the same approach, such as the Medical devices Regulation (EU) 2017/745 and the In vitro diagnostic medical devices Regulation (EU) 2017/746 already contain provisions allowing the Member States to derogate from the

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

harmonised procedures in certain cases. Therefore, it is not necessary to amend those frameworks.

- **Subsidiarity (for non-exclusive competence)**

The proposal aims to amend the harmonised rules laid down by a number of EU sectoral frameworks. These frameworks do not provide for the possibility for the Member States to adopt crisis-response measures in derogation of the harmonised rules. Considering that the Directives, which this proposal aims to amend are maximum harmonisation frameworks, such amendments may only be done at EU level.

- **Proportionality**

The economic activities across the Single Market are deeply integrated. Interaction between companies, service providers, clients, consumers and workers located in different Member States that rely on their free movement rights, is increasingly common. The experience of the past crisis has shown that often the distribution of production capacities across the EU is uneven (e.g. with the production lines of certain products primarily located in a few Member States). In parallel, in the case of a crisis, the demand for crisis-relevant goods or services across the EU territory may also be uneven. The objective of ensuring the smooth and undisrupted functioning of the Single Market cannot be achieved by means of unilateral national measures. Moreover, even if measures adopted by the Member States individually may be able to address to a certain extent the deficiencies resulting from a crisis at the national level, they are in fact more likely to further exacerbate the said crisis across the EU by adding further obstacles to the free movement and/or additional strain on products already impacted by shortages.

- **Choice of the instrument**

The proposal aims to amend 14 Directives of the European Parliament and of the Council and. In order to respect the principle of parallelism, the Proposal shall take the form of a 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

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action (‘The Strawberry Regulation’) will be repealed. According to its evaluation finalised in October 2019 and supported by an external study, this mechanism is rarely used and its information exchange system is insufficient as it is too slow and outdated[33].

- **Stakeholder consultations**

As outlined in Annex 2 to the Impact Assessment accompanying this proposal, **stakeholder consultation** activities were conducted between October 2021 and May 2022. The consultation activities included: a **call for evidence** published on the “Have your say” portal

[33] As assessed in the evaluation supporting study and the evaluation Commission Staff Working Document SWD(2019)371 final of 8 October 2019.

and open from 13 April to 11 May 2022, a **public consultation** conducted via a questionnaire published on the same portal in the same period, a **stakeholder workshop** on 6 May 2022, a **Member State survey** in May 2022 and **targeted consultations** conducted by means of meetings with Member States and specific stakeholders.

Stakeholders largely agree with the need to ensure free movement as well as greater transparency and coordination in times of crisis. Most experiences described by stakeholders came from the COVID-19 crisis. When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance. A number of Member States have voiced concern about including broad crisis preparedness measures when no crisis is looming on the horizon, without specifying targeted supply chains. While some business stakeholders voiced concerns about mandatory measures targeting economic operators, others have expressed support for a greater coordination and transparency, measures to ensure free movement of workers, fast-track notifications of national measures, fast track procedures for development and publishing of European standards, EU and national single points of information, emergency drills for experts.

- **Collection and use of expertise**

Evidence and data that were used for the development of the Impact Assessment included:

– "The impact of COVID-19 on the Internal Market", study at the request of the EP IMCO Committee;

– Evaluation of the "Strawberry Regulation" (EC) No 2679/98 and its supporting external study;

– Evaluation of the New Legislative Framework;

– Relevant information and/or evidence collected in the context of preparation of existing or proposed EU crisis response initiatives and mechanisms, including through consultation activities or impact assessment studies (e.g. the Data Act, Single Market Information Tool (SMIT), the EU Health Security Framework, Schengen Borders Code, Contingency plan for ensuring food supply and food security, the integrated political crisis response mechanism (IPCR), Contingency plan for transport, EU Digital COVID Certificate Regulation, Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic and its adaptations);

– Academic studies and literature on the effect of previous crises on the functioning of the Single Market, as well as existing position papers and other documents drawn up by relevant stakeholders;

– Newspaper articles and press materials.

The Impact Assessment further relied on the information received from consultation activities as detailed in the synopsis report contained in Annex 2 of the Impact Assessment.

The evidence base of the report is strongly limited due to the relatively low number of responses to the call for evidence and the public consultation, and the lack of a supporting study. To remedy this situation, on 6 May 2022 the Commission conducted a stakeholder workshop attended by a large number of stakeholders and conducted a series of targeted consultations, especially with Member States and stakeholders.

- **Impact assessment**

In line with its 'Better Regulation' policy, the Commission conducted an Impact Assessment[34]. The Impact Assessment evaluated three policy options establishing a governance body and a framework for contingency planning, vigilance and emergency modes. Both Single Market vigilance mode and Single Market emergency mode would be activated according to specific criteria and triggering mechanisms. Certain measures in the toolbox would need additional activation.

On the basis of analysis of problem drivers and gaps in the relevant sector-specific legislation, eight building blocks of measures were defined by grouping measures into blocks applying at different times (at all times, in vigilance mode and in emergency mode). For each building block, three policy approaches were analysed ranging from non-legislative measures (approach 1) to a hybrid approach (approach 2) to a more comprehensive legislative framework (approach 3). On the basis of this analysis, some or all approaches were retained for each building block and were combined into three realistic policy options reflecting different levels of political ambition and stakeholder support:

Mode	**Building blocks**	**Policy Option 1** **TRANSPARENCY**	**Policy Option 2** **COOPERATION**	**Policy Option 3** **SOLIDARITY**
All times	1. governance, coordination and cooperation	*Approach 2* Formal Advisory Group as the technical-level forum and obligation of the MS to share information within the group in anticipation and during the crisis		
All times	2. crisis contingency planning	*Approach 2* Recommendation to the MS for risk assessment, training and drills & compendium of crisis response measures	*Approach 3* - Recommendation to MS for risk assessment & compendium of crisis response measures and - Obligation of the Commission for Union level risk assessment - Obligation of MS to train their relevant crisis management staff regularly	
Vigilance	3. Single Market vigilance	*Approach 2* - Recommendation to the Member States on information gathering concerning identified strategic supply chains - Recommendations to the Member States for building up strategic reserves of goods of strategic importance		*Approach 3* - Obligation to MS to gather information concerning identified strategic supply chains - Obligation of the Commission to draw up and regularly update list with targets for strategic reserves - Obligations tof MS[35] to build up strategic reserves for

[34] See the accompanying Staff Working Document.

[35] Subject to additional trigger

				selected goods of strategic importance if the MS strategic reserves fall significantly short of the targets
Emergency	4. key principles and supportive measures for facilitating free movement during emergency	*Approach 2* Reinforcing key principles of free movement of crisis-relevant goods and services in binding rules where appropriate for effective crisis management		
Emergency	5. transparency and administrative assistance during emergency	*Approach 3* Binding full-fledged fast-track notification mechanism, flash peer review and possibility to declare the notified measures incompatible with EU law; contact points and electronic platform		
Emergency	6. speeding up the placing of crisis-relevant products on the market during emergency	*Approach 2* Targeted amendments of existing Single Market harmonisation legislation: faster placing of crisis-relevant products on the market; Commission can adopt technical specifications; MS prioritise market surveillance for crisis-relevant products		
Emergency	7. public procurement during emergency	*Approach 2* New provision on joint procurement/common purchasing by the Commission for some or all Member States		
Emergency	8. measures impacting crisis-relevant supply chains during emergency mode	*Approach 1* Guidance on ramping up production capacity; speeding up permitting procedures; accepting and prioritising orders of crisis relevant goods Recommendations to businesses to share crisis-relevant information	*Approach 2* Recommendations to MS for the distribution of stockpiled products; speeding up permitting procedures; encouraging economic operators to accept and prioritise orders Empowering MS[36] to oblige economic operators to ramp up production capacity and to address binding information requests to economic operators	*Approach 3* Obligations of MS[37] to distribute products previously stockpiled; speeding up permitting procedures, Obligations of businesses to accept and prioritise orders; ramp up production capacity and provide crisis-relevant information

The Impact Assessment did not present a preferred option, instead leaving the choice of options for political decision. The measures chosen in the legal proposal correspond to Policy Option 3 for all building blocks with the exception of building block 8. For building block 8, a

36 Subject to additional trigger

37 Subject to additional trigger

combination of Policy Option 1 (for ramping up production), Policy Option 2 (for distribution of stockpiled products and for speeding up permitting procedures), and Policy Option 3 (for obligations of businesses to accept and prioritise orders and to provide crisis-relevant information) has been chosen.

On 15 June 2022, the Commission submitted the Impact Assessment to the Regulatory Scrutiny Board (RSB). The RSB gave a negative opinion, noting in particular (1) the need to provide clear and detailed information related to the foreseen Single Market emergency including a definition, the criteria and decision-mechanisms for establishing and terminating it and the measures which would be implemented during it; (2) the need to provide a thorough assessment of the impacts of the policy options; and (3) the need to present alternative combinations of relevant policy options, in addition to the policy approaches, and to link the comparison to the analysis of impacts. To address these findings, the Commission provided a clear definition of a Single Market emergency, specified the criteria and decision making mechanisms, explained the three modes of functioning of SMEI and specified which building block of SMEI would be activated under which mode. It further elaborated the assessment of impacts to cover more types of impacts i.e. economic impacts for key stakeholders (businesses, Member States and Commission), impacts on SMEs, impacts on competitiveness, competition, international trade, and differentiated which impact would occur with the immediate effects and which could be expected under the vigilance and emergency modes. Further, the Impact Assessment defined three alternative policy options based on a combination of different approaches to some of the building blocks, provided an assessment of impacts of these options and extended the comparison of options to cover proportionality and subsidiarity.

On 29 July 2022, the Commission submitted the revised Impact Assessment to the RSB. The RSB then gave a positive opinion with comments. These comments related to the need to further explore the different types of crisis that may impact the functioning of the Single Market, to more clearly set out the interplay with possible measures taken on the basis of Article 4(2) TFEU and to sufficiently justify some of the measures proposed from the subsidiarity and proportionality point of view. To address these comments, indications on effects of potential future crises were added, interplay with potential measures under Article 4(2) TFEU was better explained and further details were added on the obligatory measures foreseen under emergency mode.

Further information on how the RSB recommendations are reflected in the Impact Assessment report can be found in Annex 1, point 3, of the Impact Assessment.

- **Regulatory fitness and simplification**

According to the Commission's Regulatory Fitness and Performance Programme (REFIT), all initiatives with the objective to change existing EU legislation should aim to simplify and deliver stated policy objectives more efficiently (i.e. reducing unnecessary regulatory costs).

The overall SMEI package provides a toolbox of measures to address Single Market emergency, consisting a set of measures applicable at all times as well as certain measures only applicable in vigilance or emergency modes, to be separately activated. The current proposal provides for emergency procedures for the conformity assessment, placing on the market, adoption of common specifications and market surveillance. There are **no administrative costs for businesses and citizens** that would apply with immediate effect and during the normal functioning of the Single Market.

For measures part of the overall SMEI package and likely to lead to strong impacts and potential costs for SMEs, in particular measures such as mandatory information requests,

requests to ramp up production and to accept priority-rated orders, during the additional activation of such measures specific analysis and assessment will be done as to their impact and proportionality, in particular their impact on SMEs, by the Commission. This assessment will be part of the process of additional activation of these specific measures by a Commission implementing act (additional to the overall triggering of the emergency mode). Depending on the nature of the crisis and the concerned strategic supply chains and crisis-relevant products, specific accommodations will be provided for SMEs. While it is not possible to except microenterprises completely from the scope of measures such as mandatory information requests, as these enterprises may have specific unique know-how or patents of critical importance in a crisis, specific accommodations will include simplified survey designs, less onerous reporting requirements, and longer deadlines for responses, to the extent possible in view of the need for urgency in the context of a specific crisis.

In the context of the overall SMEI package, the Regulation (EC) No. 2679/98 setting up an response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation') will be repealed. This will lead to the simplification of the legal framework.

- **Fundamental rights**

The proposal does not have an impact on the exercise of their fundamental rights of citizens or businesses.

4. BUDGETARY IMPLICATIONS

The measures in this act concern targeted amendments of existing product legislation. The implementation and application thereof is the responsibility of the Member States. There will thus not be implications on the Union budget.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

There is no specific monitoring mechanism included to this proposal. The specific monitoring requirements are already contained in the EU sectoral frameworks, which are being amended by this proposal and the amendments do not have an impact on these existing monitoring, evaluation and reporting arrangements.

- **European Economic Area**

The proposed act is of relevance to the EEA and should therefore extend thereto.

- **Detailed explanation of the specific provisions of the proposal**

The amendments, which this Proposal aims to introduce cover the following aspects:

(1) Prioritisation by the notified bodies of the conformity assessment of products designated as crisis-relevant;

(2) Possibility for the national competent authorities to issue temporary authorisations for crisis relevant products, which have not undergone the standard conformity assessment procedures, provided that the products comply with all the applicable essential requirements and provided that the authorisation is limited to the duration of the Single Market emergency and to the territory of the issuing Member State;

(3) Possibility for the manufacturers to rely on relevant international and national standards during an emergency if no harmonised standards are available and if the alternative standards ensure an equivalent level of safety;

(4) Possibility for the Commission to adopt via delegated acts voluntary or mandatory common technical specifications for crisis-relevant products;

(5) Prioritisation of the market surveillance activities for crisis-relevant goods

2022/0280 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 91 and 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[38],

Having regard to the opinion of the Committee of the Regions[39],

Acting in accordance with the ordinary legislative procedure[40],

Whereas:

(1) [*insert reference to SMEI Regulation*] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.

(2) The framework established by [*insert reference to SMEI Regulation*] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.

(3) [*insert reference to SMEI Regulation*] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.

(4) [*insert reference to SMEI Regulation*] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [*insert reference to SMEI Regulation*] applies to both goods and services.

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38 OJ C , , p. .

39 OJ C , , p. .

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

(5) In order to complement, ensure consistency and further enhance the effectiveness of such measures, it is appropriate to ensure that crisis-relevant goods referred to in [*insert reference to SMEI Regulation*] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.

(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[41], 2006/42/EC[42], 2010/35/EU[43], 2013/29/EU[44], 2014/28/EU[45], 2014/29/EU[46], 2014/30/EU[47], 2014/31/EU[48], 2014/32/EU[49], 2014/33/EU[50], 2014/34/EU[51], 2014/35/EU[52], 2014/53/EU[53] and 2014/68/EU[54] 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

41 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).

42 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).

43 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).

44 Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (OJ L 178, 28.6.2013, p. 27).

45 Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1).

46 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).

47 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).

48 Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).

49 Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149).

50 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).

51 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).

52 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).

53 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).

54 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).

and are also aligned to the reference provisions laid down by Decision 768/2008/EC EC of the European Parliament and of the Council[55].

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

(8) Experience from the past crises that have affected the Single Market has shown that the procedures laid down in the sectoral legal acts are not designed to cater the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [*insert reference to SMEI Regulation*].

(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant.

(10) To that end, emergency procedures should be laid down in Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and, 2014/68/EU. Those procedures should be available only following the activation of the Single Market emergency and only when a specific good covered by those Directives is designated as crisis-relevant mode in accordance with [*insert reference to SMEI Regulation*].

(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation.

(12) As regards products falling within the scope of those Directives that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Directives, in those cases where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they comply with the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.

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[55] 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).

(13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.

(14) A number of sectoral EU harmonised frameworks provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.

(15) With respect to Directive 2006/42/EC, Directives 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/53/EU and 2014/68/EU, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012[56] ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.

(16) Furthermore, with respect to Directives 2006/42/EC, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.

(17) With respect to Directives 2006/42/EC, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU, in exceptional and duly justified circumstances, notably in order to ensure the interoperability among products or systems, the Commission should be able to adopt by means of implementing acts common specifications laying down mandatory technical specifications, with which the manufacturers will be required to comply. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.

(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.

(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.

(20) Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU should therefore be amended accordingly.

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56 OJ L 316, 14.11.2012, p. 12.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2000/14/EC

Directive 2000/14/EC is amended as follows:

the following articles are inserted:

'*Article 17a*

Application of emergency procedures

1. Member States shall ensure that measures taken to transpose Articles 17b, 17c and 17d of this Directive only apply if Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 226 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose in Articles 17b, 17 c and 17d apply exclusively to equipment, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose in Articles 17b, 17c and 17d apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to equipment placed on the market in accordance with Article 17c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19a(2).

Article 17b

Prioritisation of the conformity assessment of crisis-relevant equipment

1. This Article shall apply to equipment listed in the implementing act referred to in Article 17a(1), which is subject to conformity assessment procedures in accordance with Article 14, which require the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of equipment designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 17a.

4. The prioritisation of applications for conformity assessment of equipment pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for equipment designated as crisis-relevant goods in respect of which they have been notified.

Article 17c

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

1. By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of specific equipment referred to in Article 12 and listed in the implementing act referred to in Article 17a(1)and for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in Article 14 have not been carried out by a notified body but for which the compliance with all the applicable requirements concerning the noise emission in the environment of this Directive has been demonstrated.

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the equipment may be placed on the market or put into service, including:

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

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

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the equipment concerned;

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

4. By way of derogation from Article 17a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation fromArticles 6 and 11, equipment, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not benefit from free movement across the Union and shall not bear the CE marking. The market surveillance authorities are not required to recognise the validity of authorisations issued by the competent national authorities of another Member State.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such equipment.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of equipment in accordance with paragraph 1.

8. The application of Articles 17a to 17d and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 17d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for equipment, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for equipment, designated as crisis-relevant goods.'

(2) Article 18, is amended as follows:

(a) In paragraph 1, the following sentence is added after the first sentence: 'That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council*.' 'The committee referred to in Article 18 shall:';; 'The committee referred to in Article 18 shall:';

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

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

Article 2

Amendments to Directive 2006/42/EC

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

'*Article 21b*

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 21c to 21h of this directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 21c to 21h are apply exclusively to machinery, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 21c to 21h apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken 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 process all applications for conformity assessment of machinery designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of machinery designated as crisis-relevant goodsshall be processed as a matter of priority, ahead of any other applications for conformity assessment of machinery, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of machinery designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 21b.

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

5. The notified bodies shall deploy their best efforts to increase their testing capacities for machinery designated as crisis-relevant goods in respect of which they have been notified.

Article 21d

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery may be placed on the market or put into service, including:

(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) specific requirements regarding the traceability of the machinery concerned;

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

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

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

4. By way of derogation from Article 21d(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3, also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 6 and 16, machinery, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive[57] with respect to such machinery.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of machinery in accordance with paragraph 1.

8. The application of Articles 21b to 21h and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 12 on the territory of the Member State concerned.

Article 21e

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that the machinery which complies with of relevant international standards or any national standards in force in

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

the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex I, complies with those essential health and safety requirements in either of the following cases:

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

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

Article 21f

Adoption of common specifications conferring a presumption of conformity

1. Where machinery has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such machinery to cover the essential health and safety requirements set out in Annex I, in either of the following cases:

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 22(3).They shall apply to machinery placed on the market until the last day of the period for which the Single Market emergency mode has been activated in accordance with Article 15(4) of [the SMEI Regulation]. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 7, machinery which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 21b(3), first subparagraph, unless there is sufficient reason to believe that the machinery covered by the common specifications

referred to in paragraph 1 of this Article presents a risk to the health or safety of persons, the machinery in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 21g

Adoption of mandatory common specifications

1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex I for machinery listed in the implementing act referred to in Article 21b(1).

2. The implementing acts establishing mandatory common specifications referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the procedure referred to in Article 22(3). They shall apply to machinery placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

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

Article 21h

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for machinery, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for machinery designated as crisis-relevant goods.’

Article 3

Amendments to Directive 2010/35/EU

Directive 2010/35/EU is amended as follows:

the following Chapter 5a is inserted:

‘‘**CHAPTER 5a**
EMERGENCY PROCEDURES

Article 33a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d apply exclusively to transportable pressure equipment, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 33b, 33c and 33d apply during Single Market emergency mode.

4. However, Article 33c(2), second subparagraph, and Article 33c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

5. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to transportable pressure equipment placed on the market in accordance with Article 33c. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 38a(2).

Article 33b

Prioritisation of the conformity assessment of crisis-relevant transportable pressure equipment

1. This Article shall apply to transportable pressure equipment designated as crisis-relevant goods, which is subject to conformity assessment procedures in accordance with Article 12, which require the mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of transportable pressure equipment designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of transportable pressure equipment designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 33a.

4. The prioritisation of applications for conformity assessment of transportable pressure equipment pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for transportable pressure equipment designated as crisis-relevant goods in respect of which they have been notified.

Article 33c

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

1. By way of derogation from Article 12, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific transportable pressure equipment designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 12 have not been carried out by a notified body but for which the compliance with all the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive has been demonstrated.

2. The manufacturer, the importer,the distributor and the user of a transportable pressure equipment subject to the authorisation procedure referred to in paragraph 1 of this Article shall declare on his sole responsibility that the transportable pressure equipment concerned complies with all the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.

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

3. Any authorisation issues 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, including:

(a) a description of the procedures, by means of which the compliance with the applicable requirements set out in the Annexes to Directive 2008/68/EC and in this Directive was successfully demonstrated;

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

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the transportable pressure equipment concerned;

(e) measures to be taken with respect to the transportable pressure equipment concerned upon expiry of the authorisation in order to ensure that the transportable pressure equipment concerned is brought back in compliance with all the requirements of this Directive.

4. By way of derogation from Article 33a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 14 and 16, transportable pressure equipment, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State that has granted the authorisation .

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such transportable pressure equipment.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a transportable pressure equipment in accordance with paragraph 1.

8. The application of Articles 33a to 33d and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 12 on the territory of the Member State concerned.

Article 33d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for transportable pressure equipment, designated as crisis-relevant goods.

   The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for transportable pressure equipment, designated as crisis-relevant goods.

2. 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.

Article 4

Amendments to Directive 2013/29/EU

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

‘CHAPTER 5a
EMERGENCY PROCEDURES

Article 42a
Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 42b to 42g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 42b to 42g apply exclusively to pyrotechnic articles, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 42b to 42g apply during the Single Market emergency mode.

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to pyrotechnic articles placed on the market in accordance with Articles 42c to 42f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 42b
Prioritisation of the conformity assessment of crisis-relevant pyrotechnic articles

1. This Article shall apply to all pyrotechnic articles designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17 requiring the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of equipment designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of pyrotechnic articles designated as crisis-relevant goods, irrespective of, whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 42a.

4. The prioritisation of applications for conformity assessment of pyrotechnic articles pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for pyrotechnic articles designated as crisis-relevant goods in respect of which they have been notified.

1. *Article 42c*
Derogation from party conformity assessment procedures requiring mandatory involvement of a notified body By way of derogation from Article 17, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific pyrotechnic article which has been designated as crisis-relevant good and for which

the conformity assessment procedures which require the mandatory involvement of a notified body referred to in Article 17 have not been carried out by a notified body but for which the compliance with all the applicable essential safety requirements has been demonstrated.

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

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

4. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the pyrotechnic article may be placed on the market, including:

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

(b) specific requirements regarding the traceability of the pyrotechnic article concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the pyrotechnic article concerned;

(e) measures to be taken with respect to the pyrotechnic article concerned upon expiry of the authorisation in order to ensure that the pyrotechnic article concerned is brought back in compliance with all the requirements of this Directive.

5. By way of derogation from Article 42a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.

6. By way of derogation from Articles 4 and 20, pyrotechnic articles, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not benefit from free movement across the Union and shall not bear the CE marking. The market surveillance authorities are not required to recognise the validity of authorisations issued by the competent national authorities of another Member State.

7. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such pyrotechnic articles.

8. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a pyrotechnic article in accordance with paragraph 1.

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

Article 42d

Presumption of conformity based on national and international standards

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

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

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

Article 42e

Adoption of common specifications conferring a presumption of conformity

1. Where pyrotechnic articles, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts for such pyrotechnic articles establishing common specifications to cover the essential safety requirements set out in Annex I in either of the following cases:

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to for pyrotechnic articles placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 16, pyrotechnic articles which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be

presumed to be in conformity with the essential safety requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 42a(3), first subparagraph, unless there is sufficient reason to believe that the pyrotechnic articles covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the pyrotechnic articles in compliance with the said common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].

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

Article 42f

Adoption of mandatory common specifications

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

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they apply to pyrotechnic articles placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 42a(3), first subparagraph, unless there is sufficient reason to believe that the pyrotechnic articles covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the pyrotechnic articles in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 42g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for pyrotechnic articles designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting

assistance or by providing logistical support such as reinforcement of the testing capacity for pyrotechnic articles designated as crisis-relevant goods.'

Article 5

Amendments to Directive 2014/28/EU

In Directive 2014/28/EU, the following Chapter 6a is inserted:

'CHAPTER 6a
EMERGENCY PROCEDURES

Article 45a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 45b to 45g of this Directive shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 45b to 45g apply exclusively to explosives, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 45b to 45g apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to explosives placed on the market in accordance with Articles 45c to 45f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

Article 45b

Prioritisation of the conformity assessment of crisis-relevant explosives

1. This Article shall apply to explosives designated as crisis-relevant goods, which are subject to conformity assessment procedures, in accordance with Article 20requiring the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of such explosives designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of explosives designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 45a.

4. The prioritisation of applications for conformity assessment of explosives pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, which have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for explosives designated as crisis-relevant goods in respect of which they have been notified.

Article 45c

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

1. By way of derogation from Article 20, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific explosive which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in that Article 20 have not been carried out by a notified body but for which the compliance with all the applicable essential safety requirements has been demonstrated.

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the explosive may be placed on the market, including:

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

(b) specific requirements regarding the traceability of the explosive concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the explosive concerned;

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

4. By way of derogation from Article 45a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 3 and 23, explosives, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all

corrective and restrictive measures at national level provided for under this Directive with respect to such explosives.

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

8. The application of Articles 45a to 45g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 20 on the territory of the Member State concerned.

Article 45d

Presumption of conformity based on national and international standards

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

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

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

Article 45e

Adoption of common specifications conferring a presumption of conformity

1. Where explosives, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts for such explosives establishing common specifications to cover the essential safety requirements set out in Annex II in either of the following cases:

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex II already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 49(3). They shall apply to the explosives placed on the market until the last day of the period for which the Single Market emergency mode remains applicable in accordance with [the SMEI Regulation]. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 19, explosives which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those common specifications or parts thereof.

4. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the explosives covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the explosives in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation*

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

Article 45f

Adoption of mandatory common specifications

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

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 49(3) and they shall apply to explosives placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the explosives covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the explosives in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive

after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 45g

Prioritisation of market surveillance activities and mutual assistance among authorities

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

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for explosives, designated as crisis-relevant goods.'

Article 6

Amendments to Directive 2014/29/EU

In Directive 2014/29/EU, the following Chapter 5a is inserted:

''**CHAPTER 5a**
EMERGENCY PROCEDURES

Article 38a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 38b to 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply exclusively to vessels, which have been designated as crisis-relevant goods in the Commission implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to vessels placed on the market in accordance with Articles 38c to 38f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 39(3).

Article 38b

Prioritisation of the conformity assessment of crisis-relevant vessels

1. This Article shall apply to vessels designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 13 requiring the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of vessels designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of vessels designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 38a.

4. The prioritisation of applications for conformity assessment of vessels pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for vessels designated as crisis-relevant goods in respect of which they have been notified.

Article 38c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the vessel may be placed on the market or put into service, including:

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

(b) specific requirements regarding the traceability of the vessel concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the vessel concerned;

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

4. By way of derogation from Article 38a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.

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

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such vessels.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a vessel in accordance with paragraph 1.

8. The application of Articles 38a to 38g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned..

Article 38d

Presumption of conformity based on national and international standards

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

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

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

Article 38e

Adoption of common specifications conferring a presumption of conformity

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

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

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

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to vessels placed on the market until the last day of the period for which the Single Market emergency mode remains active in accordance with Article 15(4) of [the SMEI Regulation]. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 12, vessels which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential safety requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the vessels covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the vessels in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 38f

Adoption of mandatory common specifications

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

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3) and they shall apply to vessels placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the

common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the vessels covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the vessels in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 38g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for vessels, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for vessels, designated as crisis-relevant goods.'

Article 7

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

the following Chapter 5a is inserted:

''CHAPTER 5a
EMERGENCY PROCEDURES

Article 40a

Application of mergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 40b to 40g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 40b to 40g apply exclusively to apparatus, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 40b to 40g apply during the Single Market emergency mode.

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

Article 40b

Prioritisation of the conformity assessment of crisis-relevant apparatus

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

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

3. All pending applications for conformity assessment of apparatus designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for equipment, which has not been designated as crisis-relevant goods. This requirement is applies with respect to all applications for conformity assessment of apparatus designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.

4. The prioritisation of applications for conformity assessment of apparatus pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for apparatus designated as crisis-relevant goods in respect to which they have been notified.

Article 40c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the apparatus may be placed on the market or put into service, including:

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

(b) specific requirements regarding the traceability of the apparatus concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the apparatus concerned;

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

4. By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3also after the deactivation or expiry of the Single Market Emergency mode.

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

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such apparatus.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of apparatus in accordance with paragraph 1.

8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 40d

Presumption of conformity based on national and international standards

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

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

(b) where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Directive and

already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

Article 40e

Adoption of common specifications conferring a presumption of conformity

1. Where apparatus, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts for such apparatus establishing common specifications to cover the essential health and safety requirements set out in Annex I, in either of the following cases:

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(2a). They shall apply to apparatus placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 13, apparatus which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the apparatus covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the apparatus in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 40f

Adoption of mandatory common specifications

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

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(2a). They shall apply to apparatus placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the apparatus covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the apparatus in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 40g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for apparatus, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for apparatus, designated as crisis-relevant goods.'

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

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

Article 8

Amendments to Directive 2014/31/EU

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

''CHAPTER 5a
EMERGENCY PROCEDURES

Article 40a

Application of emergency procedures, and their deactivation

1. Member States shall ensure that measures taken to transpose Articles 40b to 40g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 40b to 40g apply exclusively to instruments, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 40b to 40g apply during the Single Market emergency mode.

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

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

Article 40b

Prioritisation of the conformity assessment of crisis-relevant instruments

1. This Article shall apply to instruments designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 13 requiring the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of such instruments designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of instruments, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of instruments designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.

4. The prioritisation of applications for conformity assessment of instruments pursuant to paragraph 2 and 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for instruments designated as crisis-relevant goods in respect to which they have been notified.

Article 40c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the instrument may be placed on the market, including:

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

(b) specific requirements regarding the traceability of the instrument concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the instrument concerned;

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

4. By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 5 and 16, instruments, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisationand shall not bear the CE marking, nor the supplementary metrology marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such instruments.

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

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

Article 40d

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that instruments which comply with the

relevant international standards any national standards in force in the Member State of manufacture, ensuring the safety level equivalent to that required by the essential requirements set out in Annex I, comply with those essential requirements in either of the following cases:

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

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

Article 40e

Adoption of common specifications conferring a presumption of conformity

1. Where instruments, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts with respect to such instruments establishing common specifications to cover the essential requirements set out in Annex I in either of the following cases:

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(3). They shall apply to instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 12, instruments which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or

safety of persons, the instruments in compliance with the said common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 40f

Adoption of mandatory common specifications

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 41(3). They shall apply to for instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the instruments in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 40g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for instruments, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for instruments, designated as crisis-relevant goods.’

Article 9

Amendments to Directive 2014/32/EU

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

‘‘CHAPTER 5a
EMERGENCY PROCEDURES

Article 45a

Application of emergency procedures, and their deactivation

1. Member States shall ensure that measures taken to transpose Articles 45b to 45g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 45b to 45g apply exclusively to measuring instruments, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 45b to 45g apply during the Single Market emergency mode.

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

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

Article 45b

Prioritisation of the conformity assessment of crisis-relevant measuring instruments

1. This Article shall apply to all measuring instruments designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17requiring the mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of such measuring instruments shall be processed as a matter of priority, ahead of any other applications for conformity assessment of measuring instruments, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of measuring instruments designated as crisis-relevantrelevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 45a.

4. The prioritisation of applications for conformity assessment of measuring instruments pursuant to paragraph 2 and 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for measuring instruments designated as crisis-relevant goods in respect to which they have been notified.

Article 45c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the measuring instrument may be placed on the market or put into use, including:

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

(b) specific requirements regarding the traceability of the measuring instrument concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the measuring instrument concerned;

(e) measures to be taken with respect to the measuring instrument concerned upon expiry of the authorisation in order to ensure that the measuring instrument concerned is brought back in compliance with all the requirements of this Directive.

4. By way of derogation from Articles 7 and 20, measuring instruments, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking, nor the supplementary metrology marking.

5. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such measuring instruments.

6. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market and/or putting into use of a measuring instrument in accordance with paragraph 1.

7. The application of Articles 45a to 45g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned.

Article 45d

Presumption of conformity based on national and international standards

Where either:

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

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

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

Article 45e

Adoption of common specifications conferring a presumption of conformity

1. Where measuring instruments have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such measuring instruments to cover the essential requirements set out in Annex I and in the relevant instrument-specific Annexes in either of the following cases:

(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;

(b) the severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I and in the relevant instrument-specific Annexes to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 46(3). They shall remain apply to

measuring instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 14, measuring instruments which are in conformity with common specifications adopted pursuant to paragraph 2 shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those common specifications or parts thereof.

4. By way of derogation from Article 45a(3), first subparagraph, unless there is sufficient reason to believe that the measuring instruments covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the measuring instruments in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I and in the relevant instrument-specific Annexes, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.

Article 45f

Adoption of mandatory common specifications

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

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 46(3).They shall apply to measuring instruments placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 45a(3), first subparagraph, nnless there is sufficient reason to believe that the measuring instruments covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the measuring instruments in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act

adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 45g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for measuring instruments, designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for measuring instruments, designated as crisis-relevant goods.'

Article 10

Amendments to Directive 2014/33/EU

In Directive 2014/33/EU, the following Chapter Va is inserted:

'CHAPTER Va
EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 41b to 41g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 41b to 41g apply exclusively to lifts and safety components for lifts, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 41b to 41g apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken 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 16requiring mandatory involvement of a notified body.

2. The notified bodies shall process all applications for conformity assessment of lifts and safety components for lifts designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of such lifts and safety components for lifts shall be processed as a matter of priority, ahead of any other applications for conformity assessment of lifts and safety components for lifts which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of lifts and safety components for lifts designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.

4. The prioritisation of applications for conformity assessment of lifts and safety components for lifts pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for lifts and safety components for lifts designated as crisis-relevant goods in respect to which they have been notified.

Article 41c

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

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

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

3. The manufacturer of a lift or a safety component for lifts subject to the authorisation procedures referred to in paragraphs 1 or 2 shall declare on his sole responsibility that the lift or the safety component for lifts concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.

The manufacturer shall also deploy all reasonable measures to ensure that the lift or the safety component for lifts, which has been granted an authorisation pursuant to

paragraphs 1 or 2 does not leave the territory of the Member State, which has granted the authorisation.

4. Any authorisation issued by a national competent authority pursuant to paragraphs 1 or 2 shall set out the conditions and requirements under which the lift or a the safety component for lifts may be placed on the market, made available or put into service respectively, including:

(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) specific requirements regarding the traceability of the lift or safety component for lifts concerned;

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

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

(e) measures to be taken with respect to the lift or safety component for lifts concerned upon expiry of the authorisation in order to ensure that the lift or safety component for lifts concerned is brought back in compliance with all the requirements of this Directive.

5. By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 4 of this Article, also after the deactivation or expiry of the Single Market Emergency mode.

6. By way of derogation from Articles 3 and 19, lifts or safety components for lifts, for which an authorisation has been granted in accordance with paragraphs 1 or 2 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

7. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such lifts or safety components for lifts.

8. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market, making available or putting into service respectively of a lift or a safety component for lifts in accordance with paragraphs 1 or 2.

9. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 15 or 16 on the territory of the Member State concerned.

Article 41d

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, making available or putting into service respectively, their competent authorities consider that the lifts and safety components of lifts which comply with the relevant international standards or any national standards in force in the Member State of

manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex I, comply with those essential health and safety requirements in either of the following cases:

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

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

Article 41e

Adoption of common specifications conferring a presumption of conformity

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

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3). They shall apply to lifts and safety components for lifts placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 14, lifts and safety components for lifts which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the lifts and safety components for lifts covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the lifts and safety components for lifts in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 41f

Adoption of mandatory common specifications

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

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3) and they shall apply to lifts and safety components for lifts placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the lifts and safety components for lifts covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the lifts and safety components for lifts in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 41g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for lifts and safety components for lifts designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting

assistance or by providing logistical support such as reinforcement of the testing capacity for lifts and safety components for lifts designated as crisis-relevant goods.'

Article 11
Amendments to Directive 2014/34/EU

In Directive 2014/34/EU, the following Chapter 5a is inserted:

''CHAPTER 5a
EMERGENCY PROCEDURES

Article 38a
Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 38b to 38g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.
2. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply exclusively to products, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.
3. Member States shall ensure that measures taken to transpose Articles 38b to 38g apply during the Single Market emergency mode.

   However, Article 38c(2), second subparagraph, and Article 38c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.
4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to products placed on the market in accordance with Articles 38c to 38f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 39(3).

Article 38b
Prioritisation of the conformity assessment of crisis-relevant products

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

5. The notified bodies shall deploy their best efforts to increase their testing capacities for products designated as crisis-relevant goods in respect to which they have been notified.

Article 38c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the product may be placed on the market or put into service, including:

(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) specific requirements regarding the traceability of the product concerned;

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

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

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

4. By way of derogation from Article 38a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.

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

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such products.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a product in accordance with paragraph 1.

8. The application of Articles 38a to 38g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 13 on the territory of the Member State concerned.

Article 38d

Presumption of conformity based on national and international standards

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

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

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

Article 38e

Adoption of common specifications conferring a presumption of conformity

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

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Directive already published in the

Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 12, products which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof.

4. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the products in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 38f

Adoption of mandatory common specifications

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

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 39(3). They shall apply to products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 38a(3), first subparagraph, unless there is sufficient reason to believe that the products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or

safety of persons, the products in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 38g

Prioritisation of market surveillance activities and mutual assistance among authorities

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

1. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for products designated as crisis-relevant goods.'

Article 12

Amendments to Directive 2014/35/EU

In Directive 2014/35/EU, the following Chapter 4a is inserted:

''CHAPTER 4a
EMERGENCY PROCEDURES

Article 22a

Application of emergency procedures,

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

Article 22b

Adoption of common specifications conferring a presumption of conformity

1. Where electrical equipment, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such electrical equipment to cover the safety objectives referred to in Article 3 and set out in Annex I in either of the following cases:

(a) where no reference to harmonised standards covering the safety objective set out in Annex I to this Directive has been published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the safety objectives referred to in Article 3 and set out in Annex I to this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 23(2). They shall apply to electrical equipment placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union lgislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Articles 12, 13 and 14, electrical equipment which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article 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 common specifications or parts thereof.

4. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that the electrical equipment covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the electrical equipment in compliance with those common specifications which has been placed on the market, shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the safety objectives referred to in Article 3 and set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.

Article 22c

Adoption of mandatory common specifications

1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the safety objectives referred to in Article 3 and set out in Annex I for electrical equipment, which has been designated as crisis-relevant goods.

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

early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 22a(3), unless there is sufficient reason to believe that the electrical equipment covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the electrical equipment in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Directive after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 22d

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for electrical equipment designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for electrical equipment designated as crisis-relevant goods.'

Article 13

Amendments to Directive 2014/53/EU

In Directive 2014/53/EU, the following Chapter 5a is inserted:

''CHAPTER Va
EMERGENCY PROCEDURES

Article 43a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 43b to 43g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply exclusively to radio equipment, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to radio equipment placed on the market in accordance with Articles 43c to 43f. Those implementing

acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 43b

Prioritisation of the conformity assessment of crisis-relevant radio equipment

1. This Article shall apply to all radio equipment designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 17 requiring mandatory involvement of a notified body.

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

3. All pending applications for conformity assessment of such radio equipment shall be processed as a matter of priority, ahead of any other applications for conformity assessment of radio equipment, which has not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of radio equipment designated as crisis-relevantgood, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.

4. The prioritisation of applications for conformity assessment of radio equipment pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for radio equipment designated as crisis-relevant goods in respect to which they have been notified.

Article 43c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the radio equipment may be placed on the market, including:

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

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

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the radio equipment concerned;

(e) measures to be taken with respect to the radio equipment concerned upon expiry of the authorisation in order to ensure that the radio equipment concerned is brought back in compliance with all the requirements of this Directive.

4. By way of derogation from Articles 9 and 20, radio equipment, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

5. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such radio equipment.

6. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of radio equipment in accordance with paragraph 1.

7. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 17 on the territory of the Member State concerned.

Article 43d

Presumption of conformity based on national and international standards

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

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

severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Article 3 of this Directive and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 025/2012.*Article 43e*

Adoption of common specifications conferring a presumption of conformity

1. Where radio equipment, has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common

specifications for such radio equipment to cover the essential requirements set out in Article 3 in either of the following cases:

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3). They shall apply to radio equipment placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 16, radio equipment which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Article 3 covered by those common specifications or parts thereof.

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

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

Article 43f

Adoption of mandatory common specifications

1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Article 3 for radio equipment, which has been designated as crisis-relevant goods.

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3)

and they shall apply to radio equipment placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

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

Article 43g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for radio equipment designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for radio equipment designated as crisis-relevant goods.'

Article 15

Amendments to Directive 2014/68/EU

In Directive 2014/68/EU, the following Chapter 5a is inserted:

''**CHAPTER 5a**
EMERGENCY PROCEDURES

Article 43a

Application of emergency procedures,

1. Member States shall ensure that measures taken to transpose Articles 43b to 43g of this Directive only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Directive.

2. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply exclusively to pressure equipment and assemblies, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Member States shall ensure that measures taken to transpose Articles 43b to 43g apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to pressure equipment and assemblies placed on the market in accordance with Articles 43c to 43f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 43b

Prioritisation of the conformity assessment of crisis-relevant pressure equipment and assemblies

1. This Article shall apply to pressure equipment or assemblies designated as crisis-relevant goods, which are subject to conformity assessment procedures, which require the mandatory involvement of a notified body, in accordance with Article 14.

2. The notified bodies shall process all applications for conformity assessment of pressure equipment and assemblies designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of such in accordance with Article 14shall be processed as a matter of priority, ahead of any other applications for conformity assessment of pressure equipment or assemblies, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of pressure equipment and assemblies designated as crisis-relevant goods, irrespective of whether they have beenlodged before or after the activation of the emergency procedures pursuant to Article 43a.

4. The prioritisation of applications for conformity assessment of pressure equipment and assemblies pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for pressure equipment and assemblies designated as crisis-relevant goods in respect of which they have been notified.

Article 43c

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

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

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

   The manufacturer shall also deploy all reasonable measures to ensure that the pressure equipment or assembly, which has been granted an authorisation pursuant to

paragraph 1 does not leave the territory of the Member State, issued the authorisation.

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the pressure equipment or assembly may be placed on the market or put into service, including:

(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) specific requirements regarding the traceability of the pressure equipment or assembly concerned;

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the pressure equipment or assembly concerned;

(e) measures to be taken with respect to the pressure equipment or assembly concerned upon expiry of the authorisation in order to ensure that the pressure equipment or assembly concerned is brought back in compliance with all the requirements of this Directive.

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

5. By way of derogation from Articles 5 and 19, pressure equipment or assemblies, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Directive with respect to such pressure equipment or assemblies.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of a pressure equipment or assembly in accordance with paragraph 1.

8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 43d

Presumption of conformity based on national and international standards

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

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

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

Article 43e

Adoption of common specifications conferring a presumption of conformity

1. Where pressure equipment and assemblies have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts for such pressure equipment and assemblies establishing common specifications to cover the essential safety requirements set out in Annex II in either of the following cases:

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential safety requirements set out in Annex II to this Directive already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Directive shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to the pressure equipment and assemblies placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 12, pressure equipment or assemblies which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those common specifications or parts thereof.

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

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

Article 43f

Adoption of mandatory common specifications

1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential safety requirements set out in Annex II, ffor pressure equipment or assemblies, which have been designated as crisis-relevant goods.

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to pressure equipment and assemblies placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

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

Article 43g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for pressure equipment and assemblies designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for pressure equipment and assemblies designated as crisis-relevant goods.'

Article 15

Transposition

1. Member States shall adopt and publish, by [*OP – please insert date – 6 months after entry into force of this Directive*] at the latest, the laws, regulations and

administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

2. They shall apply those provisions from […[*OP please add date – 6 months after the date of entry into force of this Directive*].

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

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 16

Entry into force

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

Article 17

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

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

EUROPEAN
COMMISSION

Brussels, 19.9.2022
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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

(Text with EEA relevance)

{SEC(2022) 323 final} - {SWD(2022) 288 final} - {SWD(2022) 289 final} - {SWD(2022) 290 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The Single Market is one of the EU's greatest assets and provides the backbone for the EU's economic growth and wellbeing. Recent crises, such as the COVID-19 pandemic or Russia's invasion of Ukraine, have demonstrated some vulnerability of the Single Market and its supply chains in case of unforeseen disruptions and, at the same time, how much the European economy and all its stakeholders rely on a well-functioning Single Market. In the future, in addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. For this reason, the functioning of the Single Market needs to be guaranteed in times of emergency.

The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to the appearance of obstacles to free movement within the Single Market, thus disrupting its functioning. On the other hand, a crisis can amplify the shortages of crisis-relevant goods and services if the Single Market is fragmented and is not functioning. As a result, supply chains can swiftly become interrupted, companies face difficulties in sourcing, supplying or selling goods and services. Consumer access to key products and services becomes disrupted. Lack of information and legal clarity further exacerbate the impact of these disruptions. In addition to direct societal risks caused by the crisis, citizens, and in particular vulnerable groups, are confronted with strong negative economic impacts. The proposal therefore aims to address two separate but interrelated problems: obstacles to free movement of goods, services and persons in times of crisis and shortages of crisis-relevant goods and services.

In close cooperation with all Member States and other existing EU crisis instruments, the Single Market Emergency Instrument (SMEI) package will provide a strong agile governance structure as well as a targeted toolbox to ensure the smooth functioning of the Single Market in any type of future crisis. It is likely that not all of the tools included in this proposal will be needed simultaneously. The purpose is rather to brace the EU for the future and equip it with what may prove to be necessary in a given crisis situation severely affecting the Single Market.

The European Council in its Conclusions of 1-2 October 2020[1] stated that the EU will draw the lessons from the COVID-19 pandemic and address remaining fragmentation, barriers and weaknesses of the Single Market in facing emergency situations. In the Update of the Industrial Strategy Communication[2], the Commission announced an instrument to ensure the free movement of persons, goods and services, as well as greater transparency and coordination in times of crisis. The initiative forms part of the Commission Work Programme for 2022[3]. The European Parliament welcomed the Commission's plan to present a Single Market Emergency Instrument and called on the Commission to develop it as a legally binding structural tool to ensure the free movement of persons, goods and services in case of future crises[4].

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1 https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf.

2 COM(2021)350 final.

3 https://ec.europa.eu/info/publications/2022-commission-work-programme-key-documents_en.

4 European Parliament resolution of 17 February 2022 on tackling non-tariff and non-tax barriers in the single market (2021/2043(INI).

- **Consistency with existing policy provisions in the policy area**

A number of EU legal instruments lay down provisions which are relevant for the management of crises in general. On the other hand, certain EU frameworks and recently adopted Commission proposals lay down more targeted measures which focus on certain aspects of crisis management or are relevant for specific sectors. The Single Market Emergency Instrument will apply without prejudice to the provisions put forward by these targeted crisis management instruments, which are to be considered as *lex specialis*. Financial services, medicinal products, medical devices or other medical counter-measures and food safety products in particular are excluded from the scope of the initiative due to the existence of a dedicated crisis-relevant framework in these areas.

Interplay with horizontal crisis response mechanisms

The integrated political crisis response mechanism (IPCR)[5] is among the horizontal crisis response mechanisms[6]. The Presidency of the Council of the EU uses the IPCR to facilitate information sharing and political coordination among the Member States in responding to complex crises. The IPCR scrutinised for the first time in October 2015 the refugee and migration crisis and it has been instrumental in monitoring and supporting the response to the crisis, reporting to Coreper, the Council and the European Council. The IPCR operated the Union response to major crises caused by cyber-attacks, natural disasters, or hybrid threats. More recently, the IPCR has also operated after the outbreak of the COVID-19 pandemic and the Russian brutal aggression on Ukraine.

Another EU mechanism for general crisis response is the Union Civil Protection Mechanism and its Emergency Response Coordination Centre (ERCC)[7]. The ERCC is the Commission's central operational 24/7 hub for first emergency response, the establishment of strategic stockpiles at the EU level for emergency response ("rescEU"), disaster risk assessments, scenario building, disaster resilience goals, EU wide overview of natural and man-made disaster risks, other prevention and preparedness measures, such as training and exercises.

Interplay with horizontal Single Market mechanisms

When appropriate and necessary, coordination should be ensured between the Single Market Emergency Instrument and the activities of the Single Market Enforcement Task-Force (SMET). In particular, the Commission shall refer notified obstacles that significantly disrupt the free movement of goods and services of strategic goods and services for discussion/review to the Single Market Enforcement Task Force (SMET).

- **Consistency with other Union policies**

Interplay with measures targeting specific aspects of crisis management

The above-mentioned horizontal crisis response mechanisms are supplemented by other more targeted measures, focusing on specific aspects of the Single Market such as the free movement of goods, common rules on exports or public procurement.

One such framework is the Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to

[5] https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/.

[6] It was formally set up by Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response, on the basis of previously existing arrangements.

[7] Laid down by the Decision (EU) 1313/2013 governing the functioning of the Union Civil Protection Mechanism.

serious disruptions and requiring immediate action ('The Strawberry Regulation')[8]. This Regulation provides for a mechanism of notification as well as a system of information exchange between the Member States and the Commission. (See sections 8.1 and 8.2 for more details.)

The Regulation on common rules for exports[9] allows the Commission to subject certain categories of products to an extra-EU export surveillance or to an extra-EU export authorisation. The Commission was subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance[10] on this basis.

Other economic measures include negotiated procedure and occasional joint procurement by the Commission on behalf of the Member States[11].

Interplay with sector-specific crisis measures

Certain EU frameworks lay down more targeted measures which focus only on certain specific aspects of crisis management or only concern certain specific sectors.

The Commission communication "Contingency plan for ensuring food supply and food security"[12] draws lessons learnt during the COVID-19 pandemic and previous crises with the objective to step up coordination and crisis management including preparedness. To this end, the contingency plan puts forward key principles to be followed to ensure food supply and food security in the event of future crises. To ensure the implementation of the contingency plan and the key principles therein, the Commission in parallel established the European Food Security Crisis preparedness and response Mechanism (EFSCM), a group composed of Member States and non-EU countries representatives as well as of food supply chain stakeholders chaired by the Commission to strengthen coordination, exchange data and practices. The EFSCM was convened for the first time in March 2022 to discuss the impacts of the energy and input price increases and the consequences of Russia's invasion of Ukraine for food security and supply. The market observatories and the civil dialogue groups are other fora that ensure transparency and the flow of information in the food sector.

The Commission communication "Contingency plan for transport"[13] has the objective to ensure crisis preparedness and business continuity in the transport sector. The plan establishes a "crisis manual" that includes a toolbox consisting of 10 actions aimed at mitigating any negative impact on the transport sector, passengers and the internal market in the event of a crisis. These include among others measures rendering EU transport laws fit for crisis situations, ensuring adequate support for the transport sector, ensuring free movement of goods, services and people, sharing of transport information, testing transport contingency in real-life situations etc.[14]

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8 Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, *OJ L 337, 12.12.1998, p. 8.*

9 Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015.

10 Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021.

11 They can be adopted on the basis of 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.

12 COM(2021)689 final.

13 COM(2022)211 final.

14 Additional measures include: managing refugee flows and repatriating stranded passengers and transport workers, ensuring minimum connectivity and passenger protection, strengthening transport policy coordination through the Network of National Transport Contact Points, strengthening cybersecurity and cooperation with international partners.

Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products[15] (CMO Regulation) as well as the sister CMO Regulation for fisheries[16] provide the legal basis for collecting relevant information from Member States to improve market transparency[17].

Regulation (EU) No 2021/1139 1308/2013 establishing the European Maritime, Fisheries and Aquaculture Fund[18] (EMFAF Regulation) provides the legal basis for supporting the fisheries and aquaculture sector in case of exceptional events causing a significant disruption of markets.

Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate[19] sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Furthermore, based on Commission proposals, the Council adopted specific recommendations on the coordinated approach to the restriction of free movement in response to COVID-19 pandemic[20]. The Commission also announced in the 2020 citizenship report[21] that it intends to review the 2009 guidelines on free movement in order to improve legal certainty for EU citizens exercising their free movement rights, and to ensure a more effective and uniform application of the free movement legislation across the EU. The reviewed guidelines should address among others the application of restrictive measures on free movement, specifically those that are due to public health concerns.

Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices provides a framework to monitor and mitigate potential and actual shortages of centrally and nationally

[15] 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, *OJ L 347, 20.12.2013, p. 671.*

[16] Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000. *OJ L 354, 28.12.2013, p. 1.*

[17] Following Russia's invasion of Ukraine, the obligation for Member States to provide monthly notifications of cereal stocks has been included in an amendment to Commission Implementing Regulation (EU) 2017/1185 of 20 April 2017 laying down rules for the application of Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards notifications to the Commission of information and documents and amending and repealing several Commission Regulations, *OJ L 171, 4.7.2017, p. 113.*

[18] 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, *OJ L 347, 20.12.2013, p. 671.*

[19] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, *OJ L 211, 15.6.2021, p. 1.*

[20] Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, *OJ L 337, 14.10.2020, p. 3 and its subsequent updates.*

[21] COM(2020)730 final.

authorised medicinal products for human use considered as critical to address a given 'public health emergency' or 'major event' [22].

Finally, the Commission Decision of 16 September 2021 established the Health Emergency Preparedness and Response Authority[23] for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.

Interplay with ongoing initiatives

In parallel, a number of initiatives, which have been recently proposed and are currently being discussed, concern aspects relevant for the crisis response and preparedness. These initiatives however have a limited scope covering specific types of crisis scenarios and are not intended to set up a general horizontal crisis-management framework, nor to introduce emergency procedures in the relevant sectoral Union framework regulating the design, conformity assessment, placing on the market and market surveillance of goods. To the extent these initiatives include a sectoral crisis response and preparedness framework, the fact that the sectoral frameworks considered in the context of this initiative, which lay down the harmonised Union level rules for the design, conformity assessment, placing on the market and market surveillance of goods are maximum harmonisation frameworks, the will be no overlap with any of the ongoing initiatives.

None of the relevant ongoing initiatives lay down any sectoral emergency procedures, which are to be incorporated in the relevant sectoral harmonised frameworks regulating the free movement of goods.

The Commission proposal for a Regulation on serious cross-border threats to health, repealing Decision No 1082/2013/EU (the 'Cross-border Health Threats Decision')[24] aims at strengthening the EU's health security framework, and reinforcing the crisis preparedness and response role of key EU agencies with respect to serious cross-border health threats[25]. When adopted, it will strengthen the preparedness and response planning and reinforce epidemiological surveillance and monitoring, improve data reporting, strengthen EU interventions.

The Commission proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control[26].

The Commission proposal for a Council Regulation 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[27] provides for crisis response tools such as joint procurement, mandatory information requests for businesses about their production capacities, and repurposing production lines in case of public health crises once a public health emergency would be declared. The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis-relevant

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22 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*

23 C(2021)6712 final.

24 COM(2020)727 final.

25 The term of "cross-border" is understood as covering both any situation affecting more than one Member State ("across borders") as well as more specifically a situation affecting regions in two or more Member States sharing a common border ("border regions").

26 COM/2020/726 final

27 COM(2021)577 final.

products. The proposal covers medical countermeasures defined as medicinal products for human use, medical devices and other goods or services that are necessary for the purpose of preparedness and response to serious cross-border threats to health.

The Commission proposal for the European Chips Act[28] aims to strengthen Europe's semiconductor ecosystem. One important pillar of this strategy is to set up a mechanism for coordinated monitoring and response to shortages in the supply of semiconductors, aiming to anticipate and swiftly respond to any future supply chain disruptions, through a dedicated emergency toolbox, together with Member States and international partners. The planned mechanism is specific to a possible semiconductor crisis and will apply in an exclusive way if the crisis stage is triggered.

The Commission proposal for a Data Act[29] will allow public sector bodies to access data held by the private sector that is necessary for exceptional circumstances, particularly to implement a legal mandate if data are not otherwise available or in case of a public emergency (i.e. exceptional situation negatively affecting the population of the Union, a Member State or part of it, with a risk of serious and lasting repercussions on living conditions or economic stability, or the substantial degradation of economic assets in the Union or the relevant Member State(s)).

The Commission proposal to amend the Schengen Borders Code[30] aims to provide a common response at the internal borders in situations of threats affecting a majority of Member States. The proposed amendment will also put in place procedural safeguards in case of unilateral reintroductions of internal border controls and provide for the application of mitigating measures and specific safeguards for cross-border regions in cases where internal border controls are reintroduced. Such controls affect in particular people crossing the border for their daily life (work, education, health care, family visits) as evidenced during the COVID-19 pandemic. The proposal promotes increased use of effective alternative measures to address the identified threats to internal security or public policy instead of internal border controls, for instance increased checks by police or other authorities in border regions, subject to certain conditions. The proposal also includes the possibility for the Council to quickly adopt binding rules setting out temporary travel restrictions for third country nationals at the external borders in case of a threat to public health. It also clarifies which measures Member States can take to manage the EU's external borders effectively in a situation where migrants are instrumentalised by third countries for political purposes.

The proposal for a Directive on the resilience of critical entities adopted by the Commission in December 2020[31] has the objective to enhance the resilience of entities providing services that are essential for the maintenance of vital societal functions or important economic activities the EU. With this initiative, the aim is to create a comprehensive framework to support Member States in ensuring that critical entities providing essential services are able to prevent, protect against, respond to, resist, mitigate, absorb, accommodate and recover from significant disruptive incidents such as natural hazards, accidents or terrorism. The Directive will cover eleven key sectors, including energy, transport, banking and health.

The Joint communication of 18 May 2022 on the Defence Investment Gaps Analysis and Way Forward, identified several issues including the ability of the EU's Defence Technological and Industrial Base (as well as the global Defence Technological and Industrial Base) to address upcoming defence Member State procurement needs, and putting forward several measures.

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28 COM(2022)46 final.
29 COM (2022)68 final.
30 COM (2021)891 final.
31 COM(2020)829 final.

In the context of the General Product Safety Directive 2001/95/EC revision, the Commission intends to examine the questions whether and to what extent, or by what modalities, the production issues that are addressed by the Omnibus rules as regards goods covered by various harmonised regimes could be addressed in the distinct context of non-harmonised goods.

Consistency with the EU's external action

The European External Action Service will support the High Representative in her/his function, as Vice-President of the Commission, to coordinate the Union's external action within the Commission. Union delegations under the authority of the High Representative will exercise their functions as external representatives of the Union and assist, as relevant, in external dialogues.

Interplay with other instruments

The Commission can support Member States in designing and implementing reforms to anticipate, prepare and respond to impacts of natural or man-made crises on the Single Market through the Technical Support Instrument (TSI) laid down by Regulation (EU) 2021/240 of the European Parliament and of the Council.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Article 114 TFEU, which is the original legal basis for the adoption of the 5 sectoral frameworks, which this proposal aims to amend. These 5 sectoral frameworks are: Regulation (EU) 2016/424 on cableway installations; Regulation (EU) 2016/425 on personal protective equipment; Regulation (EU) 2016/426 on gas appliances; Regulation (EU) 2019/1009 on fertilising products and Regulation (EU) 305/2011 on construction products.

The EU sectoral frameworks, which are considered in the context of this proposal are the ones, which are among the so-called "harmonised products". What is common among these sectoral frameworks is that they lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of such products. Essentially, these sectoral frameworks introduce for each respective sector/product category the essential safety requirements which the products should meet and the procedures how to assess the compliance with these requirements. These rules lay down full harmonisation and therefore the Member States cannot derogate from these rules, even in a case of emergency, unless the respective framework provides for such a possibility.

Another common feature of these frameworks is that they are more or less closely aligned to the general principles laid down in 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[32], which lays down reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products.

Other EU harmonised frameworks, which follow the same approach, such as the Medical devices Regulation (EU) 2017/745 and the In vitro diagnostic medical devices Regulation (EU) 2017/746 already contain provisions allowing the Member States to derogate from the harmonised procedures in certain cases. Therefore, it is not necessary to amend those frameworks.

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

- **Subsidiarity (for non-exclusive competence)**

The proposal aims to amend the harmonised rules laid down by a number of EU sectoral frameworks. These frameworks do not provide for the possibility for the Member States to adopt crisis-response measures in derogation of the harmonised rules. Considering that the Regulations, which this proposal aims to amend are maximum harmonisation frameworks, such amendments may only be done at EU level.

- **Proportionality**

The economic activities across the Single Market are deeply integrated. Interaction between companies, service providers, clients, consumers and workers located in different Member States that rely on their free movement rights, is increasingly common. The experience of the past crisis has shown that often the distribution of production capacities across the EU is uneven (e.g. with the production lines of certain products primarily located in a few Member States). In parallel, in the case of a crisis, the demand for crisis-relevant goods or services across the EU territory may also be uneven. The objective of ensuring the smooth and undisrupted functioning of the Single Market cannot be achieved by means of unilateral national measures. Moreover, even if measures adopted by the Member States individually may be able to address to a certain extent the deficiencies resulting from a crisis at the national level, they are in fact more likely to further exacerbate the said crisis across the EU by adding further obstacles to the free movement and/or additional strain on products already impacted by shortages.

- **Choice of the instrument**

The proposal aims to amend 5 Regulations of the European Parliament and of the Council and. In order to respect the principle of parallelism, the Proposal shall take the form of a Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action (‘The Strawberry Regulation’) will be repealed. According to its evaluation finalised in October 2019 and supported by an external study, this mechanism is rarely used and its information exchange system is insufficient as it is too slow and outdated[33].

- **Stakeholder consultations**

As outlined in Annex 2 to the Impact Assessment accompanying this proposal, **stakeholder consultation** activities were conducted between October 2021 and May 2022. The consultation activities included: a **call for evidence** published on the “Have your say” portal and open from 13 April to 11 May 2022, a **public consultation** conducted via a questionnaire published on the same portal in the same period, a **stakeholder workshop** on 6 May 2022, a

[33] As assessed in the evaluation supporting study and the evaluation Commission Staff Working Document SWD(2019)371 final of 8 October 2019.

Member State survey in May 2022 and **targeted consultations** conducted by means of meetings with Member States and specific stakeholders.

Stakeholders largely agree with the need to ensure free movement as well as greater transparency and coordination in times of crisis. Most experiences described by stakeholders came from the COVID-19 crisis. When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance. A number of Member States have voiced concern about including broad crisis preparedness measures when no crisis is looming on the horizon, without specifying targeted supply chains. While some business stakeholders voiced concerns about mandatory measures targeting economic operators, others have expressed support for a greater coordination and transparency, measures to ensure free movement of workers, fast-track notifications of national measures, fast track procedures for development and publishing of European standards, EU and national single points of information, emergency drills for experts.

- **Collection and use of expertise**

Evidence and data that were used for the development of the Impact Assessment included:

– "The impact of COVID-19 on the Internal Market", study at the request of the EP IMCO Committee;

– Evaluation of the "Strawberry Regulation" (EC) No 2679/98 and its supporting external study;

– Evaluation of the New Legislative Framework;

– Relevant information and/or evidence collected in the context of preparation of existing or proposed EU crisis response initiatives and mechanisms, including through consultation activities or impact assessment studies (e.g. the Data Act, Single Market Information Tool (SMIT), the EU Health Security Framework, Schengen Borders Code, Contingency plan for ensuring food supply and food security, the integrated political crisis response mechanism (IPCR), Contingency plan for transport, EU Digital COVID Certificate Regulation, Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic and its adaptations);

– Academic studies and literature on the effect of previous crises on the functioning of the Single Market, as well as existing position papers and other documents drawn up by relevant stakeholders;

– Newspaper articles and press materials.

The Impact Assessment further relied on the information received from consultation activities as detailed in the synopsis report contained in Annex 2 of the Impact Assessment.

The evidence base of the report is strongly limited due to the relatively low number of responses to the call for evidence and the public consultation, and the lack of a supporting study. To remedy this situation, on 6 May 2022 the Commission conducted a stakeholder workshop attended by a large number of stakeholders and conducted a series of targeted consultations, especially with Member States and stakeholders.

- **Impact assessment**

In line with its 'Better Regulation' policy, the Commission conducted an Impact Assessment[34]. The Impact Assessment evaluated three policy options establishing a governance body and a framework for contingency planning, vigilance and emergency modes. Both Single Market vigilance mode and Single Market emergency mode would be activated according to specific criteria and triggering mechanisms. Certain measures in the toolbox would need additional activation.

On the basis of analysis of problem drivers and gaps in the relevant sector-specific legislation, eight building blocks of measures were defined by grouping measures into blocks applying at different times (at all times, in vigilance mode and in emergency mode). For each building block, three policy approaches were analysed ranging from non-legislative measures (approach 1) to a hybrid approach (approach 2) to a more comprehensive legislative framework (approach 3). On the basis of this analysis, some or all approaches were retained for each building block and were combined into three realistic policy options reflecting different levels of political ambition and stakeholder support:

Mode	**Building blocks**	**Policy Option 1** **TRANSPARENCY**	**Policy Option 2** **COOPERATION**	**Policy Option 3** **SOLIDARITY**
All times	1. governance, coordination and cooperation	*Approach 2* Formal Advisory Group as the technical-level forum and obligation of the MS to share information within the group in anticipation and during the crisis		
All times	2. crisis contingency planning	*Approach 2* Recommendation to the MS for risk assessment, training and drills & compendium of crisis response measures	*Approach 3* - Recommendation to MS for risk assessment & compendium of crisis response measures and - Obligation of the Commission for Union level risk assessment - Obligation of MS to train their relevant crisis management staff regularly	
Vigilance	3. Single Market vigilance	*Approach 2* - Recommendation to the Member States on information gathering concerning identified strategic supply chains - Recommendations to the Member States for building up strategic reserves of goods of strategic importance		*Approach 3* - Obligation to MS to gather information concerning identified strategic supply chains - Obligation of the Commission to draw up and regularly update list with targets for strategic reserves - Obligations tof MS[35] to build up strategic reserves for

[34] See the accompanying Staff Working Document SWD(2022)289.

[35] Subject to additional trigger

				selected goods of strategic importance if the MS strategic reserves fall significantly short of the targets
Emergency	4. key principles and supportive measures for facilitating free movement during emergency	*Approach 2* Reinforcing key principles of free movement of crisis-relevant goods and services in binding rules where appropriate for effective crisis management		
Emergency	5. transparency and administrative assistance during emergency	*Approach 3* Binding full-fledged fast-track notification mechanism, flash peer review and possibility to declare the notified measures incompatible with EU law; contact points and electronic platform		
Emergency	6. speeding up the placing of crisis-relevant products on the market during emergency	*Approach 2* Targeted amendments of existing Single Market harmonisation legislation: faster placing of crisis-relevant products on the market; Commission can adopt technical specifications; MS prioritise market surveillance for crisis-relevant products		
Emergency	7. public procurement during emergency	*Approach 2* New provision on joint procurement/common purchasing by the Commission for some or all Member States		
Emergency	8. measures impacting crisis-relevant supply chains during emergency mode	*Approach 1* Guidance on ramping up production capacity; speeding up permitting procedures; accepting and prioritising orders of crisis relevant goods Recommendations to businesses to share crisis-relevant information	*Approach 2* Recommendations to MS for the distribution of stockpiled products; speeding up permitting procedures; encouraging economic operators to accept and prioritise orders Empowering MS[36] to oblige economic operators to ramp up production capacity and to address binding information requests to economic operators	*Approach 3* Obligations of MS[37] to distribute products previously stockpiled; speeding up permitting procedures, Obligations of businesses to accept and prioritise orders; ramp up production capacity and provide crisis-relevant information

The Impact Assessment did not present a preferred option, instead leaving the choice of options for political decision. The measures chosen in the legal proposal correspond to Policy Option 3 for all building blocks with the exception of building block 8. For building block 8, a

36 Subject to additional trigger

37 Subject to additional trigger

combination of Policy Option 1 (for ramping up production), Policy Option 2 (for distribution of stockpiled products and for speeding up permitting procedures), and Policy Option 3 (for obligations of businesses to accept and prioritise orders and to provide crisis-relevant information) has been chosen.

On 15 June 2022, the Commission submitted the Impact Assessment to the Regulatory Scrutiny Board (RSB). The RSB gave a negative opinion, noting in particular (1) the need to provide clear and detailed information related to the foreseen Single Market emergency including a definition, the criteria and decision-mechanisms for establishing and terminating it and the measures which would be implemented during it; (2) the need to provide a thorough assessment of the impacts of the policy options; and (3) the need to present alternative combinations of relevant policy options, in addition to the policy approaches, and to link the comparison to the analysis of impacts. To address these findings, the Commission provided a clear definition of a Single Market emergency, specified the criteria and decision making mechanisms, explained the three modes of functioning of SMEI and specified which building block of SMEI would be activated under which mode. It further elaborated the assessment of impacts to cover more types of impacts i.e. economic impacts for key stakeholders (businesses, Member States and Commission), impacts on SMEs, impacts on competitiveness, competition, international trade, and differentiated which impact would occur with the immediate effects and which could be expected under the vigilance and emergency modes. Further, the Impact Assessment defined three alternative policy options based on a combination of different approaches to some of the building blocks, provided an assessment of impacts of these options and extended the comparison of options to cover proportionality and subsidiarity.

On 29 July 2022, the Commission submitted the revised Impact Assessment to the RSB. The RSB then gave a positive opinion with comments. These comments related to the need to further explore the different types of crisis that may impact the functioning of the Single Market, to more clearly set out the interplay with possible measures taken on the basis of Article 4(2) TFEU and to sufficiently justify some of the measures proposed from the subsidiarity and proportionality point of view. To address these comments, indications on effects of potential future crises were added, interplay with potential measures under Article 4(2) TFEU was better explained and further details were added on the obligatory measures foreseen under emergency mode.

Further information on how the RSB recommendations are reflected in the Impact Assessment report can be found in Annex 1, point 3, of the Impact Assessment.

- **Regulatory fitness and simplification**

According to the Commission's Regulatory Fitness and Performance Programme (REFIT), all initiatives with the objective to change existing EU legislation should aim to simplify and deliver stated policy objectives more efficiently (i.e. reducing unnecessary regulatory costs).

The overall SMEI package provides a toolbox of measures to address Single Market emergency, consisting a set of measures applicable at all times as well as certain measures only applicable in vigilance or emergency modes, to be separately activated. The current proposal provides for emergency procedures for the conformity assessment, placing on the market, adoption of common specifications and market surveillance. There are **no administrative costs for businesses and citizens** that would apply with immediate effect and during the normal functioning of the Single Market.

For measures part of the overall SMEI package and likely to lead to strong impacts and potential costs for SMEs, in particular measures such as mandatory information requests,

requests to ramp up production and to accept priority-rated orders, during the additional activation of such measures specific analysis and assessment will be done as to their impact and proportionality, in particular their impact on SMEs, by the Commission. This assessment will be part of the process of additional activation of these specific measures by a Commission implementing act (additional to the overall triggering of the emergency mode). Depending on the nature of the crisis and the concerned strategic supply chains and crisis-relevant products, specific accommodations will be provided for SMEs. While it is not possible to except microenterprises completely from the scope of measures such as mandatory information requests, as these enterprises may have specific unique know-how or patents of critical importance in a crisis, specific accommodations will include simplified survey designs, less onerous reporting requirements, and longer deadlines for responses, to the extent possible in view of the need for urgency in the context of a specific crisis.

In the context of the overall SMEI package, the Regulation (EC) No. 2679/98 setting up an response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation') will be repealed. This will lead to the simplification of the legal framework.

- **Fundamental rights**

The proposal does not have an impact on the exercise of their fundamental rights of citizens or businesses.

4. BUDGETARY IMPLICATIONS

The measures in this act concern targeted amendments of existing product legislation. The implementation and application thereof is the responsibility of the Member States. There will thus not be implications on the Union budget.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

There is no specific monitoring mechanism included to this proposal. The specific monitoring requirements are already contained in the EU sectoral frameworks, which are being amended by this proposal and the amendments do not have an impact on these existing monitoring, evaluation and reporting arrangements.

- **European Economic Area**

The proposed act is of relevance to the EEA and should therefore extend thereto.

- **Detailed explanation of the specific provisions of the proposal**

The amendments, which this Proposal aims to introduce cover the following aspects:

(1) Prioritisation by the notified bodies of the conformity assessment of products designated as crisis-relevant;

(2) Possibility for the national competent authorities to issue temporary authorisations for crisis relevant products, which have not undergone the standard conformity assessment procedures, provided that the products comply with all the applicable essential requirements and provided that the authorisation is limited to the duration of the Single Market emergency and to the territory of the issuing Member State;

(3) Possibility for the manufacturers to rely on relevant international and national standards during an emergency if no harmonised standards are available and if the alternative standards ensure an equivalent level of safety;

(4) Possibility for the Commission to adopt via delegated acts voluntary or mandatory common technical specifications for crisis-relevant products;

(5) Prioritisation of the market surveillance activities for crisis-relevant goods

2022/0279 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[38],

Acting in accordance with the ordinary legislative procedure[39],

Whereas:

(1) [*insert reference to SMEI Regulation*] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.

(2) The framework established by [*insert reference to SMEI Regulation*] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.

(3) [*insert reference to SMEI Regulation*] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.

(4) [*insert reference to SMEI Regulation*] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [*insert reference to SMEI Regulation*] applies to both goods and services.

(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that referred to in [*insert reference to SMEI*

[38] OJ C , , p. .

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

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[40], (EU) 2016/425[41], (EU) 2016/426[42], (EU) 2019/1009[43] and (EU) No 305/2011[44] of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2019/1009 are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council [45].

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

(8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [*insert reference to SMEI Regulation*].

(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant.

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

(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation.

(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations,

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40 OJ L 81, 31.3.2016, p. 1.
41 OJ L 81, 31.3.2016, p. 51.
42 OJ L 81, 31.3.2016, p. 99.
43 OJ L 170, 25.6.2019, p. 1.
44 OJ L 88, 4.4.2011, p. 5.
45 OJ L 218, 13.8.2008, p. 82.

in those cases where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they comply 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.

(13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.

(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.

(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and, (EU) 2019/1009, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012[46] ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.

(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.

(17) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, in exceptional and duly justified circumstances, notably in order to ensure the interoperability among products or systems, the Commission should be able to adopt by means of implementing acts common specifications laying down mandatory technical specifications, with which the manufacturers will be required to comply. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.

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

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

(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.

(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 should therefore be amended accordingly,

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

HAVE ADOPTED THIS REGULATION:

Article 1
Amendments to Regulation (EU) 2016/424

In Regulation (EU) 2016/424, the following Chapter VIa is inserted:

'CHAPTER VIa
EMERGENCY PROCEDURES

Article 43a
Application of emergency procedures

1. Articles 43b to 43g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.

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

3. Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to subsystems and safety components placed on the market in accordance with Articles 43c to 43f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 43b
Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components

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

2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods.

This requirement applies with respect to all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.

4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified.

Article 43c

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

1. By way of derogation from Article 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within the territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, including:

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

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

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

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

(e) measures to be taken with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that the subsystem or safety

component concerned is brought back in compliance with all the requirements of this Regulation.

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

5. By way of derogation from Articles 7 and 20, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such subsystems or safety components.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of subsystems or safety components in accordance with paragraph 1.

8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned.

Article 43d

Presumption of conformity based on national and international standards

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

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

Where

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

Article 43e

Adoption of common specifications conferring a presumption of conformity

1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing

common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 17, subsystems and safety components which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those common specifications or parts thereof.

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

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

Article 43f

Adoption of mandatory common specifications

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

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral

experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

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

Article 43g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods.

Article 2

Amendments to Regulation (EU) 2016/425

In Regulation (EU) 2016/425, the following Chapter VIa is inserted:

‘CHAPTER VIa
EMERGENCY PROCEDURES

Article 41a

Application of emergency procedures

1. Articles 41b to 41g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.

2. rticles 41b to 41g shall apply exclusively to PPE, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1.

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

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to PPE placed on the

market in accordance with Articles 41c to 41f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

Article 41b

Prioritisation of the conformity assessment of crisis-relevant PPE

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

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

3. All pending applications for conformity assessment of such PPE shall be processed as a matter of priority, ahead of any other applications for conformity assessment of PPE, which has not been designated as crisis-relevant goods. This requirement applie with respect to all applications for conformity assessment of PPE designated as crisis-relevant good, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.

4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for PPE designated as crisis-relevant goods in respect to which they have been notified.

Article 41c

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

1. By way of derogation from Article 19, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific PPE which has been designated as 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.

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 national competent authority.

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, including:

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

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

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

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;

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

4. By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode.

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

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such PPE.

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

8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned.

Article 41d

Presumption of conformity based on national and international standards

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

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

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

Article 41e

Adoption of common specifications conferring a presumption of conformity

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

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

(b) where severe disruptions in the functioning of the Single Market, which led to the activation Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall remain applicable to PPE placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 14, PPE which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof.

4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

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

Article 41f

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and

safety requirements set out in Annex II for PPE, which has been designated as crisis-relevant goods.

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article, shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to PPE placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 41g

Prioritisation of market surveillance activities and mutual assistance among authorities

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

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for PPE designated as crisis-relevant goods.'

Article 3

Amendments to Regulation (EU) 2016/426

In Regulation (EU) 2016/426, the following Chapter VIa is inserted after Chapter VI:

'CHAPTER VIa
EMERGENCY PROCEDURES

Article 40a

Applicationof emergency procedures

1. Articles 40b to 40g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.

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

3. Articles 40b to 40g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode remains active.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to appliances and fittings 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 42(3).

Article 40b

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

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

2. The notified bodies shall process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority.

3. All pending applications for conformity assessment of appliances and fittings designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for appliances and fittings, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.

4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect to which they have been notified.

Article 40c

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

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

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market, including:

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

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

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

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

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

4. By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 6 and 17, appliances or fittings, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1 shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such appliances or fittings.

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of appliances or fittings in accordance with paragraph 1.

8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned.

Article 40d

Presumption of conformity based on national and international standards

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

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

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

Article 40e

Adoption of common specifications conferring a presumption of conformity

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

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3). They shall apply to appliances and fittings placed on the market no longer than until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 13, appliances or fittings which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof.

4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if

appropriate, amend or withdraw the implementing act establishing the common specification in question.

Article 40f

Adoption of mandatory common specifications

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

2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article, shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3) and they shall apply to appliances or fittings placed on the market at the latest until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 40g

Prioritisation of market surveillance activities and mutual assistance among authorities

1. The Member States shall prioritise the market surveillance activities for appliances and fittings designated as crisis-relevant goods.

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods.

Article 4

Amendments to Regulation (EU) 2019/1009

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

CHAPTER Va
EMERGENCY PROCEDURES

Article 41a

Applicationof emergency procedures

1. Articles 41b to 41g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.

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

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

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to fertilising products placed on the market in accordance with Articles 41c to 41f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 45(3).

Article 41b

Prioritisation of the conformity assessment of crisis-relevant fertilising products

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

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

3. All pending applications for conformity assessment of fertilising products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of fertilising products, which have not been designated as crisis-relevant goods. This requirement is applicable with respect to all applications for conformity assessment of fertilising products designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.

4. The prioritisation of applications for conformity assessment of fertilising products pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

5. The notified bodies shall deploy their best efforts to increase their testing capacities for fertilising products designated as crisis-relevant goods in respect of which they have been notified.

Article 41c

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

1. By way of derogation from Article 15, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific fertilising product which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 15 have not been carried out by a notified body but for which the compliance with the requirements set out in Annexes I and II has been demonstrated.

2. The manufacturer of a fertilising product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the fertilising product concerned complies with the requirements set out in Annexes I and II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the fertilising products may be placed on the market, including:

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

(b) specific requirements regarding the traceability of the fertilising product concerned;

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

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

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

4. By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3of this Articcle also after the deactivation or expiry of the Single Market Emergency mode.

5. By way of derogation from Articles 3 and 18, fertilising products, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such fertilising products.

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

8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 15 on the territory of the Member State concerned.

Article 41d

Presumption of conformity based on national and international standards

Where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article

15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012, the Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force in the Member State of manufacture, ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III.

Article 41e

Adoption of common specifications conferring a presumption of conformity

1. Where EU fertilising products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) where severe disruptions in the functioning of the Single Market, which led to the activation of [were taken into consideration when] the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3). They shall apply to EUfertilising products placed on the market until the last day of the period for which the Single Market emergency mode remains active in accordance with [the SMEI Regulation]. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Article 13, EU fertilising products which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the requirements set out in Annex I, II or III [or tests referred to in Article 13(2)] covered by those common specifications or parts thereof.

4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed explanationand the Commission

shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question.

Article 41f

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications for EU fertilising products to cover the requirements set out in Annexes I and II which have been designated as crisis-relevant goods.

2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3) and they shall apply to EU fertilising products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the EU fertilising products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 41g

Prioritisation of market surveillance activities and mutual assistance among authorities

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

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for fertilising products designated as crisis-relevant goods.'

Article 5

Amendments to Regulation (EU) No 305/2011

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

the following Chapter VIIIa is inserted:

''**CHAPTER VIIIa**
EMERGENCY PROCEDURES

Article 59a

Application of emergency procedures

1. Articles 59b to 59f shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.

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

3. Articles 59b to 59f, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.

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

4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to construction products placed on the market in accordance with Articles 59b to 59f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)

Article 59b

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

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

2. The notified bodies shall process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority.

3. All pending applications for the performance of third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications regarding construction products, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 59a.

4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturerswho have lodged those applications.

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

Article 59c

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

1. By way of derogation from Article 28(1), the competent national authority may exceptionally authorise, on a duly justified request, the placing on the market within

the territory of the Member State concerned, of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in that Article have not been carried out by a notified body.

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

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

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the construction products may be placed on the market, including:

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

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

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

(d) any specific requirements regarding the continuous performance of third party tasks related to the assessment and verification of constancy of performance with respect to the concerned construction product;

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

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

5. Construction products, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.

6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such construction products.

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

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

Article 59d

Adoption of common specifications enabling performance assessment

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

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

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

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the common specifications adopted pursuant to paragraph 1 of this Article, may be used for assessing and declaring the performance of construction products covered by those common specifications in relation to their essential characteristics.

4. By way of derogation from Article 59a(3), first subparagraph, declaration of performance in compliance with the common specifications referred to in paragraph 1 of this Article regarding construction products which have been placed on the market shall not be affected by the subsequent expiry or repeal of the implementing act, which has laid down those common specifications, unless there is sufficient reason to believe that construction products covered by those common specifications present a risk or do not achieve the declared performance.

5. When a Member State considers that a 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 with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing at establishing the common specification in question

Article 59e

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the methods and the criteria

for assessing the performance of construction products which have been designated as crisis-relevant goods.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.

3. By way of derogation from Article 59a(3), first subparagraph, unless there is sufficient reason to believe that the construction products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the construction products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with *[the SMEI Regulation]*.

Article 59f

Prioritisation of market surveillance activities and mutual assistance among authorities

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

2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated as crisis-relevant goods.'

(2) 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 6

Entry into force

Entry into force

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

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

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

Done at Brussels,

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