Council of the European Union

Brussels, 19 September 2022
(OR. en)

12576/22

Interinstitutional File:
2022/0279(COD)

MI 673
COMPET 719
IND 350
IA 139
CODEC 1321

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	19 September 2022
To:	General Secretariat of the Council
No. Cion doc.:	COM(2022) 461 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency

Delegations will find attached document COM(2022) 461 final.

Encl.: COM(2022) 461 final

EUROPEAN
COMMISSION

Brussels, 19.9.2022
COM(2022) 461 final

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)

{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].

---

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]

---

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

---

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.

---

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,

---

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.

---

[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*