

Council of the European Union

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NOTE

From:	Presidency
To:	Delegations
No. prev. doc.:	12573/22
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
	- Presidency compromise text

In view of the upcoming Working Party for Competitiveness and Growth (Internal Market) on

31 March 2023, delegations will find in Annex to this note a Presidency compromise text.

Changes compared to the proposal (doc. 12573/22) are marked in **<u>bold and underlined</u>** for the new text and in strikethrough for deletions.

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 4546 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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² OJ C , , p. .

Whereas:

- Past crises, especially the early days of the COVID-19 pandemic, have shown that the free (1)movement on the internal market (also referred to as the "Single Market") and its supply chains can be severely affected by such crises, and. This may have consequences on crossborder 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 arewere either lacking, diddo not cover all aspects of the Single market or **did**do not allow for a timely response to such **barriers and** impacts.
- In the early phase of the COVID-19 pandemic Member States introduced barriers to (2)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 andwere insufficient. Measures to ensure the availability of crisis-relevant non-medical goods during the COVID-19 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 in regard to the COVID-19 crisis, while Member States acted independently in other situations. However, actionsActions by the Commission were delayed by several weeks due to the lack of any Union wide contingency planning measures and ofclarity 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 by the crisis. In addition it became clearappeared that uncoordinated restrictive actions and measures taken by the Member States actually did or would further aggravate the impacts of the crisis on the Single market. It emerged that there is a need for arrangements between the Member States and Union authorities as regards contingency planning, technical level coordination and cooperation and information exchange.

- Representative organisations of economic operators have suggested that economic operators (4) 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 oncould 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 internal 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. Onon the one hand, a crisis can lead to obstacles to free movement within the Single Market, thus disrupting its normalproper functioning. On the other hand, a crisis which has caused such obstacles can amplify shortages of crisis-relevant goods and services on the Single Market. 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 bothaddresses these types of impacts on the Single Market.
- (6a) In order to avoid unneccessary 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 in the maintenance of vital societal or economic activities in the Single Market.

- Since any specific aspects of future crises that would impact the Single Market and its supply (7)chains are hard to predict, this Regulation should provide for a general framework for anticipating, preparing for, mitigating and minimising the negative impacts which any crisis may cause on the Single Market and its supply chains.-
- The framework of measures set out under this Regulation should be deployed in a coherent, (8) 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.
- (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, building on on-going analysis concerning strategically important areas of the Single Market economy and the Union's continuous foresight work.
- (11) This Regulation should not duplicate the existing framework for medicinal products, medical devices or other medical counter-measures under the EU Health Security Framework, including Regulation (EU) .../... on serious cross-border health threats [SCBTH Regulation (COM/2020/727)], Council Regulation (EU) .../... on a framework of measures for ensuring the supply of crisis-relevant medical counter-measures [Emergency Framework Regulation (COM/2021/577)], Regulation (EU) .../... on the extended mandate of the ECDC [ECDC Regulation (COM/2020/726)] and Regulation (EU) 2022/123 on the extended mandate of the EMA [EMA Regulation]. Therefore, medicinal products, medical devices or other medical counter-measures, when they have been placed on the list referred to in Article 6(1) of the Emergency Framework Regulation, shall be excluded from the scope of this Regulation, except in relation to the provisions relating to free movement during the Single Market emergency, and in particular those designed to re-establish and facilitate free movement as well as the notification mechanism.
- (12) This Regulation should complement the Integrated Political Crisis Response mechanism operated by the Council under Council Implementing Decision (EU) 2018/1993 as regards its work on Single Market impacts of cross-sectoral crises that require political decision-making.
- (13) This Regulation should be without prejudice to the Union Civil Protection Mechanism ('UCPM'). This Regulation should be in complementarity with the UCPM and should support it, where neessary, as regards availability of critical goods and free movement of civil protection workers, including their equipment, for crises that fall into the remit of that mechanism.

- (14) This Regulation should be without prejudice to Articles 55 to 57 of Regulation (EC) No 178/2002 on the general plan on crisis management in the area of food and feed, implemented by Commission Decision (EU) 2019/300.
- (15) The Regulation should be without prejudice to the European Food Security Crisis preparedness and response Mechanism (EFSCM). Nevertheless, food products should be governed by the <u>free movement</u> 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 <u>EUUnion</u> law.
- (15a) This Regulation is without predjudice 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.
- (16) In order to account for the exceptional nature of and potential far-reaching consequences for the fundamental operation of the Singe Market of a Single Market emergency 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 emergency mode pursuant to Article 281(2) of the Treaty on the Functioning of the European Union. 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 intrinsincally 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.

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- (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 <u>Member States</u> 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/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 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.
- (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. 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 free movement 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.

- (21) To ensure full transparency of crisis-relevant free movement restrictions adopted by <u>Member States during a Single Market emergency, it is appropriate that the The</u> activation of the Single Market emergency mode<u>should trigger_triggers</u> an obligation for the Member States to notify<u>erisis-relevant free movement such</u> restrictions. <u>Also, to avoid</u> <u>additional efforts by Member States in the time of crisis, the notifications in accordance</u> with this Regulation should be considered as fulfilling the notification obligations laid down in Directive (EU) 2015/1535, Directive 2006/123/EC, and Directive 2005/36/EC, Directive (EU) 2018/958, on condition that the information provided in this notification meets the requirement of those directives. Therefore, it is possible for Member States to notify the restrictions only once through the information system set up for notifications under Directive (EU) 2015/1535.</u>
- (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 crisisrelevant goods or services that such measures apply to.
- (24) Furthermore, in order to ensure the proportionality of the implementing acts and due respect for the role of economic operators in crisis management, the Commission should only resort to the activation of the Single Market emergency mode, where economic operators are not able to provide a solution on a voluntary basis within a reasonable time. Why this is the case should be indicated in each such act, and in relation to all particular aspects of a crisis.

I(25) Information requests to economic operators should be used by the Commission only where the information which is necessary for responding adequately to the Single Market emergency, such as information necessary for procurement by the Commission on behalf of the Member States or estimating the production capacities of manufacturers of crisis-relevant goods the supply chains of which have been disrupted, cannot be obtained from publicly available sources or as a result of information provided voluntarily.

<u>OR</u>

(25) Information requests to economic operators should be used by the Commission only where the information which is necessary for responding adequately to the Single Market emergency, such as information necessary for procurement by the Commission on behalf of the Member States or estimating the production capacities of manufacturers of crisis-relevant goods the supply chains of which have been disrupted, cannot be obtained from publicly available sources or as a result of information provided voluntarily. When activating a mandatory structured 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 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 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.]

(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 be only valid on the territory of the issuing Member State and limited to the duration of the Single Market emergency. In addition, in order to facilitate the increase in supply of crisis-relevant products, certain flexibilities should be introduced with respect to the mechanism of presumption of conformity. In the context of a Single Market emergency, the manufacturers of crisis-relevant goods should be able to rely also on national and international standards, which provide an equivalent level of protection to the harmonised European standards. In cases where the later do not exist or the compliance with them is rendered excessively difficult by the disruptions to the Single Market, the Commission should be able to issue common technical specifications of voluntary or of mandatory application in order to provide ready-to-use technical solutions to the manufacturers.]

16

- (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 2014/35/EU, Directive 2014/53/EU, Directive 2014/68/EU, Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) 305/2011. The activation of the emergency procedures should be conditional upon the activation of the Single Market emergency and should be limited to the products designated as crisis-relevant goods.]
- (28) In cases where there are substantial risks to the functioning of the Single Market or in cases of severe shortages or an exceptionally high demand of goods of strategic <u>critical</u> importance, measures at Union level aimed to ensure the availability of crisis-relevant products, such as priority rated orders, may prove to be indispensable for the return to the normal functioning of the Single Market.
- (29) In order to leverage the purchasing power and negotiating position of the Commission during the Single Market vigilance mode and the Single Market emergency mode, Member States should be able to request the Commission to procure on their behalf.

- (30) Where there is a severe shortage of crisis-relevant products or services on the Single market during a Single Market emergency, and it is clear that the economic operators that operate on the Single market do not produce any such goods, but would in principle be able to repurpose their production lines or would have insufficient capacity to provide the goods or services needed, the Commission should be able to recommend to the Member States as a last resort to take measures to facilitate or request the ramping up or repurposing of production capacity of manufacturers or the capacity of the service providers to provide crisis-relevant services. In doing so the Commission would inform the Member States as to the severity of the shortage and the type of the crisis-relevant goods or services that are needed and would provide support and advice in relation to the flexibilities in the EU acquis for such purposes.
- (31) The measures ensuring regulatory flexibility would allow the Commission to recommend that Member States accelerate the procedures for granting permits that would be necessary for enhancement of the capacity to produce crisis-relevant goods or provide crisis-relevant services.
- (32) Additionally, to ensure that crisis relevant goods are available during the Single Market emergency, the Commission may invite the economic operators that operate in crisis relevant supply chains to prioritise the orders of inputs necessary for the production of final goods that are crisis relevant, or the orders of such final goods themselves. Should an economic operator refuse to accept and prioritise such orders, following objective evidence that the availability of crisis relevant goods is indispensable, the Commission may decide to invite the economic operators concerned to accept and prioritise certain orders, the fulfilment of which will then take precedence over any other private or public law obligations. In the event of failure to accept, the operator in question should explain its legitimate reasons for declining the request. The Commission may make such reasoned explanation or parts of it public, with due regard to business confidentiality.

- (33) Furthermore, to ensure availability of crisis-relevant goods during the Single Market emergency, the Commission may recommend that Member States distribute strategic reserves<u>those crisis-relevant goods and services</u>, 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 Council³ and Regulation (EU) 2016/679 of the European Parliament and of the Council⁴.
- (35) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the possibility to adopt supportive measures for facilitating free movement of persons..., for establishing a list of individual targets (quantities and deadlines) for those strategic reserves that the Member States should maintain, so that the objectives of the initiative are achieved.Furthermore, implementing powers should be conferred on the Commission as regards activating the vigilance mode and vigilance measures in order to carefully monitor the strategic supply chains-and coordinate the building up of strategic reserves for goods and services of strategic importance... Moreover, implementing powers should be conferred on the Commission as regards activation of specific emergency response measures at the time of a Single Market emergency, to allow for a rapid and coordinated response. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

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³ 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).

⁴ Regulation (EU) 2016/769 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (OJ L 119, 4.5.2016, p. 1).

- (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 2628 of the Charter and the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter. Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. The Regulation should not affect the autonomy of the social partners as recognised by the TFEU.
- (36a) This Regulation is without predjudice to the right of collective bargaining and action under Article 28 of the Charter of Fundamental Rights of the European Union, 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.

(36b) 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.

(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.

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20

- (38) The Union framework shall include interregional elements to establish coherent, multisectoral, 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 <u>contingency</u> framework of erisis 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.

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HAVE ADOPTED THIS REGULATION:

21

Part I General Provisions

TITLE I Scope

Article 1 Subject matter<u>and objectives</u>

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

<u>1a.</u> The framework referred to in paragraph 1 aims at:

<u>-</u> safeguarding <u>and facilitating</u> the free movement of goods, services and persons-<u>and of</u>, <u>including workers</u>,

<u>-</u> ensuring the availability of goods and services of strategic <u>critical</u> importance and crisisrelevant goods and services in the Single Market<u>- where the Member States have adopted</u> <u>or are likely to adopt divergent measures which lead to cross-border restrictions, and</u>

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

- 2. The measures<u>framework</u> referred to in paragraph 1 include<u>includes</u>, in particular the <u>following</u>:
 - (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;

22

- (c) contingency measures aiming at <u>for the</u> anticipation and planning; <u>(Single Market</u> <u>contingency planning);</u>
- (d) <u>vigilance</u> measures for addressing <u>Single Market the</u> impacts of <u>significant incidentsa</u> <u>crisis</u> that have not yet resulted in a<u>has the potential to escalate into a</u> Single Market emergency (Single Market vigilance), <u>including a set of vigilance measures and within</u> <u>the next six months</u>;
- (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 by the Commission on behalf of Member States during vigilance and emergency <u>modes.</u>
- 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

- The measures set out in this Regulation apply in relation to significant impacts of a crisis on the functioning of the Single Market and its supply chains. goods, services and persons, including workers.
- 2. This Regulation shall not apply to the following:
 - (a) medicinal products as defined in Article <u>21</u>, paragraph <u>1 point</u> 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 Council⁵;
 - (c) other medical countermeasures as defined in Article 3, point (8), of Regulation (EU)
 .../... on Serious Cross-Border Threats to Health [the SCBTH Regulation]⁶ 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 countermeasures⁷;
 - (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)⁸:
 - (e) energy products as defined in Article 2, paragraph 1, of Directive 2003/96/EC⁹, 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:

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⁵ 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.*

⁶ [reference to adopted Act to be inserted once available]

⁷ [reference to adopted Act to be inserted once available]

⁸ [reference to adopted Act to be inserted once available]

⁹ OJ L 283, 31.10.2003, p. 51.

- (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.
- (g)defence-related products as defined in Article 3 paragraph 1 of Directive2009/43/EC of the European parliament and the Council of 6 May 2009 simplifyingterms and conditions of transfers of defence-related products within theCommunity, or as defined by national legislation in the Member States.
- By way of derogation from paragraph 2, points (a), (b) and (c), Articles 16 to 20 and Article
 41 of this Regulation shall apply to the products referred to in those points-.
- 4. This Regulation is without prejudice to <u>other Union legal acts regulating other aspects</u> <u>than the subject-matter of this Regulation or specifying and complementing this</u> <u>Regulation, in particular the following:</u>
 - (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 1313/132013/EU; and
 - (b) the general plan on crisis management in the area of food and feed in accordance with Regulation (EC) No 178/2002-:
 - (c)Regulation (EU) 2016/399 of the European Parliament and of the Council of 9March 2016 on a Union Code on the rules governing the movement of personsacross borders (Schengen Borders Code) and its notification system for draftmeasures for reintroduction of internal border controls under that Regulation;

- (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 Council¹⁰.
- This Regulation is without prejudice to Union competition rules (Articles 101 to 109 TFEU 5. and implementing regulations), including antitrust, merger and State aid rules.

This Regulation is without prejudice to the Council Decision 2014/415/EU establishing 5a. the Integrated Political Crisis Response Arrangements (IPCR), including the political coordination role of the IPCR.

- 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 Council¹¹.
- 7. Any actions under this Regulation shall be consistent with Union's obligations under international law.

¹⁰ OJ L 83, 27.3.2015, p. 34.

¹¹ OJL 83, 27.3.2015, p. 34.

- 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.
- Any actions under this Regulation shall not affect the exercise of fundamental rights as <u>8a.</u> recognized by the Charter of Fundamental Rights of the European Union (the <u>'Charter').</u>
- This Regulation complements the Union Civil Protection Mechanism, supporting it, **8**b. where necessary, as regards availability of critical goods and free movement of civil protection workers, including their equipment, for the crisis that fall into the remit of that mechanism.
- This Regulation complements the Integrated Political Crisis Response mechanism 8c. 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 political decision making with technical level expertise, contingency planning and implementation of vigilance and emergency measures.
- Articles 16-20 of this Regulation apply as regards food products. The measures 8d. concerning food products notified under this Regulation may also be reviewed for their compliance with any other relevant provisions of Union law.

8e. [Critical Raw Materials Act]

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;
- (2) 'Single Market vigilance mode' means-vigilance' refers to situation where there is a possible framework for addressing a threat of significant disruption of caused by a crisis with respect to the supply of goods and services of strategie critical importance and which has the potential to escalate into a Single Market emergency within the next six months;
- (3) 'Single Market emergency' means a wide-ranging <u>negative</u> impact of a crisis on the Single Market that severely disrupts the free movement on the Single Market or the functioning of the supply chains that are indispensable in the maintenance of vital societal or economic activities in the Single Market; 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 public security, public safety, public order or public health, and the disruption, failure, loss or destruction of which would have a significant impact on the functioning of the Single Market;

- (5) 'goods and services of strategic<u>critical</u> importance' means goods and services that are indispensable for ensuring the functioning of the Single Market in strategically important areas and which cannot be substituted or diversified;
- (6) 'crisis-relevant goods and services' means goods and services that are indispensable for responding to the crisis or for addressing the impacts of the crisis on the Single Market during a Single Market emergency;
- (7) 'strategic reserves' means a stock of goods of strategic importance for which building a reserve may be necessary to prepare for a Single Market emergency, under the control of a Member State.

TITLE II Governance

Article 4 Advisory groupSingle Market Emergency Board

- An advisory group <u>A Single Market Emergency Board</u> is established., hereinafter the <u>Board.</u>
- The advisory group Board shall be composed of one representative from each Member Stateand one representative from the Commission. Each Member State shall nominate appoint a representative and an alternate representative.
- 3. The Commission <u>representative</u> shall chair the <u>advisory groupBoard</u> and ensure its secretariat. The Commission <u>representative</u> may invite a representative of the European Parliament, representatives of EFTA States that are contracting parties to the Agreement on the European Economic Area¹², representatives of economic operators, stakeholder organisations, social partners and experts, to attend <u>specific</u> meetings of the <u>advisory groupBoard</u> as observers, <u>where such attendance is relevant considering the agenda of the meeting</u>. It shall invite the representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the <u>advisory group.Board</u>.
- 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.

¹² OJ L 1, 3.1.1994, p. 3.

<u>Article 4a</u> <u>Tasks of the Board</u>

- <u>14</u>. 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 erisis protocolscontingency framework;
 - (b) assessingment of significant <u>assessing</u> incidents that the Member States have alerted the Commission topursuant 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 <u>crisis</u> 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, <u>social partners</u> and industry to collect market intelligence <u>in line with Article 40a</u>;
 - (d) analysing aggregated data received by other crisis-relevant bodies at Union and international level;
 - (e) facilitating exchanges and sharing of information, including with other relevant bodies and other crisis-relevant bodies at Union level<u>and in Member States</u>, 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;

(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:
 - analysing crisis-relevant information gathered by Member States or the Commission; (a)
 - (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;
 - facilitating exchanges and sharing of information, including with other crisis-relevant (e) bodies at Union level, as well as, as appropriate, third countries, with particular attention paid to developing countries, and international organisations.

analysing and discussing the effect of the crisis on the Single Market, with due (f) 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 groupBoard shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies at Union level. The Commission shall ensure coordination with the measures implemented through other Union mechanisms, such as the Union Civil Protection Mechanism (UCPM) or the EU Health Security Framework. The advisory groupBoard shall ensure information exchange with the Emergency Response Coordination Centre under the UCPM.
- 8. The advisory group shall meet at least three times a year. At its first meeting, on a proposal by and in agreement with the Commission, the advisory group shall adopt its rules of procedure.
- 9. The advisory group may adopt opinions, recommendations or reports in the context of its tasks set out in paragraphs 4 to 6.

Article 5 Central liaison offices

- 1. <u>Each Member States State</u> shall designate appoint a central liaison offices office.
- <u>1a. The central liaison office shall be</u> responsible for contacts, coordination and information exchange with the central liaison offices of other Member States and <u>the</u> 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.
- <u>2b.</u> The Union level central liaison office shall ensure the coordination and information exchange with the central liaison offices of the Member States <u>under this Regulation</u> for the management of the Single Market vigilance and emergency modes.

Part II Single Market contingency planning

Article 6 Crisis protocols Contingency framework

- The Commission taking into consideration the opinion <u>and the expertise</u> of the advisory group-Board and the input of relevant Union level bodies, is empowered after consulting the Member States, to adopt a delegated act to supplement this Regulation with a <u>general</u> <u>contingency</u> framework setting out crisis protocols regarding crisis preparedness cooperation, exchange of information and crisis-communication for the Single Market vigilance and emergency modes, in particular. This contingency framework shall include:
 - (a) <u>means of cooperation-between national Member States</u> and Union level competent authorities for the management of <u>in</u> 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 also vis-à-vis the public with a coordinating role for the Commission;
 - (d) the management of the framework.

- 2. The Commission and the Member States shall put in place detailed administrative <u>ensure</u> arrangements for <u>ensuring</u> 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;
 - (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 inestablished 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 <u>regularly</u> organise the training on crisis coordination, cooperation and information exchange referred to in Article 6 for the staff of the designated central liaison offices. It shall organise simulations involving the staff of the central liaison offices from all Member States based on potential scenarios of Single Market emergencies.

Article 8 Ad hoc alerts for early warning

- 1. The central liaison office of a Member State shall notify the Commission and the central liaison offices of other Member States without undue delay of any incidents that significantly disrupt or have the potential to significantly disrupt the functioning of the Single Market and its supply chains (significant incidents).
- 2. The central liaison offices and any relevant national competent authorities 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 <u>market position or</u> number of economic operators affected by the disruption or potential disruption; <u>or</u>
 - (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) <u>the existence of non-diversifiable and non-substitutable inputs in relation to the</u> <u>disruption or potential disruption and, if relevant,</u> 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

- Where the Commission, taking into consideration the opinion provided by the advisory groupBoard, considers that the threat referred to<u>conditions laid down</u> in Article 3(2) is present<u>are fulfilled</u>, it shall activate the vigilance mode for a maximum duration of six months by means of an implementing act. Such an implementing act shall contain the following:
 - (a) an assessment of the potential impact of the crisis<u>on the Single Market and its value</u> <u>chains;</u>
 - (b) <u>a</u> list of the goods and services of strategic <u>critical</u> importance <u>concerned</u><u>which are</u> <u>indispensable in the maintenance of vital societal or economic activities in the</u> <u>Single Market</u>, and
 - (c) the vigilance measures to be taken.

- 1a.When assessing whether the conditions laid down in Article 3(2) are fulfilled, the
Commission shall, based on concrete and reliable evidence, 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 the economic operators expected to be affected considering the nature of the threat; and
 - (c) the extent of goods and services of critical importance 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 4142(2).

Article 10 Extension and deactivation

- 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 groupBoard, may extend the vigilance mode for a maximum duration of six months by means of an implementing act.
- 2. Where the Commission, taking into consideration the opinion provided by the advisory groupBoard, finds that the threat referred toconditions laid down in Article 3(2) isare no longer presentfulfilled, with respect to some or all vigilance measures or for some or all of the goods and services, it shall deactivate the vigilance mode in full or in part by means of an implementing act.
- 3. Implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 42(2).

TITLE II VIGILANCE MEASURES

Article 11 Monitoring

 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 strategic 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 strategic 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 statesstate which information about factors impacting the availability of the identified goods and services of strategic 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.

41

- 6. The Commission may ask the advisory groupBoard to discuss the aggregated findings and prospects of evolution based on a Commission aggregation of the information obtained by Member States pursuant to paragraph 1 and 4 regarding their monitoring of supply chains of goods and services of strategiccritical importance., duly ensuring confidentiality and obeserving the commercial sensitivity of the information concerned.
- 7. On the basis of the information collected through the activities carried out in accordance with paragraph 1, the Commission may provide a report of the aggregated findings.

Article 12 Strategic reserves

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

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

- 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.

42

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

- 3. Taking due account of stocks held or being built up by economic operators on theirterritory, Member States shall deploy their best efforts to build up strategic reserves of the goods of strategic importance identified in accordance with paragraph 1. The Commission shall provide support to Member States to coordinate and streamline their efforts.
- 4. Where the building of strategic reserves of goods of strategic importance identified pursuant to paragraph 1 can be rendered more effective by streamlining among Member States, the Commission may draw up and regularly update, by means of implementing acts, a list of individual targets regarding the quantities and the deadlines for those strategic reserves that the Member States should maintain. When setting the individual targets for each Member State, the Commission shall take into account:
 - (a) the probability and impact of shortages referred in paragraph 1;
 - (b) the level of existing stocks of the economic operators and strategic reserves across the Union, and any information on economic operators' ongoing activities to increase their stocks;
 - (c) the costs for building and maintaining such strategic reserves.

- 5. The Member States shall regularly inform the Commission about the current state of their strategic reserves. Where a Member State has reached the individual targets referred to in paragraph 4, it shall inform the Commission if it has at its disposal any stocks of the goods in question in excess of their target. The Member States whose reserves have not reached the individual targets shall explain to the Commission the reasons for this situation. The Commission shall facilitate cooperation between the Member States which have already reached their targets and the other Member States.
- 6. Where the strategic reserves of a Member State continuously fall significantly short of the individual targets referred to in paragraph 4 and economic operators on its territory are not able to compensate that shortfall, the Commission may, at its own initiative or at the request of 14 Member States, assess the need to take further measures to build up strategic reserves of goods of strategic importance identified pursuant to paragraph 1.

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

- (a) the needs for the good in question remain unchanged or have increased compared to the situation at the time the target referred to in paragraph 4 was first set or last amended pursuant to paragraph 4,
- (b) access to the concerned good is indispensable to ensure preparedness for a Single Market emergency
- (c) the Member State concerned has not provided sufficient evidence to explain the failure to meet the individual target, and

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

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

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

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

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

Part IV **Single Market Emergency**

TITLE I EMERGENCY MODE

Article 13 Criteria for activation

- 1. When assessing the severity of a disruption need for the purposes of ascertaining whether the impact of a crisis on the Single Market qualifies as a Single Market emergency activation, the Commission and the Council shall, based on concrete and reliable evidence, taking apply following criteria :
 - (a) the crisis creates one or more obstables 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 subsituted.
- 1a. The Commission and 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);

46

- (a) the crisis has caused activation of any relevant Council crisis response mechanism. such as the Integrated Political Crisis Response mechanism operated by the Council under Council Implementing Decision (EU) 2018/1993, Union Civil Protection Mechanism or the mechanisms set up within the EU Health Security Framework, including [the proposal for] Regulation (EU) .../... on serious cross-border health threats and [the proposal for] Council Regulation (EU) .../... on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures;
- (b) an estimation of the <u>market position and</u> 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.

47

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.
- Where the Commission, taking into consideration the opinion provided by the advisory groupBoard, considers there is a Single Market emergency, it shall propose to the Council to activate the Single Market emergency mode and, where applicable, 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, hall be specified in the implementing act, and shall be a maximum of six months. The list may be amended by means of Council implementing act on 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.

48

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 an implementing act.
- 2. Where the advisory groupBoard 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 groupBoard, considers a Single Market emergency no longer exists, it shall propose to the Council without delay the deactivation of the Single Market emergency mode.

- 3. The measures taken in accordance with Articles 24 to 33 and pursuant to the emergency procedures introduced in the respective Union legal frameworks by means of the amendments to sectorial product legislation set out in Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 and introducing emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of a Single Market emergency and Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, and2014/68/EU and introducing as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of the conformity assessment, adoption of common specifications and procedures for the conformity assessment, adoption of common specifications and procedures for the conformity assessment, adoption of common specifications and procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of a 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

- 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 Union law and, <u>including as regards nondiscrimination, justification and proportionality.</u>in particular, with the requirements laid down in this Article.
- 2. <u>Member States shall ensure in particular that any measures referred to in paragraph 1</u> <u>are removed when they are no longer necessary.</u> 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.

51

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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 intraUnion export bans or other measures having equivalent effect on crisis-relevant goods or services listed in an implementing act adopted pursuant to Article 14, paragraph 35; 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-UnionEU 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 35, or
 - (ii) create or increase shortages of such goods and services in the single market;
- (c) discrimination between Member States or between citizens, including in their role as service providers or workers, discriminating against beneficiaries of the right to free movement under Union based directly on nationality or, in the case of companies, the location of the registered office, central administration or principal place of business;

52

- (d) restrictions on the free movement of persons involved in the production of crisisrelevant 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;

- 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;
 - (ee) 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 <u>35</u> or their placing on the market or to the related inspections;
 - (df) 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 in inherent to the nature of the crisis/Single Market emergency and it does not manifestly go beyond what is necessary for that purpose.

54

- (g) imposing, when safe 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:
 - (ah) Those service imposing restrictions that prevent the travel of providers that provide of crisis-relevant services that are-listed in an implementing act adopted pursuant to Article 14 paragarph 3 (5), or, business representatives or 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 anyto 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.

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Article 18 Supportive measures <u>for free movement of persons</u>

- 1. During the Single Market emergency mode, and for the purpose of reinforcing free movement of persons under points e, f, g and h of Article 17(2), 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_a. 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 erisis 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 reinforce free movement of persons points e, f, g and h of referred to in Article 42(3):17(2).
- 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(2) 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<u>those</u> persons and their equipment-during the ongoing Single Market emplates for attesting that they fulfil the relevant criteria for the application Article 17(6) in<u>use by</u> all Member States.

56

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.

57

- Member States shall use the information system set up for notifications under Directive (EU) 2015/1535 of the European Parliament and of the Council¹³ for notifications under this Article.
- 4. The Commission shall communicate the notified measures to the other Member States without delay and shall share them at the same time with the advisory group Board.
- If the advisory group Board 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 <u>with</u> 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.

58

¹³ OJ L 241, 17.9.2015, p. 1.

- 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.
- 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 requesting 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-requesting 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

- Where a Member State is required to notify a measure under Article 19 of this Regulation and under Article 5(1) of Directive (EU) 2015/1535¹⁴, 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 Council¹⁵, and on condition that the information provided in this notification meets the requirements of Articles 15(7) or 39(5) of Directive 2006/123/EC, a notification made under this Regulation shall be deemed to have satisfied also the notification obligations set out in Articles 15(7) or 39(5) of 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.

¹⁴ OJ L 241, 17.9.2015, p. 1

¹⁵ 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 Council¹⁶, and Article 11(1) of Directive EU/2018/958 and on condition that the information provided in this notification meets the requirements of Article 59(5) of Directive 2005/36/EC and of Article 11(1) of Directive EU/2018/958, that notification shall be deemed to have satisfied also the information obligation set out in Article 59(5) of Directive 2005/36/EC and in Article 11(1) of Directive EU/2018/958.

Article 21 Single points of contact in the Member States

- Member States shall operate national single points of contact that shall provide citizens, consumers, economic operators and workers and their representatives with the following assistance:
 - (a) assistance in requesting and obtaining information about national restrictions of the free movement of goods, services, persons and workers that are related to an activated Single Market emergency;
 - (b) assistance in the performance of any national level crisis procedures and formalities that have been put in place due to the activated Single Market emergency.
- 2. Member States shall ensure that it is possible for citizens, consumers, economic operators and workers and their representatives to receive, at their request and via the respective single points of contact, information from the competent authorities on the 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. <u>Member States shall make the information referred to in paragraph 1 of this Article also accessible in an official language of the Union that is broadly understood by the largest possible number of cross-border users.</u> It shall be easily accessible at a distance and by electronic means and shall be kept up to date.

61

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¹⁶ OJ L 255, 30.9.2005, p. 22.

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:
 - assistance in requesting and obtaining information as regards Union level crisis (a) 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.

62

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

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

OPTION 1:

Article 24 Information requests to economic operators

- Where there is a severe crisis-related shortages or an immediate threat thereof, the Commission may invite representative organisations or economic operators in crisis-relevant supply chains to transmit on a voluntary basis, within a set time limit, specific information to the Commission on the production capacities and possible existing stocks of crisis-relevant goods and components thereof in Union production facilities and third country facilities which it operates, contracts or purchases supply from, as well as information on any relevant supply chain disruptions within a given deadline <u>that shall not exceed 10 working days.</u> <u>This information shall only be collected for the purpose of supporting Articles 26, 34, 35 and 38 of this Regulation. Any sharing and exchange of information shall be proportionate and manipulated taking into accont the commercial sensitivity of its <u>content</u>.
 </u>
- 2. If the addressees do not transmit the information requested in accordance with paragraph 1 within the time-limit-and do not provide a valid justification for not doing so, the Commission may, by means of an implementing act, require that they<u>request them to</u> transmit the information <u>on a voluntary basis</u>, indicating in the implementing act why it is proportionate and necessary to do so, specifying the crisis-relevant goods and services and addressees concerned by the information request, and the information that is sought, providing where necessary a template with the questions that may be addressed to the economic operators.

64

- 3. The information requests referred to in paragraph 1 may concern the following: (a) targeted information to the Commission in relation to the production capacities and possible existing stocks of the crisis-relevant goods and components thereof in production facilities located in the Union and production facilities located in a third country which the organisation or the operator referred to in paragraph 1 operates, contracts or purchases supply from, while fully respecting trade and business secrets and requiring requesting them to transmit to the Commission on a voluntary basis a schedule of the expected production output for the following 3 months for production facility located in the Union as well as any relevant supply chain disruptions;
 - (b) other information necessary for assessing the nature or magnitude of a given supply chain disruption or shortage.
- Following the activation of the mandatory information requests to economic operators by means of an implementing act, the Commission shall address a formal decision to each of those representative organisations or economic operators in crisis-relevant supply chains that have been identified in the implementing act, requesting them to provide the information specified in the implementing act. The Commission shall rely, where possible, on the relevant and available contact lists of the economic operators active in the selected supply chains of erisis-relevant goods and services, compiled by the Member States. The Commission may obtain the necessary information on the relevant economic operators from the Member States.

65

- 5. The Commission Decisions containing individual information requests shall contain a reference to the implementing act referred to in paragraph 2 on which they are based and to the situations of severe crisis-related shortages or an immediate threat thereof which has given rise to them. Any information request shall be duly justified and proportionate in terms of the volume, nature and granularity of the data, as well as the frequency of access to the data requested, and shall be necessary for the management of the emergency or for compiling relevant official statistics. A request shall set out a reasonable time limit within which the information is to be provided. It shall take into account the effort required to collect and make the data available by the economic operator or representative organisation. The formal decision shall also contain safeguards for protection of data in accordance with Article 39 of this Regulation, safeguards for non-disclosure of sensitive business information contained in the reply in accordance with Article 25, and information on the possibility of contesting it before the Court of Justice of the European Union in line with relevant Union law and the fines provided for in Article 28 for failure to comply and the timeline for a reply.
- 6. The owners of the economic operators or their representatives and, in the case of legal persons, companies or firms, or associations having no legal personality, the persons authorised to represent them by law or by their constitution may supply the information requested on behalf of the economic operator or the association of economic operators concerned. Each economic operator or association of economic operators shall provide the requested information on an individual basis in line with the Union rules on competition governing the exchange of information. Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.

66

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.

7a. The Commission may present to the Board referred to in Article 4 aggregateinformation based on any information collected pursuant to Article 24.

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

Article 24

Information requests to economic operators

1. Where there isare a severe crisis-related shortages or an immediate threat thereof, the Commission may invite representative organisations or economic operators in crisis-relevant supply chains to transmit on a voluntary basis, within a set time limit, specific information to the Commission on the production capacities and possible existing stocks of crisis-relevant goods and components thereof in Union production facilities and third country facilities which it operates, contracts or purchases supply from, as well as information on any relevant supply chain disruptions within a given deadlinewhere such information is 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 and the Commission not able to obtain such information from other sources.

2. If the addressees do not transmit the information requested in accordance with gathered by the Commission, via the requests for information on a voluntary basis pursuant to paragraph 1-within the time-limit, as well as from any other sources 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 sowhether any such measures should be taken, the Commission may activate a mandatory structured request for information, by means of an implementing act, require that they transmit the information, indicating in the . Before adopting such an implementing act-why it is proportionate, the Commission shall 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 public interest objectives pursued by this Regulation. The Commission shall take due account of the administrative burden, which such a request may entail for the concerned economic operators and services and in particular SMEs. The Board shall be informed of the outcome of this assessment. Any implementing act laying down a mandatory structured request for information shall specify the crisis-relevant goods and services, the types of 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 individual economic operators.

69

- 3. The information requests referred to in paragraphparagraphs 1 and 2 may only concern the followinginformation 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 operator referred to in paragraph 1 operates, contracts or purchases supply from, while fully respecting trade and business secrets and requiring them to transmit to the Commission a schedule of the expected production output for the following 3 months for production facility located in the Union as well as any relevant supply chain disruptions;
 - (b) other information necessary for assessing the nature or magnitude of a given <u>any</u> <u>relevant</u> supply chain <u>disruption</u> or shortage.

In an information request concerning information specified in point (a), the Commission may request an economic operator to transmit a schedule of the expected production output for the following 3 months for production facility located in the Union.

Such information requests should be carried out while fully respecting trade and business secrets.

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

5. The Commission Decisions containing individual information requests 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 10 working days within which the information isor the justification for the refusal to supply such information are to be provided. HWhen setting this time limit the Commission shall in particular take into consideration the size of the undertaking concerned in terms of employees. The Commission shall also take into account the effort required to collect and make the data available by the economic operator-or representative organisation. The formal decision shall also contain safeguards for protection of data in accordance with Article 39 of this Regulation, safeguards for non-disclosure of sensitive business information contained in the reply in accordance with Article 25, and information on the possibility of contesting it before the Court of Justice of the European Union in line with relevant Union law and the fines provided for in Article 28 for failure to comply and the timeline for a reply.

- 6. The owners of the economic operators or their representatives and, in the case of legal persons, companies or firms, or associations having no legal personality, the persons authorised to represent them by law or by their constitution may supply the information requested on behalf of the economic operator or the association of economic operators concerned. Each economic operator-or association of economic operators shall provide the requested information on an individual basis in line with the Union rules on competition governing the exchange of information. Lawyers duly authorised to act may supply the information on behalf of their clients. The latter shall remain fully responsible if the information supplied is incomplete, incorrect or misleading.
- 7. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed a mandatory information request to an economic operator.
- 8. The implementing acts referred to in paragraph 2 shall be adopted in accordance with the committee procedure referred to in Article 42(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis on the Single Market, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(3).
Article 25 Confidentiality and processing of the information

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

Article 26 [Targeted amendments to harmonised product legislation]

When the Single Market emergency mode has been activated by means of a Council implementing act adopted pursuant to Article 14, and there is a shortage of crisis relevant goods the Commission may activate by means of implementing acts the emergency procedures included in the Union legal frameworks amended by [Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) No 305/2011 and introducing emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the context of a Single Market emergency and Directive of the European Parliament and of the Council amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, and2014/68/EU and introducingas regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance in the conformity assessment, adoption of common specifications and market surveillance for the conformity assessment, adoption of common specifications and market surveillance in the conformity assessment, adoption of common specifications and market surveillance in the conformity assessment, adoption of common specifications and market surveillance in the context of a Single Market] as regards crisis-relevant goods, indicating which crisis-relevant goods and emergency procedures are subject to the activation, providing reasons for such activation and its proportionality, and indicating the duration of such activation.

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

Article 27 Priority rated orders

- 1. The Commission may invite one or more economic operators in crisis relevant supply chains established in the Union to accept and prioritise certain orders for the production or supply of crisis-relevant goods ('priority rated order').
- 2. If an economic operator does not accept and prioritise priority rated orders, the Commission may, at its own initiative or at the request of 14 Member States, assess the necessity and proportionality of resorting to priority rated orders in such cases, the Commission shall give the economic operator concerned as well as any parties demonstrably affected by the potential priority rated order, the opportunity to state their position within a reasonable time limit set by the Commission in light of the circumstances of the case. In exceptional circumstances, following such an assessment, the Commission may address an implementing act to the economic operator concerned, requiring it to either accept and prioritise the priority rated orders specified in the implementing act or explain why it is not possible or appropriate for that operator to do so. The Commission's decision shall be based on objective data showing that such prioritisation is indispensable to ensure the maintenance of vital societal economic activities in the Single Market
- 3. Where the economic operator to which the decision referred to in paragraph 2 is addressed accepts the requirement to accept and prioritise the orders specified in the decision, that obligation shall take precedence over any performance obligation under private or public law.

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

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

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

76

- 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).

<u>OPTION 1:</u> Delete Articles 28-31 to align with the deletion of the mandatory element of information requests in Article 24.4, 24.5, 24.6, 24.7 and 24.8 and to the deletion of Article 27 (Priority rated orders)

<u>OR OPTION 2:</u> <u>Redraft Articles 28-31 as here below to align with the redrafting of the mandatory</u> <u>information requests in Article 24.</u>

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 <u>mandatory</u> request made pursuant to Article 24 (4), or does not supply the information <u>or a justification for not providing the requested</u> <u>information</u> within the <u>time limit</u> prescribed <u>time limit</u><u>therein</u>;
 - (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.

78

- Fines imposed in the cases referred to in paragraph 1 (a) and (b) shall not exceed 200 000 EUR.
- 3. Fines imposed in the cases referred to in paragraph 1 (c) shall not exceed 1 % of the average daily turnover in the preceding business year for each working day of non-compliance with the obligation pursuant to Article 27 (priority rated orders) calculated from the date established in the decision not exceeding 1% of total turnover in the preceding business year.
- 4. In fixing the amount of the fine, regard shall be had to the size and economic resources of the economic operator concerned, to the nature, gravity and duration of the infringement, taking due account of the principles of proportionality and appropriateness.
- 5. The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has fixed a fine. It may cancel, reduce or increase the fine imposed.

Article 29 Limitation period for the imposition of fines

- The Commission power to impose fines in accordance with Article 3028 shall be subject to the following limitation periods:
 - (a) two years in the case of infringements of provisions concerning requests of information pursuant to Article 24;
 - (b) three years in the case infringements of provisions concerning the obligation to prioritise the production of crisis-relevant goods pursuant to Article 26(2).
- 2. The time shall begin to run on the day on which the Commission becomes aware of the infringement. However, in case of continuous or repeated infringements, time shall begin to run on the day on which the infringement ceases
- 3. Any action taken by the Commission or the competent authorities of the Member States for the purposes of ensuring compliance with the provisions of this Regulation shall interrupt the limitation period.
- 4. The interruption of the limitation period shall apply for all the parties which are held responsible for the participation in the infringement.
- 5. Each interruption shall start the time running afresh. However, the limitation period shall expire at the latest on the day in which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine. That period shall be extended by the time during which the limitation period is suspended because the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.

80

Article 30 Limitation periods for enforcement of fines

- 1. The power of the Commission to enforce decisions taken pursuant to Article 28 shall be subject to a limitation period of five years.
- 2. Time shall begin to run on the day on which the decision becomes final.
- 3. The limitation period for the enforcement of fines shall be interrupted:
 - (a) by notification of a decision varying the original amount of the fine or refusing an application for variation;
 - by any action of the Commission or of a Member State, acting at the request of the (b) Commission, designed to enforce payment of the fine.
- (4.) Each interruption shall start time running afresh.
- The limitation period for the enforcement of fines shall be suspended for so long as: (5.)
 - time to pay is allowed; (a)
 - (b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union.

81

Article 31 Right to be heard for the imposition of fines

- 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.
- Undertakings and representative organisations of economic operators concerned may submit their observations to the Commission's preliminary findings within a time limit which shall be fixed by the Commission in its preliminary findings and which may not be less than 21 days.
- 3. The Commission shall base its decisions only on objections on which economic operators and representative organisations of economic operators concerned have been able to comment.
- 4. The rights of defence of the economic operator or representative organisations of economic operators concerned shall be fully respected in any proceedings. The economic operator or representative organisations of economic operators concerned shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of economic operators in the protection of their business secrets. The right of access to the file shall not extend to confidential information and internal documents of the Commission or the authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and the authorities of the Member States. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

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

Article 32

Coordinated distribution of strategic reserves crisis-relevant goods and services

Where the strategic reserves constituted by the <u>Commission is informed that crisis-relevant goods</u> and services are insufficient in a Member States in accordance with Article 12 prove to be insufficient<u>State</u> to meet the needs related to the Single Market emergency, the Commission, taking into consideration the opinion provided by the advisory group<u>Board</u>, may recommend to the <u>other</u> Member States to distribute the strategic reserves<u>these crisis-relevant goods or services</u> 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<u>crisis-relevant goods and services</u> 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 implementate specific measures to. Those measures shall ensure the efficient re-organisation of supply chains and production lines and to use existing stocks to increase the availability and supply of crisis-relevant goods and services, as quickly as possible.
- 2. In particular, the measures referred to in paragraph 1 may include measures:
 - (a) facilitating the expansion or repurposing of existing or the establishment of new production capacities for crisis-relevant goods;
 - facilitating the expansion of existing or the establishment of new capacities related to (b) service activities;
 - aiming at accelerating permitting relevant approval and authorisation procedures, (c) including environmental perits, regarding or affecting the production and distribution of crisis-relevant goods-:
 - (d) aiming at accelarating relevant relevant product approval procedures in view of placing on the market crisis-relevant goods that are not subject to Union harmonisation legislation.

84

Part V Procurement<u>Public procurement</u>

CHAPTER I

Procurement<u>Public procurement</u> of goods and services of strategic <u>critical</u> importance and crisis-relevant goods by the Commission on behalf of Member States during vigilance and emergency modes

Article 34

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

- Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategie <u>critical</u> 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(<u>35</u>).
- 2. The Commission shall assess <u>without delay</u>, the utility, necessity and proportionality of the request. <u>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 <u>concerned</u> and the <u>advisory groupBoard</u> referred to in Article 4 and give reasons for its refusal.</u>

<u>The Commission shall launch a call for other Member States to participate in the</u> <u>request.</u>

3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a<u>n</u> 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 quantities for the procurement on behalf of the participating Member States referred to in paragraph 1.

3a. If the Commission is not able to award the contract to a suitable economic operator, the Commission shall immediately inform the Member State of the case that Member States can initiate their own procurement procedure without delay.

Article 35

Establishment and implementation of the negotiating mandate of the Commission

- The agreement [referred to in Article 34(3) shall establish a negotiating mandate for the Commission to act as a central purchasing bodycontract on behalf of the participating <u>Member States</u> for relevant goods and services of strategic critical importance or crisisrelevant goods and services on behalf of the participating Member States through the conclusion of new contracts.
- In accordance<u>line</u> with the<u>this</u> agreement, the Commission mayshall 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 <u>critical</u> importance or crisis-relevant goods and services, concerning the purchase of such goods or services.
- 3. Representatives of the Commission or experts nominated by the Commission may carry out on-site visits at the locations of production facilities of relevant goods of strategic importance or crisis-relevant goods.
- Without prejudice to Article 171 of the Financial Regulation, the The Commission shall carry out the procurement procedures and <u>award and</u> conclude the resulting contracts with<u>to</u> economic operators on behalf of the participating Member States.
- 4a. The Commission shall invite participating Member States to nominate representatives totake part in the preparation of the public procurement procedures as well as thenegotiation of the Commission's mandate.

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

Where the Commission intends to conclude a contract concerning the purchase 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.

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

Article 36 Modalities of procurement by the Commission on behalf of the Member States

- 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 Council¹⁷ for its own procurement.
- 2. The contracts may include a clause stating that a Member State which has not participated in the procurement procedure may become a party to the contract after it has been signed, laying out in detail the procedure for doing so and its effects. 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 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.

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¹⁷ 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*).

A modification shall be considered to be 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 altering the subject matter of the contract or agreement where one or more of the following conditions are met:

- (a) the modification introduces or supresses significant conditions which, had they been part of the initial procurement procedure, would have allowed for the admission of other tenderers than those initially selected or for the acceptance of a tender other than that originally accepted, or would have attracted additional participants in the procurement procedure, or would not have led to the selection of the winning tenderer;
- (b) the modification significantly changes the economic balance of the contract or the agreement in favour of the contractor in a manner which was not provided for in the initial contract or agreement;
- (c) the modification significantly extends the scope of the contract or agreement.

CHAPTER II Joint Procurement during vigilance and emergency modes

Article 37 Joint procurement procedure

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

Chapter III Procurement by the Member States during the emergency mode

Article 38 Consultation and coordination regarding individual procurement by the Member States

When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall <u>make best efforts to</u> consult each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the <u>advisory group Board</u> prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(<u>3</u>5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council¹⁸. <u>The Commission shall make best efforts to inform the Board of any information it obtains to support this coordination.</u>

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¹⁸ 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*)..

Article 39 Ban of individual procurement action by participating Member States

Where the Single Market emergency mode has been activated pursuant to Article <u>1614</u> 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.

In cases referred to in Article 34(3a), participating Member States may launch their own procurement procedure.

Part VI Final provisions

Article 40 Personal data protection

- 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.
- 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.

91

<u>Article 40a</u> <u>Confidentiality and processing of the information</u>

- 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 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 TheCommission and the Member States may <u>enhance or</u> set up interoperable digital tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures may <u>also</u> be <u>enhanced or</u> developed outside the duration of the<u>during a</u> 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).

<u>Article 41a</u>

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

- 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.
- 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<u>Regulation</u> 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.

93

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

Article 4<u>44</u> Report and review

- By [OP: please insert date = [five] years from the entry into force of this Regulation] and every [five] years thereafter, the Commission shall present a report to the European Parliament and the Council on the functioning of the contingency planning, vigilance and Single Market emergency response system suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.
- This report shall include an evaluation of the work <u>functioning</u> of the advisory group<u>this</u> <u>Regulation</u> under the <u>contingency</u>, <u>vigilance and</u> emergency framework established by this <u>Regulationmodes</u>. It shall also include an assessment of the operation of the Board, and its relation to the work of other relevant Union level crisis management bodies.

Article 45 Repeal

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

Article 46 Entry into force

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

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

Done at Brussels,

For the European Parliament The President

For the Council The President

95