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Subject:	Proposal for a Regulation of the European Parliament and of the Council establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98 - Mandate for negotiations with the European Parliament

I. INTRODUCTION

1. On 19 September 2022, the Commission adopted a proposal for a Regulation of the European Parliament and the Council establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98¹. The Commission Proposal is based on Articles 114, 21 and 45 of the Treaty on the Functioning of the European Union (TFEU).

¹ Proposal for a Regulation of the European Parliament and of the Council establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98, doc. ST 12573/22 + ADD 1-5.

2. The Single Market emergency instrument (SMEI) proposal is aimed at anticipating, preparing for and responding to the impacts of crisis. It builds on the Union's lessons learnt by ensuring a continuous monitoring on possible upcoming crisis, by entering into a vigilance or emergency modes whenever a threat becomes clear and by putting in place a governance allowing the Member States to coordinate making decision. The Commission proposal also suggests asking businesses to change their stocks, orders or production.
3. On 16 December 2022, the European Parliament's Committee on Internal Market and Consumer Protection (IMCO) appointed Mr Andreas Schwab (EPP, DE) as rapporteur for the proposal.
4. The European Economic and Social Committee gave an opinion on the proposal on 14 December 2022.

II. WORK WITHIN THE COUNCIL

5. The proposal was discussed at the Competitiveness Council on 29 September 2022. Discussions in the Working Party on Competitiveness and Growth (Internal Market) started in September 2022 under the Czech Presidency and continued under the Swedish Presidency. 16 Working Party meetings have taken place.
6. The impact assessment accompanying this proposal was examined in detail during one Working Party meeting on 12 October 2022. A number of delegations had questions on the methodology used in the impact assessment and the policy options analysed. Certain delegations regretted that the impact assessment does not reflect how the proposal for SMEI Regulation would work in practice. Based on these remarks, the Commission conducted an additional study providing a retrospective analysis, looking back at a number of past crises/incidents and assessing their impacts on the functioning of the Single Market (specifically on the impacts on the freedom of movement of people, goods and services). The interim report of the study was presented to the Working Party on 17 May 2023.

7. The Swedish Presidency prepared three compromise texts, based on Member States interventions in the meeting and their written comments.
8. While delegations generally welcomed the proposal and supported its objectives, a number of delegations questioned some of the provisions of the proposal, including their legality.
9. The Council Legal Service issued its opinion on the legal basis and proportionality of the proposal for SMEI Regulation on 4 April 2023².

III. MAIN CHANGES TO THE COMMISSION PROPOSAL

10. Based on the discussions at Working Party level, the Presidency has prepared the fourth compromise text which addresses the main concerns of most of the Member States.
11. While retaining the aim, basic structure and most of the content of the proposed legal act, the Presidency amended several provisions of the Commission proposal in its compromise texts to take account of delegations' requests, with a view to improving clarity, feasibility and legal certainty. The Commission proposal was modified in line with the reflections of the Council Legal Service's opinion on the legal basis and proportionality.
12. The main changes to the Commission proposal are the following:
 - a) *Scope, objective and definitions*
13. The objective of the proposal (Article 1) was clarified and tied more closely to ensuring the proper functioning of the Single Market, by preventing the creation of obstacles to the proper functioning of the Single Market and by preventing the application of divergent measures by Member States.

² ST 7515/23 + COR 1 (EN version)

14. The scope (Article 2) of the proposed act was streamlined and the relationships with other crisis-relevant instruments were clarified.
15. All definitions (Article 3) were further framed to ensure that the purpose of the measures in the proposal is to improve the conditions for the functioning of the Single Market in line with Article 114 TFEU. For better legal clarity, the definitions of “significant incidents” and “relevant economic operators” were added.

b) The Single Market Emergency Board

16. The name of the “advisory group” was changed to the “Single Market Emergency Board” in order to reflect its strengthened role in the contingency planning, emergency and vigilance modes. Additionally, its tasks were more clearly spelled out in the compromise text (Article 4a).

c) Strategic reserves and priority rated orders

17. The provisions on strategic reserves (Article 12) and on priority rated orders (Article 27) were deleted in the compromise text as delegations considered these provisions to be too intrusive and disproportionate.
18. The rules on the distribution of crisis-relevant goods and services (Article 32) were adapted considering the deletion of the provision on strategic reserves.

d) Information sharing

19. New Article 4b was inserted to the text to encourage Member States and the Commission to share information in order to better anticipate and be prepared for any future crisis.
20. Article 25 was moved as new Article 40a, so that it now applies to *all* information received pursuant to the SMEI Regulation and it specifies Member States' and Commission's obligation to treat the information received confidentially.

e) Activation of the Single Market Vigilance and Single Market Emergency modes

21. Member States' role in the Single Market vigilance (Articles 9-10) mode was strengthened, so that it needs to be activated, prolonged and deactivated by a Council implementing act. In the Single Market emergency mode, the activation and the list of crisis-relevant goods and services are, where applicable, to be adopted by one Council implementing act (Articles 13-15). Furthermore, the Commission, when preparing the proposal for the Council implementing act, should consider the opinion of the Single Market Emergency Board.
22. The criteria for the activation of both Single Market vigilance and emergency modes were clarified and further framed in respective Articles.

f) Free movement during the Single Market Emergency

23. The compromise text aligned the wording of Article 16 so that it corresponds to the obligations set out in the Treaties. Member States' actions during the Single Market emergency mode must fully comply with the Treaties, notably with the principles of non-discrimination, justification and proportionality.
24. Article 17 was amended stipulating clearly which national measures restricting the free movement of goods, services or persons must not be taken during the Single Market emergency mode, as these are manifestly disproportionate. The rest of this Article was deleted, leaving any other national restrictive measure to be assessed against the requirements of the Treaties, including proportionality.

g) Notifications

25. Articles 19 and 20 obliging Member States to notify their draft and adopted measures restricting the free movement of goods, services and persons and introducing Commission decision coercive powers in Article 19(11) and (12) were deleted from the fourth compromise text in order not to interfere with the existing Commission powers under the notification systems pursuant to other Union legal acts (Directive (EU) 2015/1535 and Directive 2006/123/EU).

h) Information requests to economic operators

26. The provisions on information requests to the economic operators (Article 24) were further framed, taking into account the requirements of Article 114 TFEU. The scope of the information that can be requested was clearly limited to the crisis-relevant goods and services as listed in the Council implementing act activating the Single Market Emergency mode. Commission can only issue such information requests if it has not obtained that information from other sources and if it clearly shows the necessity for such information request. Furthermore, additional safeguards were introduced in the text, notably the "comply or explain" possibility for the economic operators, better involvement of the Member States in the procedure, higher confidentiality requirements and national security safeguards, as well as lower fines for SMEs.

27. Paragraph 7 of Article 24 was deleted as it was considered not in line with Article 263 of the TFEU.

i) Targeted amendments to harmonised product legislation

28. Article 26 of the proposal refers to the emergency procedures which will be introduced in the Union legal frameworks. Since the negotiations on these amendments to the Union legal frameworks are still ongoing in the Council preparatory bodies, the reference to these acts is put in square brackets and will be amended at a later stage, if needed.

j) Public procurement

29. The provisions regulating the procedure for public procurement of crisis-relevant goods and services by the Commission on behalf of Member States were further elaborated, clarifying the procedure in general and aligning the provisions to the rules of the Financial Regulation (Regulation (EU, Euratom) 2018/1046). These provisions (now in square brackets) will be replaced by those contained in the draft Recast of the Financial Regulation when the latter enters into force. However, these provisions will be deleted from the proposal for SMEI Regulation if the Recast of the Financial Regulation enters into force before SMEI.

30. The ban of individual procurement action by participating Member States (Article 39) was deleted from the compromise text. Instead, a clarification on the possibility to introduce an exclusivity clause in the agreement was introduced in Recital 29.

k) Final provisions

31. In order to have a meaningful reporting on the functioning of the SMEI Regulation, the Commission will be invited to prepare a report on the proposed Regulation in five years after its entry into force and also in 18 months after every deactivation of the Single Market vigilance or emergency mode.

32. The Council Regulation (EC) No 2679/98 is not repealed. The Presidency inserted an additional recital clarifying that the SMEI Regulation will prevail in the case of possible conflicts and overlaps between that Regulation and the proposed SMEI Regulation.
33. Following the request by Member States, the date of application of the draft SMEI Regulation was postponed to 18 months after its entry into force, to allow Member States to set up national systems to comply with the Regulation.
34. In addition to the changes of political nature reflected here above, other amendments of technical nature were made to the compromise text. Furthermore, one of the three legal bases (Article 45 TFEU) was corrected and replaced by Article 46 TFEU.

IV. CONCLUSION

35. The Presidency considers that the text, as set out in the Annex, reflects a fair and balanced compromise between the different views expressed by delegations.
36. Consequently, the Permanent Representatives Committee is therefore invited to endorse the attached compromise text and instruct the Presidency to start negotiations with the European Parliament as soon as possible, in order to reach an agreement at first reading on this basis.
37. As indicated in the Presidency note of 6 September 2019 on openness and transparency, the Presidency suggests that, if no objections are raised, the mandate approved by the Committee is made public, in accordance with the Council's Rules of Procedure.

2022/0278 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, 21, and ~~45~~**46 and 114** thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee³,

Having regard to the opinion of the Committee of the Regions⁴,

Acting in accordance with the ordinary legislative procedure,

³ OJ C , , p. .

⁴ OJ C , , p. .

Whereas:

- (1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the **free movement of goods, persons and services in the** internal market **within the meaning of Article 26(2) of TFEU** (also referred to as the “Single Market”) and its supply chains can be severely affected by such crises, and **This may have consequences on cross-border trade between Member States, thus creating obstacles to the proper functioning of the Single Market. Furthermore, during those crises** appropriate crisis management tools and coordination mechanisms ~~are~~**were** either lacking, ~~did~~**do** not cover all aspects of the Single ~~M~~**arket** or ~~did~~**do** not allow for a timely response to such **barriers and** impacts.
- (2) **In the early phase of the COVID 19 crisis Member States introduced barriers to free movement on the Single Market as well as diverging measures on the supply of goods and services that were of critical importance or were indispensable for responding to the crisis, which could not always be justified. Ad-hoc measures taken by the Commission in order to re-establish the functioning of the Single Market based on the existing rules were not sufficient.** The Union was not sufficiently prepared to ensure efficient **access,** manufacturing, procurement and distribution of crisis-relevant non-medical goods such as personal protective equipment, especially in the early phase of the COVID-19 pandemic, and the ad-hoc measures taken by the Commission in order to re-establish the functioning of the Single Market ~~and~~**were deficient. Measures** to ensure the availability of crisis-relevant non-medical goods during the COVID-19 ~~crisis~~**crisis** pandemic were necessarily reactive. The pandemic also revealed insufficient **information sharing and** overview of manufacturing capacities across the Union as well as vulnerabilities related to the **intra-EU and** global supply chains.

- (3) **The Council could through the integrated political crisis response (IPCR) quickly exchange information and coordinate certain actions with regard to the COVID 19 crisis, while Member States acted independently in other situations. However, actions** Actions by the Commission were delayed by several weeks due to the lack of any Union wide contingency planning measures and ~~of clarity~~ **of clarity** as to which part of the national administration to contact to find rapid solutions to the impact on the Single Market being caused ~~d~~ by the crisis. In addition it ~~became clear~~ **appeared** that uncoordinated restrictive actions **and measures** taken by the Member States **actually did leave an impact or did aggravate** ~~would further aggravate the impacts of the crisis on the Single M~~ market. It emerged that there is a need for arrangements between the Member States and Union authorities as regards contingency planning, technical level coordination and cooperation and information exchange.
- (4) Representative organisations of economic operators have suggested that economic operators did not have sufficient information on the **restrictions to free movement introduced and crisis response measures of the Member States during the pandemics, pandemic. This was partly due to a lack of transparency from Member State authorities, partly due to economic operators** not knowing where to obtain such information, ~~partly due to. Other reasons were~~ language constraints and the administrative burden implied in making repeated inquiries in all the Member States, especially in a constantly changing regulatory environment. This prevented them from making informed business decisions as to what extent they ~~may rely on~~ **could exercise** their free movement rights or continue cross-border business operations during the crisis. It is necessary to improve the availability of information on national and Union level **restrictions to free movement and** crisis response measures.

- (5) These recent events have also highlighted the need for the Union to be better prepared **and coordinated** for possible future crises, especially as we consider the continuing effects of climate change and resulting natural disasters as well as global economic and geopolitical instabilities. **Other crises, which could require a quicker response to prevent barriers to the free movement in the Single Market and avoid severe disruptions of supply chains that are indispensable in the maintenance of activities in the Single Market, include for example forest fires, earthquakes or large-scale cyber attacks.** Given the fact that it is not known which kind of crises could come up next and produce severe impacts on the Single Market and its supply chains in the future, it is necessary to provide for an instrument that would apply with regards to impacts on the Single Market of a wide range of crises.
- (6) ~~The impact of a crisis on the Single Market can be two-fold. On the one hand, **A crisis and the impacts thereof can** a crisis can lead to obstacles to free movement within the Single Market, thus disrupting its normal **proper** functioning. On the other hand **Furthermore**, a crisis **which has caused the aforementioned obstacles** can **also** amplify shortages of crisis-relevant goods and services on the Single Market **and hinder production**. ~~The, thus also **disrupting its proper functioning and the emergence or likely emergence of diverging national measures to address those issues regarding the supply chains in the Single Market. This** Regulation should address both **addresses these** types of impacts on the Single Market **and introduces measures to avoid obstacles that create shortages of crisis-relevant goods and services that can impact the supply chains. Such impact on the supply chains could hinder production and ultimately lead to additional barriers to trade and to the distortion of competition between Member States and between private operators.**~~~~

- (6a) In order to avoid unnecessary administrative burden on Member States, incidents reported under the ad hoc alert mechanism should be defined in such a manner that they exclude events of a negligible foreseeable consequence on the free movement of goods, services and persons, including workers, or on the supply chains of goods and services that are indispensable for the maintenance of vital societal or economic activities in the Single Market.**
- (6b) Where the provisions of Council Regulation (EC) No 2679/98 conflict or overlap with the relevant provisions of this Regulation entered into application later, the relevant provisions of this Regulation should prevail. For example, when an obstacle or a threat thereof within the meaning of Council Regulation (EC) No 2679/98 becomes a significant incident within the meaning of this Regulation, the relevant provisions of this Regulation should apply to that situation.**
- (7) Since any specific aspects of future crises that would impact the Single Market and its supply chains are hard to predict, this Regulation should provide for a ~~general~~ **contingency** framework **setting out the measures to be taken** for anticipating, preparing for, mitigating and minimising the negative impacts which any crisis may cause on the Single Market and its supply chains.
- (8) The framework of measures set out under this Regulation should be deployed in a coherent, transparent, efficient, proportionate and timely manner, having due regard to the need to maintain vital societal functions, ~~meaning~~ including public security, safety, public order, or public health ~~respecting~~. **This Regulation should not affect the competences of Member States for example with respect to national policies of public health and should be without prejudice to** the responsibility of the Member States to safeguard national security and their power to safeguard other essential state functions, including ensuring the territorial integrity of the State and maintaining law and order. **Furthermore, this Regulation does not affect Member States' emergency stocks, both physical and virtual, nor their rules on compulsory stockpiling.**

(9) To this end, this Regulation provides:

- the necessary means to ensure the continued functioning of the Single Market, the businesses that operate on the Single Market and its strategic supply chains, including the free ~~circulation~~ **movement** of goods, services and persons, **including workers**, in times of crisis and the availability of crisis-relevant goods and services to citizens, businesses and public authorities at the time of crisis;
- a forum for adequate coordination, cooperation and exchange of information; and
- the means for the timely accessibility and availability of the information which is needed for a targeted response and adequate market behaviour by businesses and citizens during a crisis.

(10) Where possible, this Regulation should allow for anticipation of events and crises **by allowing the Union to continue**; building on on-going analysis concerning strategically important areas of the Single Market economy ~~and the Union's continuous foresight work.~~

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

(11) This Regulation should not duplicate the existing framework for medicinal products, medical devices or other medical counter-measures under the EU Health Security Framework, including Regulation (EU) .../... on serious cross-border health threats [SCBTH Regulation (COM/2020/727)], Council Regulation (EU) .../... on a framework of measures for ensuring the supply of crisis-relevant medical counter-measures [Emergency Framework Regulation (COM/2021/577)], Regulation (EU) .../... on the extended mandate of the ECDC [ECDC Regulation (COM/2020/726)] and Regulation (EU) 2022/123 on the extended mandate of the EMA [EMA Regulation] **regarding crisis preparedness and response in the area of health. This EU Health Security Framework will take precedence over the Single Market Emergency Instrument when the conditions of the specific framework are met.** Therefore, medicinal products, medical devices or other medical counter-measures, when they have been placed on the list referred to in Article 6(1) of the Emergency-Framework Regulation, ~~shall~~ **should** be excluded from the scope of this Regulation, except in relation to the provisions relating to free movement **of goods, services and persons, including workers,** during the Single Market emergency, and in particular those designed to re-establish and facilitate free movement ~~as well as the notification mechanism.~~

- (12) This Regulation should **be without prejudice to** ~~complement~~ the Integrated Political Crisis Response mechanism operated by the Council under Council Implementing Decision (EU) 2018/1993, ~~as regards its work on Single Market impacts of cross-sectoral crises that require political decision-making.~~ **This Regulation should complement the Integrated Political Crisis Response mechanism operated by the Council under Council Decision 2014/415/EU of 24 June 2014 as regards its work on Single Market impacts of cross-sectoral crisis that require decision making with technical level expertise, contingency planning and implementation of vigilance and emergency measures.**
- (13) This Regulation should be without prejudice to the Union Civil Protection Mechanism ('UCPM'). This Regulation should ~~be in complementarity with~~ **complement** the UCPM and should support it, where necessary, as regards availability of critical goods and free movement of civil protection workers, including their equipment, for crises that fall into the remit of that mechanism.

- (14) ~~This Regulation should be without prejudice to Articles 55 to 57 of Regulation (EC) No 178/2002 on the general plan on crisis management in the area of food and feed, implemented by Commission Decision (EU) 2019/300~~ **This Regulation should be without prejudice to Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (the Schengen Borders Code) and its notification system for the temporary reintroduction of internal border controls.**
- (15) **This Regulation should be without prejudice to Articles 55 to 57 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, implemented by Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed.** ~~This~~ Regulation should be without prejudice to the European Food Security Crisis preparedness and response Mechanism (EFSCM). Nevertheless, food products should be governed by the **free movement** provisions of this Regulation, including those ~~concerning the notification mechanism and concerning restrictions to free movement rights~~. The measures concerning food products notified under this Regulation may be also reviewed for their compliance with any other relevant provisions of ~~EU~~ **Union** law.

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

(15b) One of the issues during the Covid 19 crisis was the lack of network for preparedness and information sharing between the Member States and the Member States and the Commission. For the purposes of this Regulation and for the Union to be better prepared for the next crisis, as well as for the use when the Single Market vigilance and Single Market emergency modes have been activated, there is a need to establish a Single Market Emergency Board (hereinafter the Board). This Board should be a forum for the Commission and the Member States to facilitate and coordinate the exchange of information and assist and advise as well as analyse and discuss relevant topics relating to the imminent or ongoing crisis.

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

(15f) An information exchange relating to ad hoc alerts should be possible through the network created between the Central Liaison Offices and the Union Central Liaison Offices. These ad hoc alerts should be notified to the Commission in cases of significant incidents in order to allow the Union to better follow the development of the potential, imminent crisis or crisis as such thus being able to have better preparedness should the crisis emerge or develop. The significant incidents in the context of this Regulation means incidents that significantly disrupt or have the potential to significantly disrupt the functioning of the Single Market and its supply chains.

(16) In order to account for the exceptional nature of and potential far-reaching consequences for the fundamental operation of the Single Market of a Single Market **vigilance or of a Single Market** emergency **and for the sensitive political consequences which it triggers**, implementing powers should exceptionally be conferred on the Council for the activation of **the Single Market vigilance or emergency mode pursuant to Article 281(2) of the Treaty on the Functioning of the European Union-291(2) of the Treaty on the Functioning of the European Union (TFEU). The Council implementing act for the activation of the Single Market vigilance mode should contain elements which are intrinsically linked to it, namely an assessment of the potential impact of the crisis on the free movement of goods, services and persons including workers in the Single Market and on its supply chains, a list of the goods and services of critical importance which are indispensable in the maintenance of vital societal or economic activities in the Single Market and the vigilance measures to be taken. Furthermore, where the activation of the Single Market emergency mode also requires the adoption of a list of crisis-relevant goods and services, such a list should be adopted at the same time as the activation and is necessary for the assessment of the criteria for the activation of this mode. It is therefore intrinsically linked to the activation. For this reason, implementing powers should also be conferred on the Council for the adoption of the list of crisis-relevant goods and services and its update. It should be possible to extend the Single Market vigilance or emergency mode through a Council implementing act on a proposal from the Commission. Should it transpire that there is no need for either of the modes to be active, then the respective mode should be deactivated.**

(16a) In order to prepare for a Single Market Emergency, information sharing between Member States is vital. When the Single Market vigilance mode has been activated, the Member States should, where necessary, share information between themselves and the Commission in the Board or with the Commission as a coordinator of the Board on goods of critical importance, as listed in the implementing act, that are under their control. This information may include the current stock of these goods in their territory, any potential for further purchase, any options for alternative supply or other available information that could ensure the availability of such goods.

~~(17) Article 21 TFEU lays down the right of EU citizens to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. The detailed conditions and limitations are laid down in Directive 2004/38/EC. This Directive sets out the general principles applicable to these limitations and the grounds that may be used to justify such measures. These grounds are public policy, public security or public health. In this context, restrictions to freedom of movement can be justified if they are proportionate and non-discriminatory. This Regulation is not intended to provide for additional grounds for the limitation of the right to free movement of persons beyond those provided for in Chapter VI of Directive 2004/38/EC.~~

~~(18) As regards the measures for re-establishing and facilitating free movement of persons and any other measures affecting the free movement of persons provided under this Regulation, they are based on Article 21 TFEU and complement Directive 2004/38/EC without affecting its application at the time of Single Market emergencies. Such measures should not result in authorising or justifying restrictions to free movement contrary to the Treaties or other provisions of Union law.~~

- (19) ~~Article 45 TFEU lays down the right to free movement of workers, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. This Regulation contains provisions which complement the existing measures in order to reinforce free movement of persons, increase transparency and provide administrative assistance during Single Market emergencies. Such measures include setting up and making available of the single points of contact to workers and their representatives in the Member States and at Union level during the Single Market vigilance and emergency modes under this regulation.~~
- (20) ~~If Member States adopt For national measures which are not harmonised under this Regulation and affecting affect the free movement of goods or persons, goods or the freedom to provide services in preparation for and during Single Market emergencies, they Member States should limit such measures to what is necessary and remove them as soon as the situation allows it. Such measures ensure that they fully comply with the Treaty and other provisions of Union law. If Member States adopt such restrictions, they should respect the principles of proportionality and non-discrimination, and should take into consideration the particular situation of border regions. They should therefore limit such measures to what is necessary. In particular, Member States should remove such measures as soon as they are no longer necessary. Furthermore, in line with these principles, such measures should not create an unnecessary administrative burden.~~
- (20a) Nothing in this Regulation should be construed as authorising or justifying restrictions to the free movement of goods, services and persons contrary to the Treaty or other provisions of Union law. For example, the fact that some types of restrictions are prohibited during a Single Market emergency should not be construed as justifying such restrictions outside a Single Market emergency.**

(20b) Article 21 TFEU lays down the right of EU citizens to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. The detailed conditions and limitations are laid down in Directive 2004/38/EC⁵. That Directive sets out the general principles applicable to these limitations and the grounds that may be used to justify such measures. These grounds are public policy, public security or public health. In this context, restrictions to the freedom of movement can be justified if they are proportionate and non-discriminatory. This Regulation is not intended to provide for additional grounds for the limitation of the right to free movement of persons beyond those provided for in Chapter VI of Directive 2004/38/EC.

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

⁵ **Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).**

(20d) Article 45 TFEU lays down the right to free movement of workers, subject to the limitations and conditions laid down in the Treaties and the measures adopted to give them effect. Article 46 TFEU is the legal basis for the adoption of measures required to bring about freedom of movement for workers as defined in Article 45 TFEU. This Regulation contains provisions which complement the existing measures in order to reinforce free movement of persons, increase transparency and provide administrative assistance during Single Market emergencies. Such measures include setting up and making available of the single points of contact to workers and their representatives in the Member States and at Union level during the Single Market vigilance and emergency modes under this Regulation.

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

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

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

- ~~(22) When examining the compatibility of any notified draft or adopted measures with the principle of proportionality, the Commission should pay due regard to the evolving crisis situation and often limited information that is at the disposal of the Member States when they seek to reduce the emerging risks in the context of the crisis. Where justified and necessary in the circumstances, the Commission may consider based on any available information, including specialised or scientific information, the merits of Member State arguments relying on the precautionary principle as a reason for adoption of free movement of persons restrictions. It is the task of the Commission to ensure that such measures comply with Union law and do not create unjustified obstacles to the functioning of the Single Market. The Commission should react to the notifications of Member States as quickly as possible, taking into account the circumstances of the particular crisis, and at the latest within the time limits set out by this Regulation.~~
- (23) In order to ensure that the specific Single Market emergency measures provided for in this Regulation are used only where this is indispensable for responding to a particular Single Market emergency, such measures should require ~~individual~~ activation by means of Commission implementing acts, which indicate the reasons for such activation and the crisis-relevant goods or services that such measures apply to.
- (24) Furthermore, in order to ensure the proportionality of the implementing acts and due respect for the role of economic operators in crisis management, the Commission should only resort to the **dual** activation of the Single Market emergency mode, where economic operators are not able to provide a solution on a voluntary basis within a reasonable time. Why this is the case should be indicated in each such act, and in relation to all particular aspects of a crisis.

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

(26) [The activation of the Single Market emergency mode, where needed, should also trigger the application of certain crisis-response procedures which introduce adjustments to the rules governing the design, manufacture, conformity assessment and the placing on the market of goods subject to Union harmonised rules. These crisis-response procedures should enable products, designated as crisis-relevant goods to be placed swiftly on the market in an emergency context. The conformity assessment bodies should prioritise the conformity assessment of crisis-relevant goods over any other ongoing applications for other products. On the other hand, in cases, where there are undue delays in the conformity assessment procedures, the ~~national~~-competent authorities **in the Member States** should be able to issue authorisations for products, which have not undergone the applicable conformity assessment procedures to be placed on their respective market, provided that they comply with the applicable safety requirements. Such authorisations ~~shall~~**should** be only valid on the territory of the issuing Member State and limited to the duration of the Single Market emergency. In addition, in order to facilitate the increase in supply of crisis-relevant products, certain flexibilities should be introduced with respect to the mechanism of presumption of conformity. In the context of a Single Market emergency, the manufacturers of crisis-relevant goods should be able to rely also on national and international standards, which provide an equivalent level of protection to the harmonised European standards. In cases where the latter do not exist or the compliance with them is rendered excessively difficult by the disruptions to the Single Market, the Commission should be able to issue common technical specifications of voluntary or of mandatory application in order to provide ready-to-use technical solutions to the manufacturers.]

- (27) The introduction of these crisis-relevant adjustments to the relevant sectorial Union harmonised rules requires targeted adjustments to the following 19 sectorial frameworks: [Directive 2000/14/EC, Directive 2006/42/EU, Directive 2010/35/EU, Directive 2013/29/EU, Directive 2014/28/EU, Directive 2014/29/EU, Directive 2014/30/EU, Directive 2014/31/EU, Directive 2014/32/EU, Directive 2014/33/EU, Directive 2014/34/EU, Directive 2014/35/EU, Directive 2014/53/EU, Directive 2014/68/EU, Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) 305/2011.] The activation of the emergency procedures should be conditional upon the activation of the Single Market emergency and should be limited to the products designated as crisis-relevant goods.
- (28) In cases where there are substantial risks to the functioning of the Single Market or in cases of ~~severe~~ **significant** shortages or an exceptionally high demand of goods of ~~strategic~~ **critical** importance, measures at Union level aimed to ensure the availability of crisis-relevant ~~products~~ **goods**, ~~such as priority rated orders~~, may prove to be indispensable for ~~the return to the normal~~ **proper** functioning of the Single Market.

(29) **In addition to the current possibility for joint procurement between the Commission and one or more Member States foreseen in the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union⁶ (Financial Regulation) In order to leverage the purchasing power and negotiating position of the Commission during the Single Market vigilance mode and the Single Market emergency mode, one or more Member States should also be able to request the Commission to procure on their behalf, in order to leverage the purchasing power and negotiating position of the Commission during the Single Market vigilance mode and the Single Market emergency mode. The agreement governing the Commission's procurement on behalf of one or more Member States or joint procurement between the Commission and one or more Member States should provide, if necessary, for an exclusivity clause, under which participating countries commit to not procuring the goods or services in question through other channels and to not running parallel negotiation processes. If such an exclusivity clause is agreed, it may also stipulate that where due to the change of circumstances the ongoing joint procurement or procurement by the Commission on behalf of the Member States is not capable of fully covering the procurement needs of the participating Member States for responding to the Single Market emergency or the underlying crisis, the participating Member States may launch their own procurement procedure [Those possibilities should be regulated in this Regulation as long as the [recast of] the Financial Regulation does not contain corresponding provisions regarding procurement on behalf of one or more Member States]⁷.**

⁶ **Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union**

⁷ **This sentence will stay as long as the recast Financial Regulation does not enter into force before this Regulation.**

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

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

(31) The measures ensuring regulatory flexibility would allow the Commission to recommend that Member States accelerate the procedures for granting permits that would be necessary for enhancement of the capacity to produce crisis-relevant goods or provide crisis-relevant services **or to accelerate the relevant approval or authorisation procedures with a view to accelerating the production and distribution of crisis-relevant goods or placing on the market of such products.**

- ~~(32) Additionally, to ensure that crisis-relevant goods are available during the Single Market emergency, the Commission may invite the economic operators that operate in crisis-relevant supply chains to prioritise the orders of inputs necessary for the production of final goods that are crisis-relevant, or the orders of such final goods themselves. Should an economic operator refuse to accept and prioritise such orders, following objective evidence that the availability of crisis-relevant goods is indispensable, the Commission may decide to invite the economic operators concerned to accept and prioritise certain orders, the fulfilment of which will then take precedence over any other private or public law obligations. In the event of failure to accept, the operator in question should explain its legitimate reasons for declining the request. The Commission may make such reasoned explanation or parts of it public, with due regard to business confidentiality.~~
- (33) Furthermore, to ensure availability of crisis-relevant goods during the Single Market emergency, the Commission may recommend that Member States distribute **strategie reserves**those crisis-relevant goods and services, having with due regard to the principles of solidarity, necessity and proportionality.
- (34) Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, such processing should comply with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/1725 of the European Parliament and of the Council⁸ and Regulation (EU) 2016/679 of the European Parliament and of the Council⁹.

⁸ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

(35) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards **specifications of the contingency framework regarding preparedness cooperation, exchange of information and crisis communication for the Single Market vigilance and emergency modes. Moreover, implementing powers should be conferred on the Commission as regards** the possibility to adopt supportive measures for facilitating free movement of persons, ~~for establishing a list of individual targets (quantities and deadlines) for those strategic reserves that the Member States should maintain, so that the objectives of the initiative are achieved.~~ Furthermore, implementing powers should be conferred on the Commission as regards ~~activating the vigilance mode and vigilance measures in order to carefully monitor the strategic supply chains and coordinate the building up of strategic reserves for goods and services of strategic importance.~~ Moreover, implementing powers should be conferred on the Commission as regards activation of specific emergency response measures at the time of a Single Market emergency, to allow for a rapid and coordinated response. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁰.

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

¹⁰ **Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).**

(36) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union (the ‘Charter’). In particular, it respects the right to privacy of the economic operators enshrined in Article 7 of the Charter, right to data protection set out in Article 8 of the Charter, the freedom to conduct business and the freedom of contract, which are protected by Article 16 of the Charter, the right to property, protected by Article 17 of the Charter, right to collective bargaining and action protected by Article ~~26~~28 of the Charter and the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter.

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

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

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

- (37) The Union remains fully committed to international solidarity and strongly supports the principle that any measures deemed necessary taken under this Regulation, including those necessary to prevent or relieve critical shortages, are implemented in a manner that is targeted, transparent, proportionate, temporary and consistent with WTO obligations.
- (38) The Union framework ~~should~~**shall** include interregional elements to establish coherent, multi-sectoral, cross-border Single Market vigilance and emergency response measures, in particular considering the resources, capacities and vulnerabilities across neighbouring regions, specifically border regions.
- ~~(39) The Commission shall also where appropriate enter into consultations or cooperation, on behalf of the Union, with relevant third countries, with particular attention paid to developing countries, with a view to seeking cooperative solutions to address supply chain disruptions, in compliance with international obligations. This shall involve, where appropriate, coordination in relevant international fora.~~
- ~~(40) In order to put in place a framework of crisis protocols the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement the regulatory framework set out in this Regulation by further specifying the modalities of cooperation of the Member States and Union authorities during the Single Market vigilance and emergency modes, secure exchange of information and risk and crisis communication. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.~~

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

(42) This Regulation should be evaluated after [five] years. In case the Single Market vigilance mode or the Single Market emergency mode has been activated, the Commission, by [18] months after the deactivation of the Single Market vigilance mode or the Single Market emergency mode, should present a report to the European Parliament and the Council on the functioning of the contingency planning, Single Market vigilance and emergency response system suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.

HAVE ADOPTED THIS REGULATION:

Part I

General Provisions

TITLE I

SCOPE

Article 1

Subject matter **and objectives**

1. This Regulation establishes a framework of **approximating** measures to anticipate, prepare for and respond to impacts of crises on the Single Market, ~~with the purpose of.~~

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

- safeguarding **and facilitating** the free movement of goods, services and persons ~~and of,~~
including workers,

- ensuring the availability of goods and services of ~~strategic~~ **critical** importance and crisis-relevant goods and services in the Single Market, **where the Member States have adopted or are likely to adopt divergent measures which lead to cross-border restrictions, and**

- preventing the creation of obstacles to the proper functioning of the Single Market.

2. The ~~measures~~ **framework** referred to in paragraph 1 ~~include~~ **includes, in particular the following:**

(a) ~~an advisory group to~~ **the establishment of a Single Market Emergency Board to assist and** advise the Commission ~~on the appropriate measures for~~ **in** anticipating, preventing or responding to the impact of a crisis on the Single Market;

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

- (c) contingency measures ~~aiming at~~ **for the** anticipation and planning; **(Single Market contingency planning)**;
- (d) **vigilance** measures for addressing Single Market ~~the~~ impacts of significant incidents ~~a~~ **crisis** that have not yet resulted in ~~a~~ **has the potential to escalate into a** Single Market emergency (Single Market vigilance), including a set of vigilance measures and **within the next six months (Single Market vigilance)**;
- (e) measures for addressing Single Market emergencies, including a set of emergency response measures **(Single Market Emergency), including re-establishing and facilitating the free movement of goods, services and persons, including workers, during Single Market Emergency mode;-**
- (ea) procurement of goods and services of critical importance and crisis-relevant goods and services by the Commission on behalf of Member States during the Single Market vigilance and emergency modes.**

- 3. ~~Member States shall regularly exchange information on all matters falling within the scope of this Regulation among themselves and with the Commission.~~
- 4. ~~The Commission may obtain any relevant specialised and/or scientific knowledge, which is necessary for the application of this Regulation.~~

Article 2
Scope of application

- 1. ~~The measures set out in this is Regulation apply~~ ~~sy~~ in relation to significant impacts of a crisis ~~on the functioning of the Single Market and its supply chains.~~ **goods, services and persons, including workers on the Single Market.**
- 2. This Regulation shall not apply to the following:
 - (a) medicinal products as defined in Article ~~2~~**1**, paragraph **1 point** 2 of Directive 2001/83/EC;

- (b) medical devices as defined in Article 2, point (e), of Regulation (EU) 2022/123 of the European Parliament and of the Council¹¹;
- (c) other medical countermeasures as defined in Article 3, point (8), of Regulation (EU) .../... on Serious Cross-Border Threats to Health [the SCBTH Regulation]¹² and included in the list established in accordance with Article 6(1) of the proposal for Council Regulation (EU) .../... on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures¹³;
- (d) semiconductors as defined in Article 2(1) of the Regulation of the Council and of the European Parliament establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)¹⁴;
- (e) energy products as defined in Article 2, paragraph 1, of Directive 2003/96/EC¹⁵, electricity as defined in Article 2, paragraph 2 of that Directive and other products as referred to in Article 2, paragraph 3, of that Directive;-
- (f) financial services, such as banking, credit, insurance and re-insurance, occupational or personal pensions, securities, investment funds, payment and investment advice, including the services listed in Annex I to Directive 2013/36, as well as settlement and clearing activities and advisory, intermediation and other auxiliary financial services;-

¹¹ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, *OJ L 20*, 31.1.2022, p. 12.

¹² [reference to adopted Act to be inserted once available]

¹³ [reference to adopted Act to be inserted once available]

¹⁴ [reference to adopted Act to be inserted once available]

¹⁵ OJ L 283, 31.10.2003, p. 51.

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

3. By way of derogation from paragraph 2, points (a), (b) and (c), **Articles 16 to 18, Articles 13 to 15 only for the purposes of Articles 16 to 18,** and Article 41 of this Regulation shall apply to the products referred to in those points-;

4. This Regulation is without prejudice to **other Union legal acts regulating other aspects than the subject-matter of this Regulation or specifying and complementing this Regulation, in particular the following:**

(a) the overall coordination role of the Emergency Response Coordination Center under the Union Civil Protection Mechanism and other elements of the Union Civil Protection Mechanism set out in Decision No 1313/432013/EU; and

(b) the general plan on crisis management in the area of food and feed in accordance with Regulation (EC) No 178/2002-;

(ba) the Integrated Political Crisis Response mechanism (IPCR) operated by the Council under Council Implementing Decision (EU) 2018/1993 and Council Decision 2014/415/EU establishing the Integrated Political Crisis Response Arrangements including the political coordination role of the IPCR;

(c) the rules applicable to the notification of temporary reintroduction of controls at internal border under Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code);

(d) the possibility of the Commission to assess whether it is appropriate to impose restrictions to exports of goods in line with the international rights and obligations of the Union under Regulation (EU) 2015/479 of the European Parliament and of the Council¹⁶;

(e) measures taken pursuant to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007;

(f) Regulation (EU) 2022/2371 on serious cross-border threats to health, the HERA Crisis Regulation (EU) 2022/2372, the ECDC Regulation (EU) 2022/2370 and the EMA Regulation (EU) 2022/123.

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

5a. This Regulation is without prejudice to Articles 55 to 57 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, implemented by Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed.

¹⁶ OJ L 83, 27.3.2015, p. 34.

6. ~~This Regulation is without prejudice to the Commission:~~
- ~~(a) entering into consultations or cooperation, on behalf of the Union, with relevant third countries, with particular attention paid to developing countries, with a view to seeking cooperative solutions to avoid supply chain disruptions, in compliance with international obligations. This may involve, where appropriate, coordination in relevant international fora; or~~
 - ~~(b) assessing whether it is appropriate to impose restrictions to exports of goods in line with the international rights and obligations of the Union under Regulation (EU) 2015/479 of the European Parliament and of the Council¹⁷.~~
7. Any actions under this Regulation shall be consistent with Union's obligations under international law.
8. This Regulation is without prejudice to the responsibility of the Member States to safeguard national security or their power to safeguard essential state functions, including ensuring the territorial integrity of the State and maintaining law and order. **In particular, national security remains the sole responsibility of each Member State.**
- 8a. This Regulation shall not be interpreted as affecting the exercise of fundamental rights, such as the right to environmental protection and the right of collective action, including strike action, in accordance with the Charter of Fundamental Rights of the European Union (the 'Charter').**

¹⁷ OJ L 83, 27.3.2015, p. 34.

Article 3
Definitions

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

- (1) ‘crisis’ means an exceptional, unexpected and sudden, natural or man-made event of extraordinary nature and scale that takes place inside or outside of the Union; **which has or may have a severe negative impact on the functioning of the Single Market and disrupts, or severely disrupts, the free movement of goods, services and persons, and its supply chains;**
- (2) ‘Single Market ~~vigilance mode~~’ means **vigilance** ~~refers to situation where there is a framework for addressing a threat of~~ **a crisis with a significant negative impact** ~~disruption on the free movement of goods, services and persons or~~ **of the disruption of** supply of goods and services of ~~strategic~~ **critical** importance **caused by an imminent crisis** ~~and which has the potential to escalate into a Single Market emergency within the next six months;~~
- (3) ‘Single Market emergency’ means a **crisis with** ~~wide-ranging~~ **significant negative** impact ~~of a crisis~~ on the Single Market that severely disrupts the free movement **of goods, services and persons** on the Single Market or the functioning of the supply chains ~~that are indispensable in the maintenance of vital societal or economic activities in the Single Market;~~ **of crisis-relevant goods and services where such a severe disruption has been or is likely to be subject to divergent national measures;**

- (4) ‘strategically important areas’ means those areas with critical importance to the Union and its Member States, in that they are of systemic and vital importance for **upholding** public security, public safety, public order or public health, and **if there is a** the disruption, failure, loss or destruction of **goods or services of critical importance in this area**, ~~which will~~ **could** have a significant **negative** impact on the functioning of the Single Market **in times of an imminent crisis as defined under the Single Market vigilance**;
- (5) ‘goods and services of ~~strategic~~ **critical** importance’ means goods and services that are **non-substitutable, non-diversifiable and** indispensable **in the maintenance of vital societal or economic activities as to** for ensuring the **proper** functioning of the Single Market **and its supply chains** in strategically important areas **in times of an imminent crisis as defined under the Single Market vigilance** and ~~which cannot be substituted or diversified~~;
- (6) ‘crisis-relevant goods and services’ means goods and services that are **non-substitutable, non-diversifiable and** indispensable **in the maintenance of vital or societal economic activities as to ensure the proper functioning of the Single Market and its supply chains and that are set out** for responding to the crisis or for addressing the **significant negative** impacts of the crisis on the Single Market during a **crisis as defined under the** Single Market emergency ;
- (7) ~~‘strategic reserves’ means a stock of goods of strategic importance for which building a reserve may be necessary to prepare for a Single Market emergency, under the control of a Member State.~~
- (7a) ‘significant incidents’ means incidents that significantly disrupt or have the potential to significantly disrupt the functioning of the Single Market and its supply chains;**
- (7b) ‘relevant economic operator’ means economic operators that have the production, or distribution ability or capacity of goods and services of critical importance or crisis-relevant goods and services or goods or services, including their inputs, along the supply chain;**

TITLE II GOVERNANCE

Article 4

~~Advisory group~~ **Single Market Emergency Board**

1. ~~An advisory group~~ **A Single Market Emergency Board** is established, ~~hereinafter the~~ **Board**.
 2. The ~~advisory group~~ **Board** shall be composed of one representative from each Member State ~~and one representative from the Commission~~. Each Member State shall ~~nominate~~ **appoint** a representative and an alternate representative. **In addition, Member States may appoint a sector-specific ad hoc representative if this is appropriate depending on the nature of the crisis.**
 3. The Commission **representative** shall chair the ~~advisory group~~ **Board** and ensure its secretariat. The Commission **representative** may invite a representative of the European Parliament, representatives of EFTA States that are contracting parties to the Agreement on the European Economic Area¹⁸, representatives of economic operators, stakeholder organisations, social partners and experts, to attend **specific** meetings of the ~~advisory group~~ **Board** as observers, **where such attendance is relevant considering the agenda of the meeting**. It shall invite the representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the ~~advisory group~~ **Board**.
- 3a. The Board shall meet at least three times a year. At its first meeting, on a proposal by and in agreement with the Commission, the Board shall adopt its rules of procedure.**
- 3b. The Board may adopt opinions, recommendations or reports in the context of its tasks set out in Article 4a. The Commission shall in a transparent manner take the utmost account of opinions, recommendations or reports by the Board.**

¹⁸ OJ L 1, 3.1.1994, p. 3.

Article 4a
Tasks of the Board

- 14.** For the purpose of contingency planning under Articles 6 to 8, the ~~advisory group~~ **Board** shall assist and advise the Commission as regards the following tasks:
- (a) proposing arrangements for administrative cooperation **to facilitate the exchange of information** between the Commission and the Member States at the time of the Single Market vigilance and emergency modes that would be contained in the ~~crisis protocols~~ **contingency framework; and**
 - (b) ~~assessment of significant~~ **assessing** incidents that the Member States have alerted the Commission ~~to~~ **pursuant to Article 8.**
- 52.** For the purpose of ~~of the~~ Single Market vigilance mode as referred to in Article 9, the ~~advisory group~~ **Board** shall assist **and advise** the Commission in the following tasks:
- (a) establishing whether the **crisis** threat referred to in Article 3(2) is present, and the scope of such threat;
 - (b) gathering foresight, data analysis and market intelligence;
 - (c) consulting the representatives of economic operators, including SMEs, **social partners** and industry to collect market intelligence **in line with Article 40a;**
 - (d) analysing aggregated data received by other crisis-relevant bodies at Union and international level;
 - (e) **coordinating and** facilitating exchanges and sharing of information, including with other relevant bodies and other crisis-relevant bodies at Union level **and in Member States**, as well as ~~third~~ countries, as appropriate, with particular attention paid to developing countries, and international organisations;

- (f) maintaining a repository of national and Union crisis measures that have been used in previous crises that have had an impact on the Single Market and its supply chains; **and**
- (g) analysing and discussing the effect of the crisis on the Single Market, with due regard to the situation in border regions, with a view to finding possible solutions.**

63. For the purposes of the Single Market emergency mode as referred to in Article 14, the advisory group **Board** shall assist **and advise** the Commission in the following tasks:

- (a) analysing crisis-relevant information gathered by Member States or the Commission;
- (b) establishing whether the criteria for activation or deactivation of the emergency mode have been fulfilled;
- (c) advising on the **identification and** implementation of the measures chosen to respond to Single Market emergency at Union level;
- (d) performing a review of national crisis measures;
- (e) **coordinating and** facilitating exchanges and sharing of information, including with other crisis-relevant bodies at Union level, as well as, as appropriate, third countries, with particular attention paid to developing countries, and international organisations; **and-**
- (f) analysing and discussing the effect of the crisis on the Single Market, with due regard to the situation in border regions, with a view to finding possible solutions.**

- ~~74.~~ The Commission shall ensure the participation of all bodies at Union level that are relevant to the respective crisis. The ~~advisory group~~ **Board** shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies at Union level [and the European Critical Raw Materials Board]. The Commission shall ensure coordination with the measures implemented through other Union mechanisms, such as the Union Civil Protection Mechanism (UCPM), ~~or~~ the Integrated Political Crisis Response (IPCR) Mechanism, the EU Health Security Framework [and the European critical raw materials framework]. The ~~advisory group~~ **Board** shall ensure information exchange with the Emergency Response Coordination Centre under the UCPM and the Integrated Situational Awareness and Analysis (ISAA) support capability under the IPCR.
- ~~8.~~ The advisory group shall meet at least three times a year. At its first meeting, on a proposal by and in agreement with the Commission, the advisory group shall adopt its rules of procedure.
- ~~9.~~ The advisory group may adopt opinions, recommendations or reports in the context of its tasks set out in paragraphs 4 to 6.

Article 4b

Information sharing between the Member States and the Commission

- 1. In order to better anticipate and be prepared for crisis Member States shall, during the contingency mode, and if necessary, also in Single Market vigilance or emergency mode, exchange information among themselves and with the Commission on matters other than those set out in Article 4a, where necessary to achieve the objectives of this Regulation.**
- 2. The information exchange shall be done in an efficient and co-operative manner avoiding unnecessary administrative burden, disruptions or significant negative impacts on the functioning of the Single Market and its supply chains and with due regard to national security, national strategic reserves and confidentiality of economic operators.**

Article 5
Central liaison offices

1. **Each Member State shall designate and appoint a central liaison office.**
 - 1a. **The central liaison office shall be** responsible for contacts, coordination and information exchange with the central liaison offices of other Member States and **the** Union level central liaison office under this Regulation. ~~Such liaison offices shall coordinate and compile the inputs from relevant national competent authorities.~~
 - 1b. **The central liaison office shall be responsible for contacts, coordination and information exchange with the relevant competent authorities in the Member State. In order to perform its tasks under this Regulation, the central liaison office shall compile input from the relevant competent authorities in the Member State.**
2. The Commission shall designate a Union level central liaison office.
 - 2a. **The Union level central liaison office shall be responsible** for contacts with the central liaison offices of the Member States ~~during the Single Market vigilance and emergency modes~~ under this Regulation.
 - 2b. **The Union level central liaison office shall ensure the coordination and information exchange with the central liaison offices of the Member States under this Regulation** for the management of the Single Market vigilance and emergency modes.

Part II

Single Market contingency planning

Article 6 ~~Crisis protocols~~ Contingency framework

1. The Commission taking into consideration the opinion **and the expertise** of the advisory group **Board** and the input of relevant Union level bodies, is empowered after consulting the Member States, to **shall** adopt an **implementing** delegated act to **specify** supplement this Regulation with a **contingency** framework setting out crisis protocols regarding crisis **preparedness** cooperation, exchange of information and crisis **crisis** communication for the Single Market vigilance and emergency modes, in particular. **This contingency framework shall specify the modalities for:**
 - (a) cooperation between national **Member States** and Union level competent authorities for the management of **in** the Single Market vigilance and emergency modes in vigilance and emergency modes across the sectors of the Single Market;
 - (b) ~~general modalities for secure exchange of information;~~ **and**
 - (c) a coordinated approach to risk and crisis communication **for the Single Market vigilance and emergency modes** also vis-à-vis the public with a coordinating role for the Commission;
 - (d) ~~the management of the framework.~~
- 1a. The implementing act referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 42(2).**

2. The Commission and the Member States shall ~~put in place detailed administrative~~ **ensure** arrangements for ~~ensuring~~ timely cooperation and secure exchange of information between the Commission, the relevant Union-level bodies and the Member States concerning:
- (a) an inventory of relevant ~~national~~-competent authorities **of the Member States**, the central liaison offices designated in accordance with Article 5 and single points of contact referred to in Article 21, their contact details, assigned roles and responsibilities during the vigilance and emergency modes of this Regulation under national law;
 - (b) consultation of the representatives of economic operators and social partners, including SMEs, on their initiatives and actions to mitigate and respond to potential supply chain disruptions and overcome potential shortages of goods and services in the Single Market;
 - (c) technical level cooperation in the vigilance and emergency modes ~~across the sectors of the Single Market;~~ **and**
 - (d) risk and emergency communication, with a coordinating role for the Commission, adequately taking into account already existing structures;
3. In order to ensure the operation of the framework ~~referred to in~~ **established in accordance with** paragraph 1, the Commission may conduct stress tests, simulations and in-action and after-action reviews with Member States, and propose the relevant Union-level bodies and the Member States to update the framework as necessary.

Article 7
Trainings and simulations

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

Article 8
Ad hoc alerts for early warning

1. The central liaison office of a Member State shall notify the Commission and the central liaison offices of other Member States without undue delay of any **significant** incidents ~~that significantly disrupt or have the potential to significantly disrupt the functioning of the Single Market and its supply chains (significant incidents).~~
2. The central liaison offices and any relevant ~~national~~ competent authorities **of the Member States** shall, in accordance with Union law and national legislation that complies with Union law, treat the information referred to in paragraph 1 in a way that respects its confidentiality, protects the security and public order of the ~~European~~ Union or its Member States, and protects the security and commercial interests of the economic operators concerned.
3. In order to determine whether the disruption or potential disruption of the functioning of the Single Market and its supply chains ~~of goods and services~~ is significant and should be the object of an alert, the central liaison office of a Member State shall take the following into account:
 - (a) the **market position or** number of economic operators affected by the disruption or potential disruption; **or**
 - (b) the duration or anticipated duration of a disruption or potential disruption; **or**
 - (c) the geographical area; the proportion of the Single Market affected by the disruption or potential disruption; the impact on specific geographical areas particularly vulnerable or exposed to supply chain disruptions including the ~~EU~~ outermost regions; **or**
 - (d) **the existence of non-diversifiable and non-substitutable inputs in relation to the disruption or potential disruption and, if relevant,** the effect of the disruption or potential disruption on non-diversifiable and non-substitutable inputs.

Part III Single Market Vigilance

TITLE I VIGILANCE MODE

Article 9 Activation

1. Where the Commission, taking into consideration the opinion provided by the ~~advisory group~~ **Board**, considers that the ~~threat referred to~~ **conditions laid down** in Article 3(2) is ~~present~~ **are fulfilled**, it **shall propose to the Council to activate the Single Market vigilance mode. The Council may activate the Single Market vigilance mode by means of a Council implementing act on a proposal from the Commission. The duration of the activation shall be specified in the implementing act, and shall be a maximum of six months.** ~~shall activate the vigilance mode for a maximum duration of six months by means of an implementing act.~~ Such ~~an~~ implementing act shall contain the following:
- (a) an assessment of the potential impact of the crisis **on the free movement of goods, services and persons, including workers, on the Single Market and on its supply chains**;
 - (b) **a list of the goods and services of strategic critical importance concerned which are indispensable in the maintenance of vital societal or economic activities in the Single Market**, and
 - (c) the vigilance measures to be taken.

1a. When assessing whether the conditions laid down in Article 3(2) are fulfilled to qualify as Single Market vigilance, the Commission and the Council shall, based on concrete and reliable evidence including information collected in the Board or through other Union-wide monitoring mechanisms, take into account at least the following criteria:

- (a) the anticipated time before the threat escalates into a Single Market Emergency;**
- (b) the number or market position of economic operators expected to be affected considering the nature of the threat; and**
- (c) the extent to which goods and services of critical importance are expected to be impacted considering the nature of the threat.**

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

Article 10
Extension and deactivation

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

2. Where the Commission, taking into consideration the opinion provided by the ~~advisory group~~**Board**, finds that the ~~threat referred to~~**conditions laid down** in Article 3(2) ~~is~~**are** no longer present **fulfilled to qualify as Single Market vigilance**, with respect to some or all vigilance measures or for some or all of the goods and services, it shall **propose to the Council to** deactivate the vigilance mode in full or in part. **On the basis of this proposal, the Council may deactivate the vigilance mode** by means of an **Council** implementing act.
3. ~~Implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 42(2).~~

TITLE II VIGILANCE MEASURES

Article 11 Monitoring

1. When the vigilance mode has been activated in accordance with Article 9, ~~national~~ competent authorities **in the Member States** shall monitor the supply chains of goods and services of ~~strategie~~ **critical** importance that have been identified in the implementing act activating the vigilance mode.
2. The Commission shall provide for standardised and secure means for the collection and processing of **aggregated** information for the purpose of paragraph 1, using electronic means. Without prejudice to national legislation **in compliance with Union law**, requiring collected information including business secrets to be kept confidential, confidentiality with regard to the commercially sensitive information and information affecting the security and public order of the Union or its Member States shall be ensured.
3. Member States shall set up and maintain an inventory of the ~~most~~ relevant economic operators established on their respective national territory that operate along the supply chains of goods and services of ~~strategie~~ **critical** importance that have been identified in the implementing act activating the vigilance mode.

4. On the basis of the inventory set up pursuant to **paragraph 3 of this** Article ~~6~~, ~~national~~, competent authorities **in the Member States** shall address requests for voluntary provision of information to the most relevant operators along the supply chains of goods and services identified in the implementing act adopted pursuant to Article 9 and other relevant stakeholders established in their respective national territory. Such requests shall in particular ~~states~~**state** which information about factors impacting the availability of the identified goods and services of ~~strategie~~ **critical** importance is requested. Each economic operator/stakeholder that voluntarily provides information shall do so on an individual basis in line with the Union rules on competition governing the exchange of information. The ~~national~~ competent authorities **in the Member States** shall transmit the relevant findings to the Commission and ~~the advisory group~~**Board** without undue delay via the respective central liaison office.
5. ~~National competent~~**Competent** authorities **in the Member States** shall have due regard to the administrative burden on economic operators and in particular SMEs, which may be associated with requests for information and ensure it is kept to a minimum.
6. The Commission may ask the ~~advisory group~~**Board** to discuss the **aggregated** findings and prospects of evolution based on **a Commission aggregation of the information obtained by Member States pursuant to paragraphs 1 and 4 regarding their monitoring of supply chains of goods and services of strategic critical importance, duly ensuring confidentiality and observing the commercial sensitivity of the information concerned.**
7. On the basis of the information collected through the **monitoring** activities carried out in accordance with paragraph 1, the Commission may provide a report of the aggregated findings.
- 7a. The Commission may also share with the Member States relevant information obtained through other monitoring means or systems.**

Article 12
Strategic reserves

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

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

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

- (a) the current stock in their territory;
- (b) any potential for further purchase;
- (c) any options for alternative supply;
- (d) further information that could ensure the availability of such goods.

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

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

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

4. ~~Where the building of strategic reserves of goods of strategic importance identified pursuant to paragraph 1 can be rendered more effective by streamlining among Member States, the Commission may draw up and regularly update, by means of implementing acts, a list of individual targets regarding the quantities and the deadlines for those strategic reserves that the Member States should maintain. When setting the individual targets for each Member State, the Commission shall take into account:~~
- ~~(a) the probability and impact of shortages referred in paragraph 1;~~
 - ~~(b) the level of existing stocks of the economic operators and strategic reserves across the Union, and any information on economic operators' ongoing activities to increase their stocks;~~
 - ~~(c) the costs for building and maintaining such strategic reserves.~~
5. ~~The Member States shall regularly inform the Commission about the current state of their strategic reserves. Where a Member State has reached the individual targets referred to in paragraph 4, it shall inform the Commission if it has at its disposal any stocks of the goods in question in excess of their target. The Member States whose reserves have not reached the individual targets shall explain to the Commission the reasons for this situation. The Commission shall facilitate cooperation between the Member States which have already reached their targets and the other Member States.~~
6. ~~Where the strategic reserves of a Member State continuously fall significantly short of the individual targets referred to in paragraph 4 and economic operators on its territory are not able to compensate that shortfall, the Commission may, at its own initiative or at the request of 14 Member States, assess the need to take further measures to build up strategic reserves of goods of strategic importance identified pursuant to paragraph 1.~~

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

- (a) ~~the needs for the good in question remain unchanged or have increased compared to the situation at the time the target referred to in paragraph 4 was first set or last amended pursuant to paragraph 4,~~
- (b) ~~access to the concerned good is indispensable to ensure preparedness for a Single Market emergency~~
- (c) ~~the Member State concerned has not provided sufficient evidence to explain the failure to meet the individual target, and~~
- (d) ~~exceptional circumstances exist, in that the failure by that Member State, considering its importance to the supply chain concerned, to build up such strategic reserves gravely imperils the Union's preparedness in the face of an impending threat of a Single Market emergency;~~

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

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

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

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

Part IV Single Market Emergency

TITLE I EMERGENCY MODE

Article 13 *Criteria for activation*

1. When assessing the severity of a disruption need for the purposes of ascertaining whether the impact of a crisis on the Single Market qualifies as the activation of the Single Market emergency mode, the Commission and the Council shall, based on concrete and reliable evidence, take apply following criteria for activation:
- (a) the crisis creates one or more obstacles to the free movement of goods, services or persons that has an impact on at least one sector of vital societal or economic activities in the Single Market, and
 - (b) in case of disruption to the functioning of the supply chains, the goods, services or workers concerned cannot be diversified or substituted.
- 1a. When applying the criteria referred to in paragraph 1, the Commission and the Council shall take into account at least the following indicators:
- (a-a) crisis relevant goods and service which have caused a number of notifications of significant incidents pursuant to Article 8(1);

- (a) the crisis has caused activation of any relevant Council crisis response mechanism, **namely the Integrated Political Crisis Response mechanism operated by the Council under Council Implementing Decision (EU) 2018/1993, of the** Union Civil Protection Mechanism or **of** the mechanisms set up within the EU Health Security Framework, including [the proposal for] Regulation (EU) .../... on serious cross-border health threats and [the proposal for] Council Regulation (EU) .../... on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures;
- (b) an estimation of the **market position and** number of economic operations or users relying on the disrupted sector or sectors of the Single Market for the provision of the goods or services concerned;
- ~~(c) the importance of the goods or services concerned for other sectors;~~
- ~~(d) the impacts in terms of degree and duration on economic and societal activities, the environment and public safety;~~
- (e) the economic operators affected have not been able to provide a solution in a reasonable time to the particular aspects of the crisis on a voluntary basis;-
- ~~(f) the market position of affected economic operators in the concerned sector or sectors;~~
- (g) the geographic area that is and could be affected, including any cross-border impacts on the functioning of supply chains that are indispensable in the maintenance of vital societal or economic activities in the Single Market;
- (h) the importance of the affected economic operator in maintaining a sufficient level of supply of the goods or services, taking into account the availability of alternative means for the provision of those goods or services; and
- (i) the absence of substitute goods, ~~inputs~~ or services.

Article 14
Activation

-1. The Single Market emergency mode shall be activated in accordance with Article 13.

1. The Single Market Emergency mode may be activated without the Single Market vigilance mode having previously been activated with regard to the same goods or services. Where the vigilance mode has previously been activated, the emergency mode may replace it partially or entirely.
2. Where the Commission, taking into consideration the opinion provided by the ~~advisory group~~ **Board**, considers there is a Single Market emergency, it shall propose to the Council to activate the Single Market emergency mode **and, where applicable, to adopt a list of crisis-relevant goods and services.**
3. The Council may activate the Single Market emergency mode, **and where applicable, adopt a list of crisis-relevant goods and services** by means of a Council implementing act **on a proposal from the Commission**. The duration of the activation, shall be specified in the implementing act, and shall be a maximum of six months. **The list of crisis-relevant goods and services may be amended by means of Council implementing act on a proposal from the Commission.**
4. The activation of the Single Market emergency mode regarding certain goods and services does not prevent the activation or continued application of the vigilance mode and deployment of the measures laid down in Article 11 ~~and 12~~ regarding the same goods and services.
5. ~~As soon as the Single Market emergency mode is activated, the Commission shall, without delay, adopt a list of crisis-relevant goods and services by means of an implementing act. The list may be amended by means of implementing acts.~~

6. ~~The Commission implementing act referred to in paragraph 5 shall be adopted in accordance with the examination procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).~~

Article 15
Extension and deactivation

1. Where the Commission considers, taking into consideration the opinion provided by the ~~advisory group~~**Board**, that an extension of the Single Market emergency mode is necessary, it shall propose to the Council to extend the Single Market emergency mode. Subject to urgent and exceptional changes in circumstances, the Commission shall endeavour to do so no later than 30 days before the expiry of the period for which the Single Market emergency mode has been activated. The Council may extend the Single Market emergency mode by no more than six months at a time by means of **a Council** ~~an~~ implementing act.
2. Where the ~~advisory group~~**Board** has concrete and reliable evidence that the Single Market emergency should be deactivated, it may formulate an opinion to that effect and transmit it to the Commission. Where the Commission, taking into consideration the opinion provided by the ~~advisory group~~**Board**, considers a Single Market emergency no longer exists, it shall propose to the Council without delay the deactivation of the Single Market emergency mode.

3. The measures taken in accordance with Articles 24 to 33 and pursuant to the emergency procedures introduced in the respective Union legal frameworks by means of the amendments to sectorial product legislation set out in [Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 ~~and introducing~~ **regards** emergency procedures for the conformity assessment, adoption of common specifications and market surveillance ~~in the context of~~ **due to** a Single Market emergency] and Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, and 2014/68/EU ~~and introducing~~ as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance ~~in the context of~~ due to a Single Market **emergency**] shall cease to apply upon deactivation of the duration of the Single Market emergency mode.
4. The Commission shall submit to the Council an assessment on the effectiveness of the measures taken in addressing the Single Market emergency no later than three months after the expiry of the measures, **including where applicable**, on the basis of the information gathered via the monitoring mechanism foreseen by Article 11.

TITLE II
FREE MOVEMENT DURING THE SINGLE MARKET EMERGENCY

Chapter I
Measures for re-establishing and facilitating free movement

Article 16

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

1. **Without prejudice to Article 17, when** ~~When~~ adopting and applying national measures in response to a Single Market emergency and the underlying crisis, Member States shall ensure that their actions fully comply with the Treaty and **other provisions of** Union law ~~and,~~ **including as regards non-discrimination, justification and proportionality.** ~~in particular,~~ with the requirements laid down in this Article.
2. **Member States shall ensure in particular that any measures referred to in paragraph 1 are removed when they are no longer necessary.** ~~Any restriction shall be limited in time and removed as soon as the situation allows it. Additionally, any restriction should take into account the situation of border regions.~~
3. ~~Any requirement imposed on citizens and businesses shall not create an undue or unnecessary administrative burden.~~
4. ~~Member States shall inform citizens, consumers, businesses, workers and their representatives about measures that affect their free movement rights in a clear and unambiguous manner.~~
5. Member States shall ensure that ~~all~~ affected stakeholders are informed of measures restricting free movement of goods, services and persons, including workers and service providers, before their entry into force. Member States shall ensure a continuous dialogue with stakeholders, including communication with social partners and international partners.

Article 17

Prohibited restrictions of free movement rights during a Single Market emergency

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

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

(a) bans on intra-Union ~~intra-Union export bans~~ or other measures having equivalent effect on crisis-relevant goods or services listed in an implementing act adopted pursuant to Article 14, paragraph ~~3~~5; **or on the transit of crisis-relevant goods listed in an implementing act adopted pursuant to Article 14, paragraph 3, or measures having equivalent effect;**

~~(b) restrictions on the~~ **restricting the** ~~intra-Union~~EU-export of goods or **the cross-border** provision or receipt of services, or measures having equivalent effect, where those restrictions do any of the following

(i) disrupt supply chains of crisis-relevant goods and services that are listed in an implementing act adopted pursuant to Article 14, paragraph ~~3~~5, or

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

~~(c) discrimination between Member States or between citizens, including in their role as service providers or workers,~~ **discriminating against beneficiaries of the right to free movement under Union law** based directly on nationality or, in the case of companies, the location of the registered office, central administration or principal place of business;

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

- (i) ~~cause shortages of necessary workforce on the Single Market and thus disrupt supply chains of crisis-relevant goods and services or create or increase shortages of such goods and services in the Single market or~~
- (ii) ~~are directly discriminatory based on nationality of the person.~~

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

- (a) ~~applying more generous rules to goods originating from a neighbouring Member State, any other Member State or a group of Member States, as compared to goods originating from other Member States;~~
- (b) ~~selectively refusing the entry of goods originating from specific other Member States to their territory;~~
- (c) ~~introducing prohibitions of the operation of freight transport;~~

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

- (a) ~~banning types of services or modes of service provision;~~
- (b) ~~blocking flows of passenger transport;~~

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

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

- ~~(b)~~**(d)** denying, to beneficiaries of the right of free movement under Union law, of the right to enter the territory of their Member State of nationality or residence, the right to exit the territory of Member States to travel to the Member State of nationality or residence, or the right to transit through a Member State in order to reach the Member State of nationality or residence;
- ~~(e)~~ prohibiting of business travel linked to the research and development, to production, **to placing on the market or to the related inspections** of crisis-related goods that are listed in an implementing act adopted pursuant to Article 14, paragraph ~~35~~ **or their placing on the market or to the related inspections**;
- ~~(f)~~ **prohibiting** ~~imposing prohibitions on travel, including travel~~ for imperative family reasons, **between Member States when such travel is permitted within the Member State in question** which are not appropriate for the achievement of any legitimate public interest purportedly pursued by such measures or which manifestly go beyond what is necessary to achieve that aim;
- ~~(e)~~ ~~imposing restrictions on workers and service providers and their representatives, unless to do so is inherent to the nature of the crisis/Single Market emergency and it does not manifestly go beyond what is necessary for that purpose.~~
- (g) imposing, when travel is possible despite the crisis, travel restrictions on service providers, business representatives and workers, preventing them from travelling between Member States to have access to their place of activity or workplace when there are no such restrictions on travel within the Member State in question;**

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

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

(a) ~~Those service providers that provide crisis-relevant services that are listed in an implementing act adopted pursuant to Article 14 **paragraph 3** (5), or, business representatives and workers that are involved in **the** production of crisis-relevant goods, or **in the** provision of crisis-relevant services that are listed in an implementing act adopted pursuant to Article 14 **paragraph 3** (5) to allow them to have access to the place of their activities, if activities in the sector concerned are still allowed in the Member State; (b), or civil protection workers to allow them to have unhindered access to their place of activity with **or** their equipment in any **to the place** of the Member States: **their activities.**~~

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

Article 18
Supportive measures for free movement of persons

1. During the Single Market emergency mode, **and for the purpose of facilitating free movement of persons under points e, f, g and h of Article 17(1)**, the Commission may provide for supportive measures to reinforce free movement of persons referred to in Article 17(6) and 17(7), by means of implementing acts. ~~Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 422(2). On duly justified imperative grounds of urgency relating to the impacts~~ **adopt administrative arrangements or put at the disposal of the Member States digital tools to facilitate the identification of the categories of persons and verification** of the crisis on the Single Market, ~~facts referred to in those provisions by the Member States in cooperation with the other relevant Member States and~~ the Commission shall adopt immediately applicable implementing acts in accordance with the procedure **to facilitate free movement of persons** referred to in **points e, f, g and h of Article 42(3)-17(1)**.

2. During the Single Market emergency mode, where the Commission establishes that Member States have put in place templates for attesting that the individual or economic operator ~~is a service provider that provides crisis-relevant services, a business representative or worker that is involved in production of crisis-relevant goods or provision of crisis-relevant services or a civil protection worker and~~ **belongs to a category of persons referred to in points e, f, g and h of Article 17(1), and** it considers that the use of different templates by each Member States is an obstacle to the free movement at the time of a Single Market emergency, the Commission may issue, if it considers it necessary for supporting the free movement of such categories of ~~those~~ persons and their equipment during the ongoing Single Market emergency, **the Commission may issue, by means of implementing acts,** templates for attesting that they fulfil the relevant criteria for the application Article 17(6) in **to be used by** all Member States ~~by means of implementing acts~~.

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

Chapter II

Transparency and administrative assistance

Article 19

Notifications

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

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

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

- ~~3. Member States shall use the information system set up for notifications under Directive (EU) 2015/1535 of the European Parliament and of the Council¹⁹ for notifications under this Article.~~

¹⁹ OJ L 241, 17.9.2015, p. 1.

- ~~4.—The Commission shall communicate the notified measures to the other Member States without delay and shall share them at the same time with the advisory group.~~
- ~~5.—If the advisory group chooses to deliver an opinion on a notified measure, it shall do so within four working days from the date of receipt by the Commission of the notification concerning that measure.~~
- ~~6.—The Commission shall ensure that citizens and businesses are informed of the notified measures, unless Member States request that the measures remain confidential, or the Commission deems disclosure of those measures would affect the security and public order of the European Union or its Member States, as well as of the decisions and Member States' comments adopted in accordance with this Article.~~
- ~~7.—Member States shall postpone the adoption of a notified draft measure for 10 days from the date of receipt by the Commission of the notification referred to in this Article.~~
- ~~8.—Within 10 days from the date of receipt of the notification, the Commission shall examine the compatibility of any draft or adopted measure with Union law, including Articles 16 and 17 of this Regulation as well as the principles of proportionality and non-discrimination, and may provide comments on the notified measure when there are immediately obvious and serious grounds to believe that it does not comply with Union law. Such comments shall be taken into account by the notifying Member State. In exceptional circumstances, in particular to receive scientific advice, evidence or technical expertise in the context of an evolving situation, the period of 10 days may be extended by the Commission. The Commission shall set out the reasons justifying any such extension, shall set a new deadline and shall inform the Member States about the new deadline and the reasons for the extension without delay.~~
- ~~9.—Member States may also provide comments to the Member State which has notified a measure; that Member State shall take such comments into account.~~

- ~~10.—The notifying Member State shall communicate the measures it intends to adopt in order to comply with the comments delivered in accordance with paragraph 8 to the Commission within 10 days after receiving them.~~
- ~~11.—If the Commission finds that the measures communicated by the notifying Member State are still not in accordance with Union law, it may issue within 30 days of that communication, a decision requiring that Member State to refrain from adopting the notified draft measure. The notifying Member State shall communicate the adopted text of a notified draft measure to the Commission without delay.~~
- ~~12.—If the Commission finds that an already adopted measure that has been notified to it, is not in accordance with Union law, it may issue within 30 days of that notification a decision requiring the Member State to abolish it. The notifying Member State shall communicate the text of a revised measure in case it modifies the notified adopted measure without delay.~~
- ~~13.—The period of 30 days referred to in paragraphs 11 and 12 may be exceptionally extended by the Commission in order to take account of a change of circumstances, in particular to receive scientific advice, evidence or technical expertise in the context of an evolving situation. The Commission shall set out the reasons justifying any such extension and shall set a new deadline and shall inform the Member States about the new deadline and the reasons for the extension without delay.~~
- ~~14.—The Commission decisions referred to in paragraphs 11 and 12 shall be based on available information and may be issued when there are immediately obvious and serious grounds to believe that the notified measures do not comply with Union law, including Article 16 or 17 of this Regulation, the principle of proportionality or the principle of non-discrimination. The adoption of those decisions shall be without prejudice to the possibility for the Commission to adopt measures at a later stage, including the launching of an infringement procedure on the basis of Article 258 TFEU.~~

- ~~15.— Information supplied under this Article shall not be confidential except at the express request of the notifying Member State. Any such request shall relate to draft measures and shall be justified.~~
- ~~16.— The Commission shall publish the text of the measures adopted by the Member States in the context of the Single market emergency that restrict free movement of goods, services and the persons, including workers, which have been communicated by means of the notifications referred to in this Article as well as via other sources. The text of the measures shall be published within one working day of its receipt by means of an electronic platform managed by the Commission.~~

~~Article 20~~

~~Link to other notification mechanisms~~

- ~~1.— Where a Member State is required to notify a measure under Article 19 of this Regulation and under Article 5(1) of Directive (EU) 2015/1535²⁰, a notification made under this Regulation shall be deemed to have satisfied also the notification obligation set out in Article 5(1) of Directive (EU) 2015/1535.~~
- ~~2.— Where a Member State is required to notify a measure under Article 19 of this Regulation and under Articles 15(7) or 39(5) of Directive 2006/123/EC of the European Parliament and of the Council²¹, a notification made under this Regulation shall be deemed to have satisfied also the notification obligations set out in Directive 2006/123/EC. Similarly the Commission Decisions referred to in Article 19(11) and 19(12) of this Regulation are deemed to be a Decision taken under Article 15(7) of Directive 2006/123/EC for the purposes of that Directive.~~

²⁰ — OJ L 241, 17.9.2015, p. 1

²¹ — OJ L 376, 27.12.2006, p. 36.

3. ~~Where a Member State is required to notify a measure under Article 19 of this Regulation and to inform the Commission in accordance with Article 59(5) of Directive 2005/36/EC of the European Parliament and of the Council²², that notification shall be deemed to have satisfied also the information obligation set out in Article 59(5) of Directive 2005/36/EC.~~

Article 21

Single points of contact in the Member States

1. Member States shall operate national single points of contact that shall provide citizens, consumers, economic operators and workers and their representatives with the following assistance:
- (a) assistance in requesting and obtaining information about national restrictions of the free movement of goods, services, persons and workers that are related to an activated Single Market emergency;
 - (b) assistance in the performance of any national level crisis procedures and formalities that have been put in place due to the activated Single Market emergency.

²² ~~OJ L 255, 30.9.2005, p. 22.~~

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

Article 22
Union level single point of contact

1. The Commission shall set up and operate a Union level single point of contact.
2. The Union level single point of contact shall provide citizens, consumers, economic operators, workers and their representatives with the following ~~assistance~~:
 - (a) assistance in requesting and obtaining information as regards Union level crisis response measures that are relevant to the activated Single Market emergency or which affect the exercise of the free movement of goods, services, persons and workers;
 - (b) assistance in the performance of any crisis procedures and formalities that have been put in place at the Union level due to the activated Single Market emergency;
 - (c) putting together **and publishing** a list with all national crisis measures and national contact points.

TITLE III
SINGLE MARKET EMERGENCY RESPONSE MEASURES

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

Article 23
Requirement of dual activation

1. Binding measures included in this Chapter may be adopted by the Commission by means of implementing acts in accordance with Articles 24(2), **and the** first subparagraph of Article 26 ~~and Article 27(2) may be adopted~~ only after a Single Market Emergency has been activated by means of a Council implementing act in accordance with Article 14.
2. An implementing act introducing a measure included in this Chapter shall clearly and specifically list the crisis-relevant goods and services **referred to in Article 14(3)** to which such measure applies. That measure shall apply only for the duration of the emergency mode.

Article 24
Information requests to economic operators

1. ~~Where there is a severe crisis-related shortages or an immediate threat thereof, the~~ **The** Commission may invite ~~representative organisations or~~ **the relevant** economic operators in crisis-relevant supply chains to transmit on a voluntary basis, within a set time limit, specific information to the Commission on the production capacities and possible existing stocks of crisis-relevant goods and components thereof in Union production facilities and third country facilities which it operates, contracts or purchases supply from, as well as information on any relevant supply chain disruptions, ~~within a given deadline~~ **where:**
- (a) **there are severe shortages of crisis-relevant goods or services or an immediate threat thereof;**
 - (b) **the information sought is strictly necessary for assessing whether any of the measures laid down in Article 26, or Articles 32 to 37 would be capable of reducing such shortages or the threat thereof;**
 - (c) **the information provided through the Board or through other means from the Member States in the contingency or Single Market vigilance mode is not sufficient;**
 - (d) **the Commission is not able to obtain such information from other sources.**
- The Commission shall assess the existence of the conditions referred to in the first subparagraph in cooperation with the Board.**

2. **If no information is transmitted to the Commission on a voluntary basis within the set time limit pursuant to paragraph 1 and if** ~~If the addressees do not transmit the information requested in accordance with~~ **gathered by the Commission, through the requests for information on a voluntary basis pursuant to** ~~paragraph 1 within the time limit,~~ **or from any other sources as listed in the contingency or Single Market vigilance mode, remains insufficient for assessing whether the deployment of the measures laid down in Article 26, or Articles 32 to 37 would allow reducing the severe shortages of crisis-relevant goods or services or the threat thereof** ~~and do not provide a valid justification for not doing so~~ **whether any such measures should be taken**, the Commission may **make a mandatory, request for information**, by means of an implementing act, ~~require that they transmit the information, indicating in the~~.

2a. Before adopting such an ~~implementing act why it is proportionate,~~ **the Commission shall:**

- (a) **assess the necessity** ~~and necessary to do so,~~ **specifying the crisis-relevant goods** ~~the~~ **proportionality of such a mandatory information request for the achievement of the envisaged objectives laid down in paragraph 1(b); and**
- (b) **take due account of the administrative burden, which such a request may entail for the concerned economic operators** ~~and services and~~ **in particular for small and medium-sized enterprises as defined in the Annex of Commission Recommendation 2003/361/EC (SMEs) and modulate the timelines for submitting the information accordingly.**

~~addressees concerned by the information request, and the information that is sought, providing where necessary a template with the questions that may be addressed to the economic operators.~~

3. The information requests referred to in ~~paragraph~~**paragraphs 1 and 2** may **only** concern **targeted** the following **information about**:
- (a) ~~targeted information to the Commission in relation to the production capacities and possible existing stocks of the crisis-relevant goods and components thereof in production facilities located in the Union and production facilities located in a third country which the organisation or the~~ **relevant** operator referred to in ~~paragraph 1~~ operates, contracts or purchases supply from, while fully respecting trade and business secrets;
 - (b) ~~and requiring them to transmit to the Commission a~~ **the** schedule of the expected production output for the following 3 months for production facility located in the Union as well as any relevant supply chain disruptions;
 - (c) ~~other information necessary for assessing the nature or magnitude of a given~~ **any** **relevant** supply chain ~~disruption~~**disruptions** or shortages.

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

- (a) **specify the crisis-relevant goods and services as defined in the list according to Article 14 (3) that are relevant for the information request,**
- (b) **specify the relevant economic operators concerned by the information request,**
- (c) **specify the information that is sought, including providing where necessary a template with the questions that may be addressed to the individual relevant economic operators;**
- (d) **demonstrate the existence of the exceptional need referred to in paragraph 1 point b for which the information are requested;**
- (e) **explain the purpose of the request, the intended use of the information requested, and the duration of that use;**
- (f) **specify the timeline by which the economic operator may ask the Commission to modify the request;**
- (g) **be expressed in a clear, concise and understandable language;**
- (h) **take into account the protection of trade secrets; and**
- (i) **take into account the economic operator's effort required to make the information available on a voluntary basis, especially if it is an SME.**

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

- 4a. When the processing of a mandatory information request by a relevant economic operator has the potential to significantly disrupt its operations, the said economic operator may refuse to supply the requested information. The relevant economic operator shall provide to the Commission the reasons for any refusal to supply requested information. The Commission shall not forward or publish an economic operator's refusal to supply the requested information or their reasoning for doing so.**
- 4b. The Commission shall without delay forward a copy of any request for information referred to in paragraphs 1 and 2 to the competent authority of the Member State in whose territory the economic operator is situated. If the competent authority of the Member States so requires, the Commission shall transmit the information acquired from the respective economic operator in accordance with Union law.**
- 4c. The Commission receiving information pursuant to a request for information referred to in paragraphs 1 and 2 shall:**
- (a) not use the information in a manner incompatible with the purpose for which the information was requested;**
 - (b) have implemented, insofar as the processing of personal data is necessary, technical and organisational measures that preserve the confidentiality and integrity of the requested information, including in particular personal data, as well as safeguard the rights and freedoms of data subjects;**
 - (c) erase the information as soon as they are no longer necessary for the stated purpose and inform the economic operator and the relevant competent authority of the Member State without undue delay that the information has been erased unless archiving of the information is required for transparency purposes in accordance with national law.**

5. The Commission ~~D~~decisions containing individual information requests **adopted pursuant to paragraph 4** shall contain a reference to the implementing act referred to in paragraph 2 on which they are based and to the situations of severe crisis-related shortages or an immediate threat thereof which has given rise to them. Any information request shall be duly justified and proportionate in terms of the volume, nature and granularity of the data, as well as the frequency of access to the data requested, and shall be necessary for the management of the emergency ~~or for compiling relevant official statistics.~~ A request shall set out a reasonable time limit **not exceeding 20 working days** within which the information is ~~or the~~ **justification for the refusal to supply such information are** to be provided. ~~#~~**When setting this time limit the Commission** shall **in particular take into consideration the size of the undertaking concerned in terms of employees.** ~~take into account the effort required to collect and make the data available by the economic operator or representative organisation.~~ The ~~formal~~ decision shall also contain safeguards for protection of data in accordance with Article 39 of this Regulation, safeguards for non-disclosure of sensitive business information **and trade secrets** contained in the reply in accordance with Article ~~40 a~~**25**, and information on the possibility of contesting it before the Court of Justice of the European Union in line with relevant Union law and the fines provided for in Article 28 for failure to comply and the timeline for a reply.
6. ~~The owners of the~~**Relevant** economic operators **or anyone duly authorised to represent the economic operator** ~~or their representatives and, in the case of legal persons, companies or firms, or associations having no legal personality, the persons authorised to represent them by law or by their constitution~~ may supply the information requested on behalf of the economic operator ~~or the association of economic operators concerned.~~ Each **relevant** economic operator ~~or association of economic operators~~ shall provide the requested information on an individual basis in line with the Union rules on competition governing the exchange of information. ~~Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.~~

7. — ~~The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed a mandatory information request to an economic operator.~~
8. The implementing acts referred to in paragraph 2 shall be adopted in accordance with the ~~committee~~ **examination** procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

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

Article 25

Confidentiality and processing of the information

1. — ~~Information received as a result of the application of this Regulation shall be used only for the purpose for which it was requested.~~
2. — ~~Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive and confidential information acquired and generated in application of this Regulation, including recommendations and measures to be taken, in accordance with Union and the respective national law.~~
3. — ~~Member States and the Commission shall ensure that classified information provided or exchanged under this Regulation is not downgraded or declassified without the prior written consent of the originator.~~
4. — ~~The Commission may present to the advisory group referred to in Article 4 aggregate information based on any information collected pursuant to Article 24.~~
5. — ~~The Commission shall not share any information in a way that can lead to the identification of an individual operator when the sharing of the information results in potential commercial or reputational damage to this operator or in divulging any trade secrets.~~

Article 26
Targeted amendments to harmonised product legislation

When the Single Market emergency mode has been activated by means of a Council implementing act adopted pursuant to Article 14, and there is a shortage of crisis-relevant goods the Commission may activate by means of implementing acts the emergency procedures included in the Union legal frameworks amended by [Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 ~~and introducing~~ **as regards** emergency procedures for the conformity assessment, adoption of common specifications and market surveillance ~~in the context of~~ **due to** a Single Market emergency and Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, and 2014/68/EU ~~and introducing~~ **as regard** emergency procedures for the conformity assessment, adoption of common specifications and market surveillance ~~in the context of~~ **due to** a Single Market **emergency**]²³ as regards crisis-relevant goods, indicating which crisis-relevant goods and emergency procedures are subject to the activation, providing reasons for such activation and its proportionality, and indicating the duration of such activation.

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

²³ **Discussions on these proposals ongoing in the Council preparatory bodies.**

Article 27
Priority rated orders

1. — ~~The Commission may invite one or more economic operators in crisis-relevant supply chains established in the Union to accept and prioritise certain orders for the production or supply of crisis-relevant goods ('priority rated order').~~
2. — ~~If an economic operator does not accept and prioritise priority rated orders, the Commission may, at its own initiative or at the request of 14 Member States, assess the necessity and proportionality of resorting to priority rated orders in such cases, the Commission shall give the economic operator concerned as well as any parties demonstrably affected by the potential priority rated order, the opportunity to state their position within a reasonable time limit set by the Commission in light of the circumstances of the case. In exceptional circumstances, following such an assessment, the Commission may address an implementing act to the economic operator concerned, requiring it to either accept and prioritise the priority rated orders specified in the implementing act or explain why it is not possible or appropriate for that operator to do so. The Commission's decision shall be based on objective data showing that such prioritisation is indispensable to ensure the maintenance of vital societal economic activities in the Single Market~~
3. — ~~Where the economic operator to which the decision referred to in paragraph 2 is addressed accepts the requirement to accept and prioritise the orders specified in the decision, that obligation shall take precedence over any performance obligation under private or public law.~~
4. — ~~Where the economic operator to which the decision referred to in paragraph 2 is addressed declines to accept the requirement to accept and prioritise the orders specified in the decision, it shall provide to the Commission, within 10 days from the notification of the decision, a reasoned explanation setting out duly justified reasons why it is not possible or appropriate, in light of the objectives of this provision, for it to comply with the requirement. Such reasons include the inability of the operator to perform the priority rated order on account of insufficient production capacity or a serious risk that accepting the order would entail particular hardship or economic burden for the operator, or other considerations of comparable gravity.~~

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

5. When an economic operator established in the Union is subject to a measure of a third country which entails a priority rated order, it shall inform the Commission thereof.
6. The Commission shall take the decision referred to in paragraph 2 in accordance with applicable Union law, including the principles of necessity and proportionality, and the Union's obligations under international law. The decision shall in particular take into account the legitimate interests of the economic operator concerned and any available information concerning the cost and effort required for any change in production sequence. It shall state the legal basis for its adoption, fix the time limits within which the priority rated order is to be performed and, where applicable, specify the product and quantity. It shall state the fines provided for in Article 28 for failure to comply with the decision. The priority rated order shall be placed at a fair and reasonable price.
7. Where an economic operator accepts and prioritises a priority rated order, it shall not be liable for any breach of contractual obligations governed by the law of a Member State that is required to comply with the priority rated order. Liability shall be excluded only to the extent the violation of contractual obligations is necessary for compliance with the required prioritisation.
8. The implementing acts referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).

Article 28

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

1. The Commission may, by means of a decision, where deemed necessary and proportionate, impose fines:
 - (a) ~~where a representative organisation of economic operators or an economic operator, intentionally or through gross negligence, supplies incorrect, incomplete or misleading information in response to a **mandatory** request made pursuant to **a decision referred to in Article 24 (4)**, or does not supply the information **which it had accepted to provide, or does not supply a justification for not providing the requested information** within the **time limit** prescribed ~~time limit~~ **in the decision referred to in Article 24(4)**;~~
 - (b) ~~where an economic operator, intentionally or through gross negligence, does not comply with the obligation to inform the Commission of a third country obligation pursuant to Article 27 or fails to explain why it has not accepted a priority rated order;~~
 - (c) ~~where an economic operator, intentionally or through gross negligence, does not comply with an obligation which it has accepted to prioritise certain orders of crisis relevant goods ('priority rated order') pursuant to Article 27~~
2. Fines imposed in the cases referred to in paragraph 1 (a) ~~and (b)~~ shall not exceed **1200 000 EUR. If the concerned economic operator is an SME, the fines imposed shall not exceed EUR 50 000.**
3. ~~Fines imposed in the cases referred to in paragraph 1 (c) shall not exceed 1 % of the average daily turnover in the preceding business year for each working day of non-compliance with the obligation pursuant to Article 27 (priority rated orders) calculated from the date established in the decision not exceeding 1% of total turnover in the preceding business year.~~

4. In fixing the amount of the fine, regard shall be had to the size and economic resources of the economic operator concerned, to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness.
5. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine. It may cancel, reduce or increase the fine imposed.

Article 29
Limitation period for the imposition of fines

1. The Commission power to impose fines in accordance with Article ~~30~~**28** shall be subject to the following limitation periods:
 - (a) two years in the case of infringements of provisions concerning **mandatory** requests of information **made** pursuant to **the decision referred to in** Article 24**(4)**;
 - ~~(b) three years in the case of infringements of provisions concerning the obligation to prioritise the production of crisis-relevant goods pursuant to Article 26(2).~~
2. The time shall begin to run on the day on which the Commission becomes aware of the infringement. However, in case of continuous or repeated infringements, time shall begin to run on the day on which the infringement ceases.
3. Any action taken by the Commission or the competent authorities of the Member States for the purposes of ensuring compliance with the provisions of this Regulation shall interrupt the limitation period.

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

Article 30
Limitation periods for enforcement of fines

1. The power of the Commission to enforce decisions taken pursuant to Article 28 shall be subject to a limitation period of **three**five years.
2. Time shall begin to run on the day on which the decision becomes final.
3. The limitation period for the enforcement of fines shall be interrupted:
 - (a) by notification of a decision varying the original amount of the fine or refusing an application for variation;
 - (b) by any action of the Commission or of a Member State, acting at the request of the Commission, designed to enforce payment of the fine.

- (4.) Each interruption shall start time running afresh.
- (5.) The limitation period for the enforcement of fines shall be suspended for so long as:
- (a) time to pay is allowed;
 - (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union.

Article 31
Right to be heard for the imposition of fines

1. Before adopting a decision pursuant to Article 28, the Commission shall give the economic operator ~~or representative organisations of economic operators~~ concerned the opportunity of being heard on:
 - (a) preliminary findings of the Commission, including any matter to which the Commission has taken objections;
 - (b) measures that the Commission may intend to take in view of the preliminary findings pursuant to point (a) of this paragraph.
2. ~~Undertakings and representative organisations of e~~Economic operators concerned may submit their observations to the Commission's preliminary findings within a time limit which shall be fixed by the Commission in its preliminary findings and which may not be less than 21 days.

3. The Commission shall base its decisions only on objections on which economic operators ~~and representative organisations of economic operators~~ concerned have been able to comment.
4. The rights of defence of the **relevant** economic operator ~~or representative organisations of economic operators~~ concerned shall be fully respected in any proceedings. The **relevant** economic operator ~~or representative organisations of economic operators~~ concerned shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of economic operators in the protection of their business secrets. The right of access to the file shall not extend to confidential information and internal documents of the Commission or the authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and the authorities of the Member States. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

Chapter II

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

Article 32

*Coordinated distribution of ~~strategic reserves~~ **crisis-relevant goods and services***

Where the ~~strategic reserves~~ constituted by the **Commission is informed that crisis-relevant goods and services are insufficient in a** Member States in accordance with Article 12 ~~prove to be insufficient~~ **State** to meet the needs related to the Single Market emergency, the Commission, taking into consideration the opinion provided by the ~~advisory group~~ **Board and the information collected under this Regulation**, may recommend to the ~~other~~ **other** Member States to distribute the ~~strategic reserves~~ **these crisis-relevant goods or services** in a targeted way, where possible, having regard to the need not to further aggravate disruptions on the Single Market, including in geographical areas particularly affected by such disruptions and in accordance with the principles of necessity, proportionality and solidarity and establishing the most efficient use of ~~reserves~~ **crisis-relevant goods and services** with a view to ending the Single Market emergency.

Article 33

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

1. **Where the** ~~The Commission may, when it considers~~ **is informed** that there is a risk of a shortage of crisis-relevant goods **and services in a Member State to meet the needs related to the Single Market emergency, it may, taking into consideration the opinion by the Board,** recommend that Member States ~~implement~~ **take** specific measures ~~to~~. **Those measures shall** ensure the efficient re-organisation of supply chains and production lines and ~~to the use of~~ **existing stocks to increase the availability and supply of crisis-relevant goods and services, as quickly as possible. When issuing its recommendations, the Commission shall consider the impact on economic operators of the measures recommended.**

2. In particular, the measures referred to in paragraph 1 may include measures:
 - (a) facilitating the expansion or repurposing of existing or the establishment of new production capacities for crisis-relevant goods;
 - (b) facilitating the expansion of existing or the establishment of new capacities related to service activities;
 - (c) aiming at accelerating ~~permitting~~ **relevant approval and authorisation procedures, including environmental permits, regarding or affecting the production and distribution** of crisis-relevant goods;
 - (d) **aiming at accelerating relevant product approval procedures in view of placing on the market crisis-relevant goods that are not subject to any Union legislation harmonising the conditions for the marketing of products.**

Part V
ProcurementPublic procurement

CHAPTER I
ProcurementPublic procurement of goods and services of strategie critical importance and crisis-relevant goods and services by the Commission on behalf of Member States during vigilance and emergency modes

[Article 34

Request of Member States to the Commission to procure goods and services on their behalf

1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing, **or renting,** of goods and services of **strategie critical importance** listed in an implementing act adopted pursuant to Article 9(1) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(~~35~~).
2. The Commission shall assess **without delay,** the utility, necessity and proportionality of the request. **If the Commission decides to launch a procurement on behalf of the Member States, it shall inform all Member States and the Board of its intention to carry out the procurement and invite the interested Member States to participate.** Where the Commission intends not to follow the request, it shall inform the Member States ~~concerned~~ and the ~~advisory group~~**Board** referred to in Article 4 and give reasons for its refusal.
3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for ~~an~~ **framework**-agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions, **including the proposed maximum quantities, the conditions of the common purchasing or renting, including prices, and delivery timeframes,** for the procurement on behalf of the participating Member States referred to in paragraph 1.

3a. If the Commission cancels the procurement procedure in accordance with Article 171 of the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council²⁴ (Financial Regulation) , the Commission shall immediately inform the participating Member State thereof, so that the participating Member States can initiate their own procurement procedure without delay.

Article 35

Establishment and implementation of the negotiating mandate of the Commission

1. The agreement referred to in Article 34(3) shall establish a negotiating mandate for the Commission to ~~act as a central purchasing body~~ **contract on behalf of the participating Member States** for relevant goods and services of ~~strategic~~ **critical** importance or crisis-relevant goods and services on behalf of the participating Member States through the conclusion of new contracts.
2. In accordance ~~with the~~ **line** with ~~the~~ **this** agreement, the Commission ~~may~~ **shall** be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of ~~strategic~~ **critical** importance or crisis-relevant goods and services, concerning the purchase **or renting** of such goods or services.
3. ~~Representatives of the Commission or experts nominated by the Commission may carry out on-site visits at the locations of production facilities of relevant goods of strategic importance or crisis-relevant goods.~~
4. **Without prejudice to Article 171 of the Financial Regulation, the** The Commission shall carry out the procurement procedures and **award and** conclude the resulting contracts ~~with~~ **to** economic operators on behalf of the participating Member States.

²⁴ **Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).**

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

4b. All participating Member States shall be associated to the procurement procedure via their representatives.

Where the Commission intends to conclude a contract concerning the purchase or renting of goods and services of critical importance or crisis-relevant goods and services, it shall inform the participating Member States of such intention and the detailed terms. The participating Member States shall have the opportunity to express their comments on the draft contract.

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

Article 36

Modalities of procurement by the Commission on behalf of the Member States

1. Procurement under this Regulation shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council²⁵ for its own procurement.

²⁵ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (*OJ L 193, 30.7.2018, p. 1*).

2. The contracts may include a clause stating that a Member State which has not participated in the procurement procedure may become a party to the contract after it has been signed, laying out in detail the procedure for doing so and its effects. When duly justified by the extreme urgency or when strictly necessary in order to adapt to unforeseen circumstances in the evolution of the Single Market emergency, and provided the modification does not substantially alter the subject matter of the contract or agreement, the Commission may:

- (a) in agreement with the contractor, modify the contract which has been signed, beyond the threshold of 50% and up to 100% of the initial contract value, provided that this is justified as strictly necessary to respond to the evolution of the Single Market emergency,
- (b) in common agreement with the participating Member States, allow other Member States to join a signed contract for procurement by the Commission on behalf of the Member States provided that this is justified as strictly necessary to respond to the evolution of the Single Market emergency.

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

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

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

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

CHAPTER II

Joint Procurement during vigilance and emergency modes

Article 37

Joint procurement procedure

Where it is necessary to carry out a joint procurement between the Commission and one or more contracting authorities from **the participating** Member States in accordance with the rules set out in Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, the Member States may acquire, rent or lease fully the capacities jointly procured.²⁶

²⁶ This sentence will stay as long as the recast Financial Regulation does not enter into force before this Regulation.

Chapter III

Procurement by the Member States during the emergency mode

Article 38

Consultation and coordination regarding individual procurement by the Member States

When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall **make best efforts to** consult each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the ~~advisory group~~ **Board** prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(35) in accordance with Directive 2014/24/EU of the European Parliament and of the Council²⁷. **The Commission shall make best efforts to inform the Board of any information it obtains to support this coordination.**

Article 39

Member States Ban of individual procurement action by participating

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

²⁷ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (*OJ L 94, 28.3.2014, p. 65*).

Part VI

Final provisions

Article 40

Personal data protection

1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) ~~No~~ 2018/1725, when fulfilling their responsibilities.
2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of this Regulation. In such cases, the conditions of Regulation (EU) ~~No~~ 2016/679 and Regulation (EU) ~~No~~ 2018/1725 shall apply as appropriate.
3. Where processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.

Article 40a
Confidentiality and processing of the information

- 1. Information received as a result of the application of this Regulation shall be used only for the purpose for which it was requested.**
- 2. Member States and the Commission shall ensure the protection of trade and business secrets and other sensitive and confidential information acquired and generated in application of this Regulation, including recommendations and measures to be taken, in accordance with Union and national law.**
- 3. Member States and the Commission shall ensure that classified information provided or exchanged under this Regulation is not downgraded or declassified without the prior written consent of the originator.**
- 4. The Commission shall not share any information in a way that can lead to the identification of an individual operator when the sharing of the information results in potential commercial or reputational damage to this operator or in divulging any trade secrets.**

Article 41
Digital tools

Where the existing tools or IT infrastructures are not fit for purpose, the ~~The~~ Commission and the Member States may **enhance or** set up interoperable digital tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures may **also be enhanced or** developed ~~outside the duration of the~~ **during a** Single Market Emergency.

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

Article 41a

Scientific information collection for the application of the regulation

Where necessary for the application of this Regulation, the Commission shall ask and obtain from relevant Union bodies, agencies and Committees any relevant specialised or scientific knowledge.

Article 42
Committee

1. The Commission shall be assisted by a Single Market Emergency Instrument Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 43
Delegated acts

- ~~1.—The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.~~
- ~~2.—The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.~~
- ~~3.—The delegation of power referred to in Article 6 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.~~

4. ~~Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.~~
5. ~~As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.~~

Article 444
Report and review

1. By [*OP: please insert date = [five] years from the entry into force of this Regulation*] ~~and every five years thereafter,~~ **and by [18] months after every deactivation of the Single Market vigilance and/or emergency mode,** the Commission shall present a report, **including an evaluation,** to the European Parliament and the Council on the functioning of the contingency planning, **Single Market** vigilance and Single Market emergency response systems suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.
2. This report shall include **amongst others:**
- (a) an evaluation of the contribution of this Regulation to the smooth and efficient functioning of the Single market, in particular as regards the free movement of goods, services and persons and the avoidance of divergent national measures which would create cross-border restrictions;**
 - (b) an evaluation of the work functioning of the advisory group this Regulation under the contingency, vigilance and emergency framework established by this Regulation modes.**
 - (c) an assessment of the operation of the Board,** and its relation to the work of other relevant Union level crisis management bodies, **in particular the IPCR, HERA, UCPM;**
 - (d) an evaluation of the application of the proportionality and necessity principles to the binding market intervention measures referred to in Article 24.**

Article 45
Repeal

~~Council Regulation (EC) No. 2679/98 is repealed with effect from [date].~~

Article 46
Entry into force

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

It shall apply from [18 months after the entry into force].

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President