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WK 3828/2023 REV 2

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#### **NOTE**

From: To:	Presidency Delegations
Subject:	SMEI: Consolidated comments on articles 34-46

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
2022/0278 (COD)		
Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98		
(Text with EEA relevance)		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, 21 and 45 thereof,		BE (Comments):  BE questions the proposed legal basis and would like the Commission to explain its decision to choose those articles and waits for the Council Legal Service to give its opinion on it.
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national parliaments,		

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Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,		
Having regard to the opinion of the Committee of the Regions <sup>2</sup> ,		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the internal market (also referred to as the Single Market and its supply chains can be severely affected by such crises, and appropriate crisis management tools and coordination mechanisms are either lacking, do not cover all aspects of the Single market or do not allow for a timely response to such impacts.	BE (Drafting):  (1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the internal market (also referred to as the Single Market) and its supply chains can be severely affected by such crises, particuliarly at crossborder level, and appropriate crisis management tools and coordination mechanisms are either lacking, do not cover all aspects of the Single market or do not allow for a timely response to such impacts.  DK (Drafting):	BE (Comments): The most obvious difficulties during the COVID crisis were cross-border and are not reflected in the text.  DK (Comments): Typo

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	(1) Past crises, especially the early days of the COVID-19 pandemic, have shown that the internal market (also referred to as the Single Market) and its supply chains can be severely affected by such crises, and appropriate crisis management tools and coordination mechanisms are either lacking, do not cover all aspects of the Single market or do not allow for a timely response to such impacts.	
(2) The Union was not sufficiently prepared to ensure efficient manufacturing, procurement and distribution of crisis-relevant non-medical goods such as personal protective equipment, especially in the early phase of the COVID-19 pandemic and the ad-hoc measures taken by the Commission in order to re-establish the functioning of the Single Market and to ensure the availability of crisis-relevant non-medical goods during the COVID-19 pandemic were necessarily reactive The pandemic also revealed insufficient overview of manufacturing capacities across the Union as well as vulnerabilities related to the global supply chains.		
(3) Actions by the Commission were delayed by several weeks due to the lack of any Union wide contingency planning measures and ofclarity as to which part of the national		

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administration to contact to find rapid solutions to the impact on the Single Market being cause by the crisis. In addition it became clear that uncoordinated restrictive actions taken by the Member States would further aggravate the impacts of the crisis on the Single market. It emerged that there is a need for arrangements between the Member States and Union authorities as regards contingency planning, technical level coordination and cooperation and information exchange.		
(4) Representative organisations of economic operators have suggested that economic operators did not have sufficient information on the crisis response measures of the Member States during the pandemics, partly due to not knowing where to obtain such information, partly due to language constraints and the administrative burden implied in making repeated inquiries in all the Member States, especially in a constantly changing regulatory environment. This prevented them from making informed business decisions as to what extent they may rely on their free movement rights or continue cross-border business operations during the crisis. It is necessary to improve the availability of information on national and Union level crisis response measures		

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highlighted the need for the Union to be better prepared for possible future crises, especially as we consider the continuing effects of climate change and resulting natural disasters as well as global economic and geopolitical instabilities. Given the fact that it is not known which kind of crises could come up next and produce severe impacts on the Single Market and its supply chains in the future, it is necessary to provide for an instrument that would apply with regards to impacts on the Single Market of a wide range of crises.		
(6) The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to obstacles to free movement within the Single Market, thus disrupting its normal functioning. On the other hand, a crisis can amplify shortages of crisis-relevant goods and services on the Single Market. The Regulation should address both types of impacts on the Single Market.		
(7) Since any specific aspects of future	DK (Drafting):	DK (Comments):
crises that would impact the Single Market and its supply chains are hard to predict, this Regulation should provide for a general framework for anticipating, preparing for, mitigating and minimising the negative impacts	(7) Since any specific aspects of future crises that would impact the Single Market and its supply chains are hard to predict, this Regulation should provide for a general	Typo.

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which any crisis may cause on the Single Market and its supply chains.	framework for anticipating, preparing for, mitigating and minimising the negative impacts which any crisis may cause on the Single Market and its supply chains.	
(8) The framework of measures set out under this Regulation should be deployed in a coherent, transparent, efficient, proportionate and timely manner, having due regard to the need to maintain vital societal functions, meaning including public security, safety, public order, or public health respecting, the responsibility of the Member States to safeguard national security and their power to safeguard other essential state functions, including ensuring the territorial integrity of the State and maintaining law and order.		
(9) To this end, this Regulation provides:		
the necessary means to ensure the continued functioning of the Single Market, the businesses that operate on the Single Market and its strategic supply chains, including the free circulation of goods, services and persons in times of crisis and the availability of crisis relevant goods and services to citizens, businesses and public authorities at the time of crisis;		

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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.	DK (Drafting):  (10) Where possible, this Regulation should allow for anticipation of events and crises, building on on-going analysis concerning strategically critically important areas of the Single Market economy and the Union's continuous foresight work.	<b>DK (Comments):</b> Ammended following proposed changes in Article 3.
		BE (Comments):  BE recalls the importance of consistency between this new proposal and pre-existing or future instruments, especially sectorial emergency instruments, as well as ongoing initiatives. A specific provision should be inserted in the text, notably in the recitals, specifying the articulation between the SMEI and the other emergency instruments.
(11) This Regulation should not duplicate the existing framework for medicinal products,		BE (Comments): Recitals 11 to 15 do not really clarify the

Commission proposal  medical devices or other medical counter-	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments  SMEI's relationship with pre-existing and future
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.		EU emergency mechanisms, such as the Green Lanes Initiative, the Solidarity Corridors, the Chips Act, and the Raw Materials Act. BE would like to see a specific reference to coherence with both pre-existing and future mechanisms in the text and would welcome further clarifications in this regard in the recitals. For example, is it possible to build up semiconductor reserves on the basis of the SMEI when this is not foreseen by the Chips Act?
(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		BE (Comments):  BE would like to see a specific reference to coherence with both pre-existing and future mechanisms in the text and would welcome further clarifications in this regard in the recitals. For more details, see full comment on

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decision-making.		recital 11.
(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.		BE (Comments):  BE would like to see a specific reference to coherence with both pre-existing and future mechanisms in the text and would welcome further clarifications in this regard in the recitals. For more details, see full comment on recital 11.
(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.		BE (Comments):  BE would like to see a specific reference to coherence with both pre-existing and future mechanisms in the text and would welcome further clarifications in this regard in the recitals. For more details, see full comment on recital 11.
(15) The Regulation should be without prejudice to the European Food Security Crisis preparedness and response Mechanism (EFSCM). Nevertheless, food products should be governed by the provisions of this Regulation, including those concerning the notification mechanism and concerning restrictions to free movement rights. The measures concerning food products notified		BE (Comments):  BE would like to see a specific reference to coherence with both pre-existing and future mechanisms in the text and would welcome further clarifications in this regard in the recitals. For more details, see full comment on recital 11.

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under this Regulation may be also reviewed for their compliance with any other relevant provisions of EU law.		
(16) In order to account for the exceptional nature of and potential far-reaching consequences for the fundamental operation of the Singe Market of a Single Market emergency, implementing powers should exceptionally be conferred on the Council for the activation of Single Market emergency mode pursuant to Article 281(2) of the Treaty on the Functioning of the European Union.	BE (Drafting):  (16) In order to account for the exceptional nature of Single Market emergency and potential far-reaching consequences for the fundamental operation of the Singe Market, implementing powers should exceptionally be conferred on the Council for the activation of Single Market vigilance and emergency modes pursuant to Article 281(2) of the Treaty on the Functioning of the European Union.  DK (Drafting):  (16) In order to account for the exceptional nature of and potential far-reaching consequences for the fundamental operation of the Singe Market of a Single Market emergency, implementing powers should exceptionally be conferred on the Council for the activation of Single Market vigilance and emergency mode pursuant to Article 2981(2) of the Treaty on the	BE (Comments):  To ensure that the Member States are adequately involved in important decisions, BE considers there is a need for a Council Implementing Decision in order to activate the vigilance mode and delineate its scope. Such a Council Implementing Decision can be also objectively justified on the basis of the farreaching consequences of the vigilance mode with regard to strategic reserves (Article 12).  DK (Comments):  Receital on Council implementing acts updated to reflect suggestions on the activation of vigilance mode in article 9(1) – 9(1a).  Proposal references wrong TFEU article.
	Functioning of the European Union.	
(17) Article 21 TFEU lays down the right of EU citizens to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the		

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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 reestablishing 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		BE (Comments): Recital 19 is the only recital dealing with the

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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.		Single Point of Contact and seems to only target workers and their representatives. BE would like the Single Point of Contact to be available also for service providers, consumers and citizen.
(20) If Member States adopt measures affecting free movement of goods or persons, goods or the freedom to provide services in preparation for and during Single Market emergencies, they should limit such measures to what is necessary and remove them as soon as the situation allows it. Such measures should respect the principles of proportionality and non-discrimination and should take into consideration the particular situation of border regions.		
(21) The activation of the Single Market emergency mode should trigger an obligation for the Member States to notify crisis-relevant free movement restrictions.		

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(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		

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should require individual activation by means of Commission implementing acts, which indicate the reasons for such activation and the crisis-relevant goods or services that such measures apply to.		
(24) Furthermore, in order to ensure the		
proportionality of the implementing acts and due respect for the role of economic operators in crisis management, the Commission should only resort to the activation of the Single Market emergency mode, where economic operators are not able to provide a solution on a voluntary basis within a reasonable time. Why this is the case should be indicated in each such act, and in relation to all particular aspects of a crisis.		
(25) Information requests to economic operators should be used by the Commission only where the information which is necessary for responding adequately to the Single Market emergency, such as information necessary for procurement by the Commission on behalf of the Member States or estimating the production capacities of manufacturers of crisis-relevant goods the supply chains of which have been disrupted, cannot be obtained from publicly available sources or as a result of information provided voluntarily.		

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(26) The activation of the Single Market emergency mode, where needed, should also trigger the application of certain crisis-response procedures which introduce adjustments to the rules governing the design, manufacture, conformity assessment and the placing on the market of goods subject to Union harmonised rules. These crisis-response procedures should enable products, designated as crisis-relevant goods to be placed swiftly on the market in an emergency context. The conformity assessment bodies should prioritise the conformity assessment of crisis-relevant goods over any other ongoing applications for other products. On the other hand, in cases, where there are undue delays in the conformity assessment procedures, the national competent authorities should be able to issue authorisations for products, which have not undergone the applicable conformity assessment procedures to be placed on their respective market, provided that they comply with the applicable safety requirements. Such authorisations shall be only valid on the territory of the issuing Member State and limited to the duration of the Single Market emergency. In addition, in order to facilitate the increase in supply of crisis-relevant products, certain flexibilities should be introduced with respect to the mechanism of presumption of conformity. In the context of a	BE (Drafting):  (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 competent authorities of 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	BE (Comments): The term "National competent authorities" should be replaced by the term "competent authorities of the Member States", in order to reflect the complex division of powers in many Member States regarding this matter.

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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.	the mechanism of presumption of conformity. In the context of a Single Market emergency, the manufacturers of crisis-relevant goods should be able to rely also on national and international standards, which provide an equivalent level of protection to the harmonised European standards. In cases where the later do not exist or the compliance with them is rendered excessively difficult by the disruptions to the Single Market, the Commission should be able to issue common technical specifications of voluntary or of mandatory application in order to provide ready-to-use technical solutions to the manufacturers.	
(27) The introduction of these crisis-relevant adjustments to the relevant sectorial Union harmonised rules requires targeted adjustments to the following 19 sectorial frameworks: Directive 2000/14/EC, Directive 2006/42/EU, Directive 2010/35/EU, Directive 2013/29/EU, Directive 2014/28/EU, Directive 2014/29/EU, Directive 2014/30/EU, Directive 2014/31/EU, Directive 2014/32/EU, Directive 2014/33/EU, Directive 2014/34/EU, Directive 2014/35/EU, Directive 2014/53/EU, Directive 2014/68/EU, Regulation (EU) 2016/424, Regulation (EU) 2016/425, Regulation (EU) 2016/426, Regulation (EU) 2019/1009 and Regulation (EU) 305/2011. The activation of the emergency procedures should be conditional upon the		

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activation of the Single Market emergency and should be limited to the products designated as crisis-relevant goods.		
(28) In cases where there are substantial risks to the functioning of the Single Market or in cases of severe shortages or an exceptionally high demand of goods of strategic importance, measures at Union level aimed to ensure the availability of crisis-relevant products, such as priority rated orders, may prove to be indispensable for the return to the normal functioning of the Single Market.		
(29) In order to leverage the purchasing power and negotiating position of the Commission during the Single Market vigilance mode and the Single Market emergency mode, Member States should be able to request the Commission to procure on their behalf.	FR (Drafting)  29 a (new) It should be ensured that the principles governing public procurement, in particular proportionality, non-discrimination, equal treatment, transparency and competition, are respected as regards all economic operators involved in the public procurement procedure laid down in this regulation.  29 b (new) There is a strong trend emerging across Union public procurement markets towards the aggregation of demand by public purchasers, with a view to obtaining economies of scale, including lower prices and transaction costs, and to improving and	FR (Comments)  It is important to refer to the respect of the fundamental principles of public procurement which are not mentioned in the proposed regulation.  This recital replicates the recital 48 recently used in the Foreign subsidies Regulation.  Part V of the proposal provides for mechanisms to centralise public purchase. It is important to take up the existing clarifications on this technique.  This recital replicates the recital 59 used in the directive 2014/24/EU on public procurement.

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	professionalising procurement management. This can be achieved by concentrating purchases either by the number of contracting authorities involved or by volume and value over time. However, the aggregation and centralisation of purchases should be carefully monitored in order to avoid excessive concentration of purchasing power and collusion, and to preserve transparency and competition, as well as market access opportunities for SMEs.	
(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		

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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		

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explanation or parts of it public, with due regard to business confidentiality.		
(33) Furthermore, to ensure availability of crisis-relevant goods during the Single Market emergency, the Commission may recommend that Member States distribute strategic reserves, having with due regard to the principles of solidarity, necessity and proportionality.		
(34) Where the activities to be carried out pursuant to this Regulation involve the processing of personal data, such processing should comply with the relevant Union legislation on personal data protection, namely Regulation (EU) 2018/1725 of the European Parliament and of the Council <sup>3</sup> and Regulation (EU) 2016/679 of the European Parliament and of the Council <sup>4</sup> .		
(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	DK (Drafting):  (35) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on	<b>DK (Comments):</b> Ammended following proposed changes in Article 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).

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).

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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.	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 critical importance. Moreover, implementing powers should be conferred on the Commission as regards activation of specific emergency response measures at the time of a Single Market emergency, to allow for a rapid and coordinated response. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.	
(36) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union (the 'Charter'). In particular, it respects the right to privacy of the economic operators enshrined in Article 7 of the Charter, right to data protection set out in Article 8 of the Charter, the freedom to conduct	BE (Drafting):  (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	BE (Comments):  BE finds that this recital does not sufficiently precise whether this regulation does not affect the right to strike, due to the repealing of Council Regulation (EC) 2679/98. This recital should at least mention that the right to strike is included in the art 28 of the Charter. For a better guarantee, it should be integrated in the articles

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business and the freedom of contract, which are protected by Article 16 of the Charter, the right to property, protected by Article 17 of the Charter, right to collective bargaining and action protected by Article 26 of the Charter and the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter. Since the objective of this Regulation cannot be sufficiently achieved by the Member States and can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. The Regulation should not affect the autonomy of the social partners as recognised by the TFEU.

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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, including the right to strike, protected by Article 28 of the Charter and the right to an effective judicial remedy and to a fair trial as provided for in Article 47 of the Charter. 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.

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of the proposal.

Moreover the reference is incorrect: The right to collective bargaining and action is protected by Article 28 and not 26 of the Charter.

(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.

#### DK (Drafting):

(37) The Single Market Emergency
Instrument shall not in any way affect the exercise of fundamental rights as recognised in the Member States and at Union level, including the right or freedom to strike or to take other action covered by the specific industrial relations systems in Member States, in accordance with national law

#### **DK (Comments):**

It is important to ensure that the repeal of the Strawberry Regulation, does not affect the execise of fundamental right to strike or other action.

We propose an addition, drawing inspiration from similar wording in Directive 96/71/EC, Article 1(b)(1a).

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	and/or practice. Nor does it affect the right to negotiate, to conclude and enforce collective agreements, or to take collective action in accordance with national law and/or practice.	
(38) The Union framework shall include interregional elements to establish coherent, multi-sectoral, cross-border Single Market vigilance and emergency response measures, in particular considering the resources, capacities and vulnerabilities across neighbouring regions, specifically border regions.		
(39) The Commission shall also where appropriate enter into consultations or cooperation, on behalf of the Union, with relevant third countries, with particular attention paid to developing countries, with a view to seeking cooperative solutions to address supply chain disruptions, in compliance with international obligations. This shall involve, where appropriate, coordination in relevant international fora.		
(40) In order to put in place a framework of crisis protocols the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement the regulatory framework set out in this Regulation	AT (Drafting):  (40) In order to put in place a framework of crisis protocols the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to supplement the	AT (Comments): As indicated in previous discussions, AT suggests to delete Art. 6 on the delegated acts. Therefore, recital 40 is not necessary anymore.

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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.	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.		BE (Comments): The repeal of Regulation (EC) No 2679/98 must not affect the right to strike. The inclusion of a reference to Article 28 of the Charter of Fundamental Rights in Recital 36 is in no way sufficient to guarantee the protection of the right to strike. Therefore BE requests that the right to strike be guaranteed by an article in the proposed regulation.

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HAVE ADOPTED THIS REGULATION:	FR (Drafting) Part V Public Procurement	FR (Comments) The title of Part V should be changed to
		General remarks on Part V (Procurement):  Given the size of these tenders, the Commission should ensure that SMEs can take part in them, for example by constituting lots (e.g. geographical, type of service, task, etc.) with lot selection criteria, by facilitating the possibility of working in the form of an alliance/consortium, etc.  BE asks to clarify the existing relationship between the EU public procurement directives on the one hand and the SMEI provisions on public procurement on the other hand and the explicit references to Regulation 2018/1046 that these provisions contain.  AT (Comments):  It is essential that the participation of MS in procurement procedures by the COM under Part V remains voluntary and the decision "to use" the COM to act on their behalf remains exclusively with the MS. Even in the vigilance and emergency mode of a single market emergency, individual Member States may face different needs, which may also be addressed differently through procurement. In this context, Art. 38 of the proposal is very problematic (see

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		below).
Article 34 Request of Member States to the Commission to procure goods and services on their behalf		PT (Comments): We consider important the fact that Member States' participation in such Commission procurement procedures is voluntary and that the decision to have the Commission to act on their behalf remains exclusively with the Member States.
1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategic importance listed in an implementing act adopted pursuant to Article 9(1) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).	FR (Drafting)  1. Where approriate, t\(^{\text{T}}\)wo or more Member States may request that the Commission launch a public procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategic importance listed in an implementing act adopted pursuant to Article 9(1) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).  FI (Drafting):  1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategic	IT (Comments):  The relationship between the rules on procurement managed by the Commission on behalf of Member States and the rules on priority rated orders (article 27 of the draft Reg.) should be clarified. More specifically, it should be clearly set out whether priority rated orders under article 27 and procurement procedures under article 34 may be jointly and/or separately activated and, if so, what would be the effect of the interaction of these measures, vis-a-vis the Member States that did not participate in the joint procurement procedure envisioned by article 34.  PL (Comments):  This point should be adjusted to match the definitions from Art. 3.5. and Art. 3.6. as well as implementing acts from art. 9 and 14.

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	adopted pursuant to Article 9(1 <u>b</u> ) or crisis- relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).	
	NL (Drafting):	
	1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategic importance listed in an implementing act adopted pursuant to Article 9(1b) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).	
	BE (Drafting):	BE (Comments):
	1a. This request should be submitted to the steering committee in order to give the opportunity to other interested Member States to join the request.	In Article 34, will other MS be informed of this request and will they have the opportunity to join the request? Such a request should be submitted to the advisory group (or rather steering committee – see previous comment on Art 4, repeated below in Art 34 (2)) in order to allow interested MS to join the request and to allow COM to better assess the request.
2. The Commission shall assess the utility,	BE (Drafting):	PT (Comments):
necessity and proportionality of the request. Where the Commission intends not to follow the request, it shall inform the Member States concerned and the advisory group referred to in	2. The Commission shall assess the utility, necessity and proportionality of the request. Where the Commission intends not to follow the request, it shall inform the Member States	For the sake of clarity it would be important to add the <i>criteria</i> on how that assessment by the COM will be made.

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
Article 4 and give reasons for its refusal.	concerned and the steering committee referred to in Article 4 and give reasons for its refusal.  FR (Drafting)  2. The Commission shall assess without delay the utility, necessity and proportionality of the request. Where the Commission intends not to follow the request, it shall inform the Member States concerned and the advisory group referred to in Article 4 and give reasons for its refusal.	BE (Comments): As reminder (see previous comment on article 4), for BE, it is important that the advisory group is able to work as an effective steering body for cooperation between the Commission and the Member States, to better reflect the fact that steering is done under the leadership of COM, but in close coordination with the MS.  DK (Comments): Amended following proposed changes to Article
	DK (Drafting):  1. Two or more Member States may request that the Commission launch a procurement on behalf of the Member States that wish to be represented by the Commission ('participating Member States'), for the purchasing of goods and services of strategic critical importance listed in an implementing act adopted pursuant to Article 9(1b) or crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5).  FI (Drafting):	FI (Comments):  We believe it is important that the advisory group or member states are informed if the Commission decides to launch a public procurement procedure on behalf of member states, as this could have an effect on the market for other contracting authorities, especially for those which are not part of the public procurement procedure by the Commission.  This will also enable other Member States that have not made a request to the Commission to assess their willingness to participate in the
	2. The Commission shall assess the utility, necessity and proportionality of the request. If the Commission decides to launch a procurement on behalf of the Member States, it shall inform all Member States and the advisory group of its intention to carry out the procurement. Where the Commission	procurement as early as possible.  NL (Comments):  We believe it is important that the advisory group and all member states are informed if the Commission decides to launch a public procurement procedure on behalf of member states, as this could have an effect on the market

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intends not to follow the request, it shall inform the Member States concerned and the advisory group referred to in Article 4 and give reasons for its refusal.

# The Commission shall launch a call for other Member States to participate in the request. NL (Drafting):

2. The Commission shall assess the utility, necessity and proportionality of the request. If the Commission decides to launch a procurement on behalf of the Member States, it shall inform all Member States and the advisory group of its intention to carry out the procurement. Where the Commission intends not to follow the request, it shall inform the all Member States concerned and the advisory group referred to in Article 4 and give reasons for its refusal.

# The Commission shall launch a call for other Member States to participate in the request. IE (Drafting):

2. The Commission shall assess the utility, necessity and proportionality of the request. If the Commission decides to launch a procurement on behalf of the Member States, it shall inform all Member States and the advisory group of its intention to carry out the procurement. Where the Commission intends not to follow the request, it shall inform the all Member States concerned and the

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for other contracting authorities, especially for those which are not part of the public procurement procedure by the Commission. This second suggestion will also enable other Member States that have not made a request to the Commission to assess their willingness to participate in the procurement as early as possible.

#### IT (Comments):

It is not clear how this assessment would be carried out by the Commission. The wording here should therefore add some criteria for consideration.

#### LU (Comments):

We support fixing a timeframe for the Commission within which this assessment needs to be carried out. We also suggest that more details are given in recitals on what "utility, necessity and proportionality" mean in this context to give further framing to the Commission's assessment.

#### **IE** (Comments):

We believe it is important that the advisory group and all member states are informed if the Commission decides to launch a public procurement procedure on behalf of member states, as this could have an effect on the market for other contracting authorities, especially for those which are not part of the public procurement procedure by the Commission.

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
	advisory group referred to in Article 4 and give reasons for its refusal.  The Commission shall launch a call for other Member States to participate in the request.	This second suggestion will also enable other Member States that have not made a request to the Commission to assess their willingness to participate in the procurement as early as possible.
3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a framework agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.	AT (Drafting):  3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a framework agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.  EE (Drafting):  3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a framework agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.  FR (Drafting)  3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for a framework agreement	Regarding the use of the term "framework contract", Estonia presents the position that the use of such a term is not in accordance with Article 33(1) of Directive 2014/24/EU, according to which a framework agreement means an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged. A framework contract is a public procurement contract, which, according to Directive 2014/24/EU, art 2 paragraph 1 (5), is a contract for pecuniary interest concluded in writing between one or more economic operators and one or more contracting authorities and having as their object the execution of works, the supply of products or the provision of services. Due to the above, the use of the term "framework agreement" is misleading, and art 34 (3) should be reworded using the word "agreement".

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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 public procurement on behalf of the participating Member States referred to in paragraph 1. This agreement shall include procedural rules for the initiation, preparation of procurement procedures set out in this article, the modalities for Member States free participation, as well as the modalities for the involvement of participating Member States throughout the procurement process as well as allocation procedures.

#### **DK (Drafting):**

2. The Commission shall assess the utility, necessity and proportionality of the request.

Where the Commissions intends to follow the request, it shall inform the Member States concerned and the advisory group of its intentional to carry out the joint procurement. Where the Commission intends not to follow the request, it shall inform the Member States concerned and the advisory group referred to in Article 4 and give reasons for its refusal.

#### FI (Drafting):

3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for an framework agreement

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#### PT (Comments):

• We consider important to clarify if and to what extent the proposed framework agreement can be discussed and amended by the Member State (so as not to constitute an "imposition" of an agreement).

#### AT (Comments):

In this paragraph the term "framework agreement" could be misleading. According to Art. 33 Dir 2014/24/EU a framework agreement has the purpose to establish the terms governing contracts to be awarded during a given period in the future, in particular with regard to price and/or the quantity envisaged. However, the "framework agreement" in Art. 34 para. 3 of the proposal is a contractual relationship which serves the purpose of governing the relationship between the COM and the participating MS concerning the procurement by the COM. It is already a "contract" on its own and does not regulate possible future awards of contracts between the COM and the participating MS (see also Art. 35 para. 1 of the proposal). AT therefore suggests to replace the term "framework agreement" in Art. 34 para. 3 with the term "agreement".

#### FR (Comments)

It is not a framework agreement in the context of public procurement law.

A more appropriate term should be used, such

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to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.

#### NL (Drafting):

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

#### **IE (Drafting):**

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

#### PL (Drafting):

3. Where the Commission agrees to procure on behalf of the Member States, it shall draw up a proposal for an framework

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as agreement (or convention).

We propose to reproduce here part of Article 8 of Regulation 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures.

#### **DK** (Comments):

It is important that that Commission ensures full transparency and makes the advisory group aware of any assessment made, whether such assessment is to follow the request or not.

#### FI (Comments):

The term 'framework agreement' has a different meaning in the public procurement directives.

#### **NL** (Comments):

The term 'framework agreement' has a different meaning in the public procurement directives.

#### IT (Comments):

The difference between, on the one hand, the "framework agreement" as per article 34 paragraph 3 and, on the other hand, new contracts under article 35, paragraph 1, is unclear. By reading the proposed text, it may be inferred that with the expression "framework agreement" the legislator is not referring to the "framework agreements" as set forth under Directive 2014/24/EU. It is more likely that by using the aforesaid expression the legislator intends to refer to agreements between public administrations. Therefore, it is advisable to modify the text of the proposed paragraph so as

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Commission proposal	authorising agreement to be concluded with the participating Member States allowing the Commission to procure on their behalf. This agreement shall lay down the detailed conditions for the procurement on behalf of the participating Member States referred to in paragraph 1.	not to use the wording "framework agreement" but, for example, more simply "agreement".  LU (Comments):  We wonder if it's useful to indicate, possibly in a recital, that the term « framework agreement » is different to the one used in the Public procurement directives, or else use another term altogether.  IE (Comments):  The term 'framework agreement' has a different meaning in the public procurement directives.  PL (Comments):  The term "framework agreement" in EU procurement legislation already exists and refers to contracts of a different nature (Article 2(31) and Article 165 of the Financial Regulation 2018 /1046 or Article 33 of Directive 2014/24/EU on classic procurement), i.e. to contracts between the contracting authority and the contractor or contractors, specifying the rules for the performance of contracts between them. For that reason in Article 34.3 of SMEI we propose to apply another term, for example "authorising agreement".  ES (Comments):  It should be clarified in the text the following issues regarding this paragraph:  If these joint procurements are going to be
		possible on products for which conformity assessment conditions have been modified, there

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		may be cases where Member States have different requirements or authorization conditions for placing a product on their national markets.
		This may happen in the emergency mode for harmonized products but also non-harmonised products are regulated at national level.
		Will this joint procurement only be carried out if national requirements for the relevant products in Member States are similar? Who will assess that?
		Or, will the national requirements for placing a product on the market not apply when it comes to a joint procurement made by the Commission?
		Are these joint procurements only going to be feasible if there is an adoption of common specifications conferring a presumption of conformity from the Commission? (according to articles Ie and If of the Template provisions for SMEI Omnibus Directive and SMEI Omnibus Regulation)
		All this should be clear in the text.
	FI (Drafting):	FI (Comments):
	4. (new) 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	There is a need to add in Article 34 Member States a possibility to start a procurement themselves if the Commission does not find a suitable undertaking via its procurement.
	Member States can initiate their own procurement procedure without delay.	NL (Comments): There is a need to add in Article 34 Member

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
	NL (Drafting):  4. (new) 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.  IT (Drafting):  4. The Commission shall have due regard in the procurement of crisis-relevant goods and services such that small and medium-sized enterprises are not put at a disadvantage, while also avoiding hindering research and development as well as innovative undertakings.  IE (Drafting):  4. (new) 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.	States a possibility to start a procurement themselves if the Commission does not find a suitable undertaking via its procurement.  IT (Comments):  An additional provision for joint procurement should be added that considers the structural principles of public purchasing in the relevant sectors. A safeguard should be created ensuring that joint procurement procedures do not substantially harm SMEs, research and development, and innovative undertakings while maintaining the competitive structure in the respective sectors.  IE (Comments):  There is a need to add in Article 34 Member States a possibility to start a procurement themselves if the Commission does not find a suitable undertaking via its procurement.
Article 35 Establishment and implementation of the negotiating mandate of the Commission		PT (Comments):  • Procurement practices should positively impact on SME's participation. Reference should be made to this.  Are these procurement provisions aligned with other provisions for joint procurement in emergencies (e.g., similar provisions in the Chips Act, in the EU Civil Protection

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		Mechanism etc). Reference should be made to this. This should also be considered in a recital.
1. The agreement [referred to in Article 34(3) shall establish a negotiating mandate for the Commission to act as a central purchasing body for relevant goods and services of strategic importance or crisis-relevant goods and services on behalf of the participating Member States through the conclusion of new contracts.	FR (Drafting) The agreement [referred to in Article 34(3) shall establish a negotiating mandate for the Commission to act as a central purchasing body, as defined in Article 37 of the Directive 2014/24/EU, for relevant goods and services of strategic importance or crisis-relevant goods and services on behalf of the participating Member States through the conclusion of new procurements based on such an agreement contracts.	In addition to this reference, it should be explicitly stated that the Commission can act as an intermediary but also as a wholesaler (recital 69 of Directive 2014/24/EU and Article 2, §14 Directive 2014/24). It should also be noted that Regulation 2020/521 of 14 April 2020 (activation of covid emergency aid19), which constituted the legal basis for the Commission's action for the purchase of vaccines, provides for three mechanisms and makes a clear distinction between procurement on behalf of the MS on the basis of an agreement concluded between the Commission and the MS and procurement in which the Commission acts as a wholesaler (Article 4(5)).
2. In accordance with the agreement, the Commission may be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of strategic importance or crisis-relevant goods and services, concerning the purchase of such goods or services.	AT (Drafting):  2. In accordance with the agreement, the Commission may be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of strategic importance or crisis relevant goods and services, concerning the purchase of such goods or services.	AT (Comments): The COM shall carry out the procurement according to the Regulation (EU, Euratom) 2018/1046 (see Art. 36 para. 1 of the proposal). Since Title VII of this Regulation provides for a procurement procedure leading to the conclusion of a contract with economic operators, it is unclear what purpose Art. 35 para. 2 of the proposal serves. What else should

**ES** (Comments):

*It should be clarified whether these contracts* 

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	FR (Drafting)  2. In accordance line with theis agreement, the Commission may have the ability and responsibility, on behalf of participating Member States and according to their needs, to enter into contracts be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of strategic importance or crisis-relevant goods and services, concerning the purchase of such goods or services.  DK (Drafting):	be the outcome of a procurement by the COM acting as a central purchasing body (see Art. 35 para. 1 of the proposal)? The same applies to Art. 35 para. 4 of the proposal. What purpose does Art. 35 para. 3 serve, specifically in regards to the procurement by the COM on behalf of the MS?  FR (Comments)  Terminology of of Article 8(7) of Regulation 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures. Reminder of the Commission's responsibility in this area.
	1. The agreement [(referred to in Article 34(3)) shall establish a negotiating mandate for the Commission to act as a central purchasing body for relevant goods and services of strategic critical importance or crisis-relevant goods and services on behalf of the participating Member States through the conclusion of new contracts.	DK (Comments):  Amended following proposed changes to Article 3.  IT (Comments):  Article 35, paragraph 2 is not clear as it appears to make available to the European Commission an additional mode of procuring goods and services by way of direct purchases from economic operators which mode would be an addition with respect to the procedures set forth under article 34. It is, thus, desirable for the Commission to clarify that the procedure set forth under the present article is not a duplicative mode of procurement of goods and services and, if so, when it would be employed.

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		with the Commission can be prioritised by economic operators if these operators have already agreed orders from another Member State
3. Representatives of the Commission or	FR (Drafting)	PT (Comments):
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.	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, and provided that the Member State where the facility is identified agrees the visit beforehand. These visits and the reports that may result from them should take into account the confidentiality and commercial sensitivity of the information.  DK (Drafting):  2. In accordance with the agreement, the Commission may be entitled, on behalf of the participating Member States, to enter into contracts with economic operators, including individual producers of goods and services of strategic critical importance or crisis-relevant goods and services, concerning the purchase of such goods or services.  NL (Drafting):  3. Representatives of the Commission or experts nominated by the Commission may carry out on site visits at the locations of	This provision allows the COM on-site visits to production facilities of relevant goods of strategic importance or crisis-relevant goods. What is the aim of these visits? It should be clarified.  LV (Comments):  Latvia has concerns regarding provision of onsite visits at the locations of production facilities. The scope of such visits should be clearly defined and a mutual agreement with the production facility representatives reached. Besides, the provision for such on-site visits should be narrowed and only apply to goods purchased through the public procurement. Also it would be necessary to clarify whether on-site visits would also include supervision related activities?  BE (Comments):  What purpose does paragraph 3 serve specifically with regard to the COM acquiring goods for the MS?  Is the scope of this paragraph restricted to the goods specified in the agreement referred to in

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	production facilities of relevant goods of strategic importance or crisis-relevant goods.  LU (Drafting):  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.  The Commission shall, prior to carrying out such on-site visits, inform the Member State in which the production facilities are located.	France would like a clarification on this article: will these visits be organized before the signature of a contract between the operator and the Commission or after the signature of this same contract?  DK (Comments): Amended following proposed changes to Article 3.  NL (Comments): Could the Commission explain why it is necessary to explicitly create a legal basis to carry out on-site visits at the locations of production facilities of strategic or crisis-relevant goods?  It would be better to include such a clause in the specific contract after the Commission's mandate has been established. This way companies can decide to participate in the public procurement procedure or not in case they do not wish to have on-site visits.
		IT (Comments):
		Article 35, paragraph 3 should be revised according to the principles of proportionality. Indeed, the ability of the Commission to conduct on-site visits should be subject to procedural and substantive safeguards protecting the rights of economic operators. By way of compromise, a system of mandatory

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		delegation of this power to national authorities should be considered. Finally, the proposed article should clearly set out the possible consequences of an economic operator's noncompliance with this provision.
		LU (Comments):
		LU supports that the Member State in which the visit is carried out needs to be informed ex ante about such on-site visits.
4. The Commission shall carry out the	FR (Drafting)	FR (Comments)
procurement procedures and conclude the	(new)	Necessary information of Member States and
resulting contracts with economic operators on behalf of the participating Member States.	5. All participating Member States and the advisory group referred to in Article 4 shall be associated to the procurement process. To that effect, the Commission shall invite participating Member States to nominate	the advisory group and participation during drafting purchase contracts (modelled on Article 8(5) of the medical countermeasures regulation). Such a provision would also limit the legal risks concerning the competent jurisdiction.
	representatives to take part in the	DK (Comments):
	preparation of the procurement procedures as well as the negotiation of the contracts. Representatives of participating Member	Amended following proposed changes to Article 3.
	States shall have the status of experts associated to the procurement process, in accordance with Regulation (EU, Euratom) 2018/1046.	NL (Comments): This text proposal is inspired by the HERA regulation. It would be good to involve experts from participating MS in preparing the
	Where the Commission intends to conclude a	procurement.
	contract concerning the purchase of goods	
	and services of strategic importance or crisis-	
	relevant goods and services, it shall inform the participating Member States and the	

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	advisory group of such intention and the detailed terms. The participating Member States shall have the opportunity to express their comments on the draft contracts, that the Commission shall take into consideration. (new)  6. The Commission shall ensure that participating Member States are treated equally when carrying out the procurement procedures and when implementing the	
	resulting agreements.  DK (Drafting):	
	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 <a href="mailto:critical">critical</a> strategic importance or crisis-relevant goods.	
	FI (Drafting):	
	4. (1) The Commission shall carry out the procurement procedures and <u>award</u> the resulting contracts <u>to</u> economic operators on behalf of the participating Member States.	
	(2) The Commission shall invite participating Member States to nominate representatives	
	to take part in the preparation of the public procurement procedures as well as the negotiation of the Commission's mandate.  NL (Drafting):	
	4. (1) The Commission shall carry out the	

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	procurement procedures and <u>award</u> the resulting contracts <u>to</u> economic operators on behalf of the participating Member States.	
	(2) The Commission shall invite participating Member States to nominate representatives to take part in the preparation of the public procurement procedures as well as the negotiation of the Commission's mandate.	
	IE (Drafting):	IE (Comments):
	4. (1) The Commission shall carry out the procurement procedures and <u>award</u> the resulting contracts <u>to</u> economic operators on behalf of the participating Member States.  (2) The Commission shall invite participating Member States to nominate representatives to take part in the preparation of the public procurement procedures as well as the negotiation of the Commission's mandate.	This text proposal is inspired by the HERA regulation. It would be good to involve experts from participating MS in preparing the procurement.
Article 36 Modalities of procurement by the Commission on behalf of the Member States		AT (Comments):  AT would like to point out, that some clarifications should be made concerning the interplay between Art. 36 and Directive 2014/24/EU for reasons of legal clarity/security: If COM concludes contracts "on behalf" of MS (and not acting as a "central purchasing body (CPB)" (as for ex. under Art. 35) the question of applicable law needs to be addressed: in AT an "agent" (who is acting on behalf of someone else) must obey the legal regime the represented person is submitted to (which would not be the

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		FR). However, if COM - acting as a CPB - would conclude contracts, COM would apply the FR and the MS could acquire the products/services without any problems (see Art. 37 (2) of Directive 2014/24/EU). If COM - acting as a CPB - would conclude framework agreements and MS would, based on this framework agreement conduct a reopening of competition to award contracts, MS would be responsible for the latter phase and the legal regime of the respective MS would be applicable (see in this regard Art. 37 (2) 3rd subpara of Directive 2014/24/EU). Same applies if a contract would be awarded under a Dynamic Purchasing System established by COM (acting as a CPB; see again Art. 37 (2) of Dir. 2014/24/EU). AT suggests to clarify these aspects (not in the text but maybe in a Recital) so as to give guidance for contracting authorities in the framework of SMEI.  IT (Comments):  As a general proposition, greater communication between all contracting authorities and contractors at the outset of and during the crisis period should be encouraged.
1. Procurement under this Regulation shall be carried out by the Commission in accordance with the rules set out in Regulation (EU, Euratom) 2018/1046 of the European		

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Parliament and of the Council <sup>5</sup> 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.	BE (Drafting):  2. The contracts may include a clause stating that, with the agreement of the contracting parties, 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.  EE (Drafting): delete  FR (Drafting)  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.	This article along with article 39 is a disproportionate restriction, which limits the possibilities of these Member States to organize public procurement for the same products or services and endangers a level playing field, seeing as the Member State that does not express their interest in the EC joint procurement, is then free to conduct their public procurement, while other Member States are not. The Member States that do not join the joint procurement then finds themselves in a more favorable position, as they are still free to join the public procurement contract after it has been signed. We propose the ban of individual procurement action by participating Member States be eliminated from the text.
	2. When duly justified by the extreme urgency or when strictly necessary in order to adapt to unforeseen circumstances in the evolution of the emergency, the following simplifications of procurement procedures may be used:	Estonia shares the concerns of other Member States with regard to the quantity of the public procurement contract if the provisions set out in art 36 (2) should be engaged and a Member State which has not participated in the procurement procedure may become a party to

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*).

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	(a) by way of derogation from Article 137 of Regulation (EU, Euratom) 2018/1046, possibility to provide, after the signature of the contract, proof or evidence on exclusion and selection criteria, provided that a declaration on honour has been submitted in that regard before the award;
	(b) by way of derogation from Article 172(2) of Regulation (EU, Euratom) 2018/1046, the Commission may modify the contract as necessary to adapt it to the evolution of the emergency;
	(c)by way of derogation from Article 165 of Regulation (EU, Euratom) 2018/1046, possibility to add, after the signature of the contract, contracting authorities that are not identified in procurement documents;
	(d) by way of derogation from Article 172(1) of Regulation (EU, Euratom) 2018/1046, the contracting authorities shall be entitled to request the delivery of goods or services from the date on which the draft contracts resulting from the procurement carried out for the purposes of this Regulation are sent,
	which shall be no later than 24 hours as from the award.
	FI (Drafting):
	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,

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the contract after it has been signed. However, we find that to some extent this can be overcome by planning with excess in mind, however we find it implausible that the EC could plan for eg 10 or more Member States (and the quantities involved) becoming party to the contract after it has been signed.

#### PT (Comments):

• It would be important to clarify if this extension of the application of the contracting has a limitation of Member State or if it may cover all of them at a later stage, as a last resort.

This paragraph allows a contractual clause that enables a Member State that has not participated in the procurement procedure to become a party to the contract after its signature. Such an additional party to the contract could lead to an expansion of the contract volume, which could mean that the economic operator could, in the event, be contractually liable for non-performance. This paragraph deserves further clarification.

#### **BE** (Comments):

Before the contract is signed, can a Member State which has not signed the framework agreement under Article 34(3) still join the procedure? If so, is there not a risk that the procedure will have to be restarted and thus be delayed?

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	laying out in detail the procedure for doing so and its effects. A Member State wishing to participate in procurement procedure must	Allowing a MS to join the contract, after the contract has been signed, may be problematic in terms of the potentially significant increase in
	state the particular reasons why it wants to participate only at this stage.	the volume of the contract. This would create great uncertainty for contractors faced with the
	The Member States which have participated	increase in volume and who might potentially no longer be in a position to perform the
	in the procurement before the signing of the contract shall have priority to obtain products and services if the delivery cannot	contract. This authorisation should be subject to the agreement of the contractors.
	be carried out for all the participating	AT (Comments):
	Member States at the same time.  Recital 25a (new) A Member State which has	Art. 36 para. 2 of the proposal allows a contract clause allowing a MS which has not participated
	not participated in the procurement procedure but wishes to participate in the	in the procurement procedure to become a party to the contract after it has been signed. This is
	procurement procedure after the contract has been signed, must state the particular	highly problematic for various reasons:  First and foremost, such an additional party to
	reasons why it wants to participate only at this stage. Particular reasons may include for	the contract (the MS) would typically lead to a (significant) expansion of the contract volume.
	instance the insufficiency of the volume of the Member State's own contract or the	Such a "substantive" contract modification would typically not be allowed without a new
	enlargement of the crisis to the territory of a Member State.	procurement procedure [see Art. 172 of Regulation (EU, Euratom) 2018/1046
	NL (Drafting):  2. The contracts may include a clause	[hereinafter: FR] or Art. 72 of Dir 2014/24/EU; see in this regard as well the relevant constant
	stating that a Member State which has not	jurisprudence of the ECJ].
	participated in the procurement procedure may become a party to the contract after it has been	Second, if Art. 36 para 2 is seen as a lex specialis, it poses a risk for the economic
	signed, laying out in detail the procedure for doing so and its effects.	operator (the contractor) and could violate the principle of transparency. During the procurement procedure and even at the time of
		the conclusion of the contract, the economic

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		operator would not be aware of any additional MS needs. The ECJ stressed the importance of (maximum) contract values, otherwise the contracting authority could flout that maximum quantity. As a result, the economic operator could be held contractually liable for non-performance if he were to fail to supply the quantities requested (mutatis mutandis on framework agreements see ECJ C-23/20, Simonsen & Weel, para. 64).
		Thirdly, the COM has to estimate the contract value when starting the procedure (see Point 34.1. of Annex 1 of the FR). How is COM supposed to do that correctly if COM does not know at this stage of the procedure if additional MS will become a party to that procedure? Can COM explain how these problems are supposed to be dealt with?
		FR (Comments) We have doubts about the compatibility between this provision and the case law of the CJEU (Case 216/17). Indeed, if a contracting authority which is not directly party to a framework agreement can benefit from it, this contracting authority must nevertheless determine the volume of its acquisitions in order to guarantee the requirements of advertising, legal certainty and transparency.
		This clause may affect the quality of the competition and increase prices.  Moreover, it may reduce the interest of the

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		States to join the agreement between the Commission and the Member States from, which could have an interest to wait the implementation of the acquisitions.
		Finally, how will such a clause be implemented in practice, in particular with regard to a possible order of priority between the first Member States to join the agreement and those that come after?
		We propose to incorporate elements of Article 8(6) of Regulation 2022/2372/EU which are more developed.
		It is also possible to include the wording in the drafting of the new Financial Regulation:
		Art. 169: "In a situation of extreme urgency resulting from a crisis, new contracting authorities may be added after the launch of the procurement procedure and before contract signature, subject to the conditions set out in Article 164(6)."
		DK (Comments):
		It is important that changes in the finalized revision of Regulation 2018/1046 ("the Financial Regulation") are reflected in the relevant articles on public procurement in the SMEI.
		FI (Comments):
		It is important to include this opt-in clause in the Regulation. However, necessary to specify that those Member States, who participate in the

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		procurement procedure in an early stage before signing of the contract shall have priority to obtain products and services if the delivery cannot be carried out for all the participating Member States at the same time.
		The opt-in clause should be used only in exceptional circumstances. The Member States should be encouraged to undertake joint procurement at a very early stage by means of effective information exchange with the Member States and in the advisory committee.
		NL (Comments):
		Please refer to our proposal for a new article in Chapter III below.
		IT (Comments):
		The option given to member States by article 36, paragraph 2 (i.e., the right accorded to non-participating member States to become a party of an already existing procurement contract) is somewhat problematic because it contradicts the core of certain competition and public procurement contract principles. The possible extension of the contract to non-parties which was not envisioned in the call for tender would probably hinder competition because tendering parties set forth a bid based on a proposed contractual performance which was quantitatively and qualitatively different from the performance resulting from the extension of the contract to non-parties. In this respect, The Court of Justice has already set precedent (see,

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		e.g., fourth Chamber, 17 June 2021, case C-23/20; eight Chamber, 19 December 2018, case C-216/17). Therefore, on this point, it would be desirable to have a more detailed provision or, at least, detailed guidelines by the Commission. In sum, there should be greater consistency between Article 36 (modalities of procurement) and the contract provisions set out in Directive 2014/24/EU and Regulation (EU, Euratom) 2018/1046.
		LU (Comments):
		Luxembourg wonders what happens to already concluded contracts? Do they need to be terminated?
CHAPTER II Joint Procurement during vigilance and emergency modes		
Article 37 Joint procurement procedure		PT (Comments): We would welcome some further clarification on this article.
Where it is necessary to carry out a joint procurement between the Commission and one or more contracting authorities from Member States in accordance with the rules set out in Article 165(2) of Regulation (EU, Euratom)	FR (Drafting)  1. Where it is necessary to carry out a joint procurement between the Commission and one or more contracting authorities from Member States in accordance with the rules set out in	LV (Comments):  It is unclear (1) what procedures Member States should use to acquire, rent or lease goods purchased through joint public procurement (2) how it will be determined whether goods should

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	procurement procedure; that assessment shall take into account the need to ensure security of supply to the participating countries. Based on the joint procurement assessment and the relevant information provided therein, such as on envisaged price ranges, manufacturers, delivery time frames and the proposed deadline for decision on participation, the parties to the Joint Procurement Agreement shall express their interest in participating at an early stage. Those parties to the Joint Procurement Agreement which have expressed their interest shall subsequently decide on their participation in the joint procurement procedure under the conditions jointly agreed with the Commission, taking into account the information proposed in the joint procurement assessment;	
	(d) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade and does not cause distortion of competition; and	
	(e) the joint procurement does not have any direct financial impact on the budget of the countries referred to in point (a) that do not participate in the joint procurement.	
	4. The Commission shall inform the European Parliament about procedures concerning the joint procurement and, upon request, grant access to the contracts that are	

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	concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall communicate information to the European Parliament regarding sensitive documents in accordance with Article 9(7) of Regulation (EC) No 1049/2001.	
Chapter III Procurement by the Member States during the emergency mode		DK (Comments):  It is important that changes in the finalized revision of Regulation 2018/1046 ("the Financial Regulation") are reflected in the relevant articles on public procurement in the SMEI.
Article 38 Consultation and coordination regarding individual procurement by the Member States		
		IE (Comments):  IE would appreciate further clarification on how it is foreseen that this consultation and coordination would be carried out.
When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult each other and the Commission and coordinate their actions with the Commission and the representatives of the	AT (Drafting): DELETE or When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall can choose to consult	BE (Comments):  COM needs to provide more details on how coordination and consultation would look like in practice.  In an emergency mode, crisis-relevant goods

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other Member States in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council<sup>6</sup>.

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each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council<sup>7</sup>.

#### **BE (Drafting):**

When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the steering committee prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council<sup>8</sup>.

#### FR (Drafting)

When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult each other and the

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and services must be made available as quickly as possible. Prior consultation could delay the process. The practical arrangements for such consultation and coordination should be specified.

#### AT (Comments):

Art. 38 of the proposal requires MS to consult each other and the COM and coordinate their actions in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act.

This poses serious questions: "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 (Art. 3 para. 6 of the proposal). These goods and service are therefore of utmost importance to MS and their delivery – by their very nature ("indispensable for responding to the crisis") – is necessary in the shortest time possible! Taking such unforeseeable extremely urgent needs into account, Dir 2014/24/EU specifically addresses such situations and, among others, allows a negotiated procedure

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*)..

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*)..

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*)..

#### AT BE DK EE ES FI FR IE IT LU LV NL AT BE DK EE ES FI FR IE IT LU LV NL **Commission proposal PL PT Drafting Suggestions PL PT Comments** without prior publication (see Art. 32 para. 2 Commission without delay and coordinate their actions with the Commission and the letter c of the Dir 2014/24/EU). This procedure representatives of the other Member States in was used extensively during the early stages of fighting the COVID pandemic (see also the the advisory group prior to launching, in Guidance from the European Commission on accordance with Directive 2014/24/EU of the **European Parliament and of the Council.** using the public procurement framework in the procurement of crisis-relevant goods and emergency situation related to the COVID-19 services listed in an implementing act adopted crisis, 2020/C 108 I/01). Any mandatory upfront pursuant to Article 14(5) in accordance with coordination effort and any resulting delay in Directive 2014/24/EU of the European procuring such goods and services can cause Parliament and of the Council<sup>9</sup> serious harm to MS and its citizens. AT therefore cannot support Art. 38 as is. FI (Drafting): In addition, the ways and means of consultation When the Single Market emergency mode has as well as coordination are unspecified. What is been activated pursuant to Article 14, Member meant in practice by the phrases "consult" and States shall make best efforts to consult each "coordinate"? In a sudden emergency situation, other and the Commission and to coordinate does this require extensive advance planning their actions with the Commission and the instead of immediate action? No time lines are representatives of the other Member States in indicated (for ex. how quickly must the the advisory group prior to launching Advisory Group be convened), no consequences procurement of crisis-relevant goods and are mentioned. services listed in an implementing act adopted pursuant to Article 14(5) in accordance with FI (Comments): Directive 2014/24/EU of the European For MS with a decentralized system, it will be Parliament and of the Council<sup>10</sup>. **The** challenging to coordinate the actions of all our Commission shall make best efforts to inform contracting authorities in times of crises before the advisory group of any information it they have launched a public procurement obtains to support this coordination. procedure of the crisis-relevant goods and

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*)..

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*)..

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	When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall make best efforts to consult each other and the Commission and to coordinate their actions with the Commission and the representatives of the other Member States in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council 11. The Commission shall make best efforts to inform the advisory group of any information it obtains to support this coordination.  IT (Drafting):  When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the advisory group in order to act, inter alia, under Article 34, prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European	services.  NL (Comments):  For MS with a decentralized system like the Netherlands, it will be challenging to coordinate the actions of all our contracting authorities (1872) in times of crises before they have launched a public procurement procedure of the crisis-relevant goods and services.  IT (Comments):  The consultation and coordination within the Advisory group concerning procurement of crisis-relevant goods should be also aimed at allowing Member States and the Commission to evaluate whether to act pursuant to Article 34 (participation in a procurement procedure managed by the Commission).  Additionally, it should be noted that article 38 has a considerable impact on the ability of member States' contracting authorities to launch calls for bids for urgently needed goods and services, given the timeframe of crisis in which it would be implemented. Thus, both a more detailed timeframe for this procedure and a clarification of the impact of these provisions vis-a-vis a possible procurement procedure previously launched by the member States should be set out in this article.  PL (Comments):

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*)..

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	Parliament and of the Council.  PL (Drafting):  1. When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall consult exchange available information with each other and the Commission and coordinate their actions with the Commission and the representatives of the other Member States in the advisory group prior on their procurement demand of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(3). The advisory group may make proposals for voluntary coordination of actions of the Commission and Member States regarding launching procurement of crisis-relevant goods and services listed in an implementing act adopted pursuant to Article 14(3) in accordance with Directive 2014/24/EU of the European Parliament and of the Council <sup>6</sup> .	In our opinion, activation of emergency mode and determination of the list of "crisis-relevant goods and services" should not result in legal obligation of Member States and their contracting authorities to refrain from any relevant procurement until they consult other Member States and the Commission and coordinate their actions. Such provision could be a source of additional serious supply chains' disruptions in Member States as it could put on hold important public procurement.  The procedure for required consultation and coordination in the advisory group is not specified, and so it is not clear when " actions with the Commission and the representatives of the other Member States in the advisory group", can be considered as consulted and coordinated. Should every single procurement of even small local government entities be consulted?  Procurement in EU countries is decentralized and is awarded independently by thousands of contracting authorities, so the ban would be difficult if not impossible to enforce.  Because of possible consequences to Member States of putting goods and services on the list of crisis-relevant goods and services, every position on the list should be approved by the Council.  ES (Comments):  As far as coordination is concerned, the implications of Article 38 are not clear. From its

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		literal wording it seems that any public purchasing in the emergency mode requires some sort of prior validation within this consultative group.
		Even considering consultation actions, this provision is difficult to comply with, specially concerning consultation prior to any procurement of the goods listed in an implementing act. In first place because we would be dealing with emergency situations, which requiere very short deadlines and secondly, by the fact that this would be very difficult in the case of specially decentralised countries such as Spain, where the contracting
		bodies of the Spanish territorial entities operate independently and autonomously from the national administration's procurement.  Finally, we are also concerned with the compatibility of this provision with national powers on grounds of public order or national security (which can be expected in a crisis context where national states of emergency are
		also likely to be activated).  All these being said, we consider this Article should be expressed in terms of desirable actions of coordination, to promote as far as possible coordination at a EU level, so that Member States can supply each other with goods and services, in such a way that their needs are covered, and there is no market imbalance or lack of effciency in EU public

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		procurement.
	IE (Drafting):  When the Single Market emergency mode has been activated pursuant to Article 14, Member States shall make best efforts to consult each other and the Commission and to coordinate their actions with the Commission and the representatives of the other Member States in the advisory group prior to launching procurement of crisis-relevant goods and services listed in an implementing act adopted	IE (Comments): For MS with a decentralized system, it will be challenging to coordinate the actions of all our contracting authorities in times of crises before they have launched a public procurement procedure of the crisis-relevant goods and services.  PL (Comments): SMEI's provisions on public procurement when
	pursuant to Article 14(5) in accordance with Directive 2014/24/EU of the European Parliament and of the Council <sup>12</sup> . The Commission shall make best efforts to inform the advisory group of any information it obtains to support this coordination.  PL (Drafting):  2. Where Emergency mode has been	Emergency mode is activated should facilitate the award of procurement in crisis situation for crisis relevant goods or services, for example by allowing for: 1) exemption from other EU public procurement requirements or restrictions established in or on the grounds of UE Regulations 2022/1031 IPI and 2022/2560 on foreign subsidies, 2) accelerated procurement procedures, 3) further exemptions from
	activated, contracting authorities and contracting entities of the Member States in relation to procurement of crisis-relevant goods and services may on that basis decide not to apply an IPI measures adopted according to Regulation 2022/1031 of 23 June 2022.  3. Article 32 (2) of Regulation 2022/2560 of 14 December 2022 is not applied, when	obligation to publish contract notice.  This proposal for a provision is reflecting draft provision of the draft recast of the EU Financial Regulation (draft Article 173 (1)).  This proposal for a provision is reflecting draft provision of the draft recast of the EU Financial Regulation (draft Article 176 (5)).

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*)..

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	contracting authorities and contracting entities of Member States are awarding public contract on crisis-relevant goods and services, included on the list adopted pursuant to Article 14 (3), when only one valid tender has been filed in the contract award procedure.	
	4. Where Emergency mode has been activated, the contracting authority or contracting entity may contact in writing all invited candidates before the time limit for receipt of requests to participate or tenders, with the sole purpose of clarifying their intention to submit a request to participate or a tender. Where Emergency mode has been activated, the contracting authority may, in agreement with the economic operator, modify a contract or a framework contract beyond the threshold referred to in Directive 2014/24/EU, Directive 2014/25/EU, provided that it does not exceed 100% of the initial contract value, and that it is justified as strictly necessary to respond to the evolution of the crisis.	
Article 39 Ban of individual procurement action by	EE (Drafting): Delete	EE (Comments): Regarding art 39 and art 36 (2), more
participating Member States	FR (Drafting) Article 39 Ban of individual procurement action by participating Member States	specifically the prohibition of organizing individual public procurements in a situation where a Member State has decided to participate in EC joint procurement, while according to art 36 (2) of the EC, if it is set out in the of the

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		public procurement documents, those Member States that did not express their desire to participate in the public procurement may also join the contract after the contract has been concluded. We find this is a disproportionate restriction, which limits the possibilities of these Member States to organize public procurement for the same products or services and endangers a level playing field, seeing as the Member State that does not express their interest in the EC joint procurement, is then free to conduct their public procurement, while other Member States are not. The Member States that do not join the joint procurement then finds themselves in a more favorable position, as they are still free to join the public procurement contract after it has been signed. We propose the ban of individual procurement action by participating Member States be eliminated from the text.
		BE (Comments):
		BE wonders what will happen to any contracts previously in place at Member State level?  Moreover, what if a MS finds a sudden and unexpected way to get the goods much faster and/or cheaper?
		In case of urgency, a MS will not be inclined to refuse desperately needed goods or services if they are suddenly available, especially if waiting for the procurement process by COM would take much longer and therefore impose disproportionate economic damage or even cost

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		lives. As such, BE suggests adding a second paragraph allowing exceptionally a MS to obtain the goods and services, in coordination with COM.
Where the Single Market emergency mode has	BE (Drafting):	LV (Comments):
been activated pursuant to Article 16 and procurement by the Commission on behalf of Member States has been launched in accordance with Articles 34 to 36, the contracting authorities of the participating Member States shall not procure goods or services covered by such procurement by other means.	Where the Single Market emergency mode has been activated pursuant to Article 14 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.  LV (Drafting):  Where the Single Market emergency mode has been activated pursuant to Article 16 Article 14 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.  FR (Drafting)  Where the Single Market emergency mode has been activated pursuant to Article 16 and procurement by the Commission on behalf of Member States has been launched in accordance with Articles 34 to 36, the contracting	Latvia is of view that Article 39 is not justified and proportional as it will restrict Member States' discretionary powers and it is unclear what Member States should do if jointly purchased goods are still not enough for all participating Member States. We also have concerns that ban of individual procurement will lead to artificial price increase for goods that are identified as strategic and crisis-relevant.  There is also a technical error regarding reference to Article 16 as it does not foresee activation of the Single Market emergency mode.  AT (Comments):  Art. 39 of the proposal bans participating MS in a procurement by the COM (acc. to Art. 34 to 36 of the proposal) in a situation where the SM emergency mode has been activated from procuring goods and service by other means.  This provision should be part of Chapter I of this title. Furthermore: is the reference to Art. 16 correct (or should Art. 39 refer to Art. 14 instead)? AT points out, that from a "temporal" perspective, the current wording of the

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authorities of the participating Member States shall not procure goods or services covered by such procurement by other means.

#### FI (Drafting):

Where the Single Market emergency mode has been activated pursuant to Article 16 14 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.

# Subject to Article 34 (4), participating Member States may launch their own procurement procedure.

#### **NL (Drafting):**

Where the Single Market emergency mode has been activated pursuant to Article 16 14 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.

# Subject to Article 34 (4), participating Member States may launch their own procurement procedure.

#### IT (Drafting):

Where the Single Market emergency mode has been activated pursuant to Article 16 and

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provision would ban the procurement activities for an undetermined time and would not be limited to the conduct of a specific procedure. AT suggests to have a better drafting of this "ban" as regards the temporal aspect and possible exceptions to that ban (for ex. If a MS is offered the needed good/service at once/to very advantageous conditions).

#### FR (Comments)

The prohibition for participating Member States to procure goods or services by other means is excessive and inappropriate.

They must only comply with the procurement obligations set out in the agreement with the Commission.

#### FI (Comments):

Please refer to our suggestions in article 34.

#### **NL** (Comments):

Please refer to our suggestions in article 34.

### IT (Comments):

It appears that article 39 excessively hinders the ability of member States to procure goods and services by means of an already existing procedure. Thus, the ban on procuring goods and services should be replaced with a ban on launching a new call for tender. This amendment would safeguard the ability of member States to procure goods and services via an existing procedure, e.g., via a central purchasing authority. The proposed

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	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 autonomously launch a call for tender for goods or services covered by such procurement by other means.  PL (Drafting):  1. Where the Single Market emergency mode has been activated pursuant to Article 16 14 and procurement by the Commission on behalf of Member States has been launched in accordance with Articles 34 to 36, the defined contracting authorities of the participating Member States shall-can be obliged in the authorizing agreement concluded with the Commission pursuant to Article 34(3) not to procure goods or services covered by such procurement by other means.  2. On a request of a participating Member State every ban on individual procurement action of the contracting authorities established by the authorizing agreement concluded pursuant to Article 34 (3), can be waived by the Commission when such a ban will result in severe and disproportionate disruptions in Member States.	amendment's wording would also be in line with the caption of article 39.  LU (Comments):  How does the Commission consider enforcing this provision? Has the Commission assessed the proportionality and feasability?  PL (Comments):  It is not clear whether the disposition of this provision for EU countries, that they "shall not procure goods or services" also applies to tenders in progress or completed, or even concluded framework agreements, or active dynamic purchasing systems.  We are of the opinion that any ban on award of public contracts in a Member States should always be preceded by appropriate, dedicated analysis of its necessity. It would also require the Member State's consent that would be indicated clearly the entities to which it applies. General ban on individual awarding of public contracts in MS is problematic due to the decentralization of public procurement in the EU where thousands of contracting authorities are active on the market, and who rarely coordinate the award of public contracts.  General ban does not seem to be justified in every case and always for all categories of contracting authorities of a given participating country.
	BE (Drafting):	BE (Comments):

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	If, after procurement by the Commission on behalf of the Member States has been launched, the goods or services covered by the procurement become available to a Member State under such advantageous conditions that declining to obtain them would severely and disproportionally restrict the Member State's response to the crisis at hand, the Member State shall be allowed to obtain the goods and services in coordination with the Commission.  IE (Drafting):	See previous comment.  IE (Comments):  Please refer to our suggestions in article 34.
	Where the Single Market emergency mode has been activated pursuant to Article 16 14 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.	
	Subject to Article 34 (4), participating Member States may launch their own procurement procedure.	
Part VI Final provisions	DK (Drafting): Where the Single Market emergency mode has been activated pursuant to Article 146 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	<b>DK (Comments):</b> Typo.

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	such procurement by other means.  NL (Drafting): Article 40 (new)	
	NL (Drafting):  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.  A Member State wishing to participate in procurement procedure must state the particular reasons why it wants to participate only at this stage. The Commission shall assess these reasons and share its opinion with the participating Member States.  Member States shall not join the contract after it has been signed for financial reasons, i.e. because the Commission's contract offers a better price.  The Member States which have participated in the procurement before the signing of the contract shall have priority to obtain products and services if the delivery cannot be carried out for all the participating Member States at the same time.	NL (Comments):  We believe this should only be possible during the emergency mode in exceptional circumstances, on the condition that participating MS before the signing of the contract shall have priority. This option should lead to as little market distortion as possible.
Article 40 Personal data protection		

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1. This Regulation shall be without prejudice to the obligations of Member States relating to their processing of personal data under Regulation (EU) No 2016/679 and Directive 2002/58/EC on privacy and electronic communications, or the obligations of the Commission and, where appropriate, other Union institutions and bodies, relating to their processing of personal data under Regulation (EU) No 2018/1725, when fulfilling their responsibilities.		
2. Personal data shall not be processed or communicated except in cases where this is strictly necessary to the purposes of this Regulation. In such cases, the conditions of Regulation (EU) No 2016/679 and Regulation (EU) No 2018/1725 shall apply as appropriate.		
3. Where processing of personal data is not strictly necessary to the fulfilment of the mechanisms established in this Regulation, personal data shall be rendered anonymous in such a manner that the data subject is not identifiable.		
Article 41 <i>Digital tools</i>		PT (Comments): Which tools has the COM in mind? It should be

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		clarified. <b>BE (Comments):</b> BE wondered about the tools already envisaged by the Commission.  For example, does COM envisage developing a digital tool for managing the strategic reserves foreseen under the SMEI? Indeed, when we talk about stocks, BE is of the opinion that there must be a good "stock management system". Stocks should be monitored and renewed in time, information on stocks should be readily available. Some products have a limited shelf life due to the possibility of deterioration, quality decline or technical ageing.
		Also, as suggested in Art. 27 (6), it seems appropriate to us to provide a methodology and a tool to easily and quickly determine "fair prices" for purchasing "critical products" in case of crisis.
		IE (Comments):  IE would appreciate clarification on how new digital tools or IT infrastructures would be funded- would financial support be provided to Member States? Does the Commission have examples of the kinds of new tools that may be required?
The Commission and the Member States may set up interoperable digital tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures may be	LU (Drafting): The Commission and the Member States shall rely on existing may set up interoperable digital	AT (Comments): In AT's view, it should be a <u>COM</u> obligation, if any, to set up EU-wide interoperable digital

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developed outside the duration of the Single Market Emergency.	tools or IT infrastructures supporting the objectives of this Regulation. Such tools or infrastructures may be <u>further</u> developed outside the duration of the Single Market Emergency.	tools or IT infrastructures supporting the objectives of this Regulation, not a MS' obligation, since the digital tools need to be operable accross the Union/Single Market. Here, COM resources could prove of added value. COM shall not restrict itself to, by means of implementing acts, set out the technical aspects of such tools or infrastructures. It should also bring along the financial resources to develop the tools themselves, as appropriate, and ensure their compatibility with existing digital tools in Member States, if any, where possible and appropriate in accordance with Member States' laws and practices.  FI (Comments):  We see it necessary that the Commission clarifies, how these digital tools and IT infrastructure will be financied. Will they be carried out EU's budjet or should Member States to cover the cost too?  LU (Comments):  We would suggest making a clear reference to an existing tool in order to avoid unnecessary costs and doubling up of tools/processes. We support IMI to be used.
The Commission shall, by means of	LU (Drafting):	AT (Comments):
implementing acts, set out the technical aspects of such tools or infrastructures. Those	The Commission shall, by means of	AT believes that implementing acts adopted
implementing acts shall be adopted in	implementing acts, set out the technical aspects of such tools or infrastructures. Those	under ordinary NONA examination procedure can be adopted fast enough and their discussion

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accordance with the examination procedure referred to in Article 42(2).	implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(2).	in the Committee according to Art. 42(1) can make them more legitimate and smooth the procedure of MS' implementation.
		Therefore, examination procedure in Art. 42(2) need to be amended with a clause referring to the « no opinion, no action » (NONA) comitology procedure.
		→ See comment on Article 42(2).
Article 42 Committee		
The Commission shall be assisted by a Single Market Emergency Instrument		AT (Comments):
Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		Linked to Article 4 (Advisory group).  AT kindly asks CLS for its detailed assessment, which of the tasks given by Article 4 to Advisory group could instead be transferred to the Committee according to Article 42 in conformity with the Treaties, in particular with regard to Art. 291, which attributes the task of « implementation of EU law » to Member States, (not European Parliament - reference to EPs demand in the trilog for the Chips Act to widen the circle of representatives and/or observers in the expert Group).
		In AT's view, matters of implementation of EU law should be dealt with in the (Comitology) Committee according to Article 42, and not in the Advisory Group.

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		Therefore, AT believes the following wording should be added here as a subpara (alignment vid. taken from Directive 2014/28/EU):  « The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure. »
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	AT (Drafting):  Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.  FR (Drafting)  2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.  The implementing act cannot be adopted by the Commission if the Member States do not deliver an opinion.	AT (Comments):  AT believes any response to a Single Market Emergency calls for appropriate involvement of Member States. Therefore, the reference to Article 5 need be amended, so as to refer to the more inclusive « no opinion, no action » (NONA) comitology procedure.  AT wants this horizontal Article on NONA to be referenced in all the individual provisions that delegate implementing powers to EC in this Regulation, e.g. Article 41 (Digital tools), Article 27 (Priority rated orders, if any), Article 26 (Targeted amendments to harmonised product legislation), Article 24 (Information requests to economic operators, if any), Article 18 (Supportive measures, if any), Article 12 (Strategic reserves, if any).  AT kindly asks CLS for its detailed legal opinion on the compatibility, in particular, of the following Articles with subsidiarity principle: Art. 6 (crisis protocols), Art. 12

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		(strategic reserves), Art. 18 (supportive measures), Article 24 (Information requests to economic operators) and Art. 27 (Priority rated orders), Article 9 and 10 (Vigilance Mode activation, extension and deactivation).
		AT wants implementing powers pursuant to Article 14 (Activation) and Article 15 (Extension and deactivation) of the Single Market Emergency mode to be delegated pursuant to Article 291(2) to COUNCIL. AT deems a Single Market Emergency to constitute a « duly justified specific case » in the sense of that provision. In Article 14 (Activation), AT wants the implementing powers stipulated in
		Article 14(3) and (6) to be merged and delegated to COUNCIL. COUNCIL should, via one and the same implementing act, activate the Single Market Emergency Mode and specify the goods/services to which the Emergency pertains as they are lacking for critical sectors or critical infrastructures in the Union to fully operate, thereby justfying the activation of a Single Market Emergency Mode with respect to those goods/services.
		AT wants implementing powers on Vigilance Mode ( <u>if any</u> ) pursuant to Article 9 (Activation) and Article 10 (Extension and deactivation) to be delegated pursuant to Article 291(2) to COUNCIL.  FR (comments)
		It would be necessary to provide in the draft

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		regulation that the implementing act cannot be adopted by the Commission if the MS do not give an opinion.
3. Where reference is made to this	PL (Drafting):	PL (Comments):
paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No	According to art. 8 of Regulation (EU) No 182/2011:
thereof, shall apply.	182/2011, in conjunction with Article 5 thereof, shall apply. The SMEI Committee is obliged to review such implementing act with undue delay. In case the SMEI Committee delivers a negative decision, such decision needs to be taken as soon as possible.	"2.The Commission shall adopt an implementing act which shall apply immediately, without its prior submission to a committee, and shall remain in force for a period not exceeding 6 months unless the basic act provides otherwise."
		The SMEI Committee should deliver its opinion on the implementing act as soon as possible even it is "the urgency procedure" because such procedure could be used to activate highly sensitive measures such as activation of the Single Market Emergency Mode and the list of crisis-relevant goods and services, compulsory information requests to economic operators, priority rated orders, targeted amendments to harmonised product legislation. The SMEI Committee/ Member States should have real influence on the text of the implementing acts.
	EE (Drafting):	EE (Comments):
	4. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of	From initating vigilence mode to subscribing strategic reserves to a Member State, we see a need for higher involvement of the Member

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	Article 5(4) of Regulation (EU) No 182/2011 shall apply	States
Article 43 Delegated acts	AT (Drafting): Article 43 Delegated acts EE (Drafting): Delete PL (Drafting): Article 43 Delegated acts	EE (Comments):  We prefer to regulate the crisis procols in SMEI as we see them an inherent part of the Regulation.  PT (Comments):  • The objectives, content, and scope of the delegation of powers should also be spelled out, as should the duration. Note that it would be important for the Commission to consult experts designated by each Member State before adopting such acts.  PL (Comments):  We propose to delete this Article as a consequence of our proposal to delete delegated act in Article 6
The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	AT (Drafting):  1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.  EE (Drafting): Delete DK (Drafting): Article 43 Delegated acts PL (Drafting):	AT (Comments): As indicated in previous discussions, AT suggests to delete Art. 6 on the delegated acts. Therefore, Art. 43 is not necessary anymore.  DK (Comments): Amended following proposal to delete the use of delegated acts in Article 6.

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	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.	AT (Drafting):  2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.  LV (Drafting):  2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive Regulation or any other date set by the co-legislators.  EE (Drafting): Delete	LV (Comments): Technical error regarding the reference.
	DK (Drafting):  1. — The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.  PL (Drafting):  2. — The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.	

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
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.	AT (Drafting):  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.  EE (Drafting):  Delete  DK (Drafting):  2. The power to adopt delegated acts referred to in Article 6 shall be conferred on the Commission for a period of five years from date of entry into force of this Directive or any other date set by the co-legislators.  PL (Drafting):  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	

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	of any delegated acts already in force.	
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	AT (Drafting):  4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	
	DK (Drafting):	
	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.	
	PL (Drafting):	
	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	
5. As soon as it adopts a delegated act, the	AT (Drafting):	

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Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
	DK (Drafting):  4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	
	PL (Drafting):  5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
Article 44 Report and review	PL (Drafting): Article 44 Report, and review and evaluation	
		IE (Comments):  IE feels that five years review terms is too long and should be reconsidered. IE also believes an evaluation of the functioning of the instruments should be carried out after each deactivation of the different modes.
1. By [OP: please insert date = five years from the entry into force of this Regulation] and every five years thereafter, the Commission shall present a report to the European Parliament and the Council on the functioning of	AT (Drafting):  1. By [OP: please insert date = five two years from the entry into force of this Regulation] and every five two years thereafter,	LV (Comments):  The report and review period should be shorter due to complexity of the file to evaluate its effectiveness and interaction with other relevant

### **Commission proposal**

the contingency planning, vigilance and Single Market emergency response system suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.

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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.

#### LV (Drafting):

1. By [OP: please insert date = five three years from the entry into force of this Regulation] and every five years three 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.

#### **DK** (Drafting):

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

#### FI (Drafting):

1. By [OP: please insert date = five years from the entry into force of this Regulation] and every five years thereafter, and after every deactivation of the vigilance and/or emergency mode, the Commission shall present a report to the European Parliament and the Council on the functioning of the contingency planning, vigilance and Single Market

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Union level crises mechanisms to propose the necessary adjustments if needed in a timely manner.

#### AT (Comments):

A first review only after 5 years seems rather late, therefore we propose to evaluate already after 2 years of application.

#### DK (Comments):

Typo.

#### FI (Comments):

We believe it is important to evaluate the functioning of the instrument after each deactivation of the different modes.

#### IT (Comments):

The 5-year timeframe set forth in this article for reporting to the European Parliament and to the Council is too long. Thus, the aforesaid timeframe is not very effective for acquiring the relevant information needed to quell the ongoing crisis. Generally speaking, the timeframe should not exceed 2 years.

#### LU (Comments):

Given the novelty of the SMEI, the first report shall be drawn up much sooner than 5 years after the entry into force. We suggest 2 years.

#### PL (Comments):

The period of five years to submit the first and subsequent reports is too long. In our opinion, the first report should be presented after two

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	emergency response system suggesting any improvements if necessary, accompanied, where appropriate, by relevant legislative proposals.	years, and then every three years.  The report should contain not only an assessment of the work of the advisory group,
	LU ( <b>Drafting</b> ):  1. By [OP: please insert date = five years from the entry into force of this Regulation] and every five two years thereafter, the Commission shall present a report to the European	but the Commission shall carry out an evaluation of the effectiveness of the Regulation and submit the report on its functioning to the European Parliament, to the Council and to the European Economic and Social Committee.
	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.	ES (Comments): In the event that the report requires data to be sent by the Member States, and taking into account that all information requests and data collection involve a great deal of coordination, especially in highly decentralised countries such
	PL (Drafting):  1. By [OP: please insert date = five two years from the entry into force of this Regulation] and every five three years thereafter, the Commission shall carry out an	as Spain, we consider is it essential that any collection of information is carried out in the most automated and parameterised way possible, and channelled through the standard forms of Commission Implementing Regulation
	evaluation of the effectiveness of this Regulation and shall present submit a report on the functioning of the Regulation to the European Parliament, and to the Council and to the European Economic and Social	(EU) 2019/1780 of 23 September 2019 establishing standard forms for the publication of notices in the field of public procurement and repealing Implementing Regulation (EU) 2015/1986. Reference to this instrument could also be made in Article 41 of the proposal
	Committee. on the functioning of the contingency planning, vigilance and Single Market emergency response system suggesting any improvements if necessary, The report shall be accompanied, where appropriate, by relevant legislative proposals.	referring to "digital tools" available under the Regulation.

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
2. This report shall include an evaluation of the work of the advisory group under the emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis management bodies.		
	1. By [OP: please insert date = five years from the entry into force of this Regulation] and every	the crisis. These reports shall become the

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
	five years thereafter, and after every deactivation of the vigilance and/or emergency mode, 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.	"lessons learnt" for any future application of the SMEI.
	LU (Drafting):  2. This report shall include an evaluation of, amongs others:	
	(a) the contribution of this Regulation to the smooth and efficient functioning of the Single market, in particular as regards the free movement of goods, services and persons;	
	(b) the work of the advisory group under the emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis management bodies;	
	(c) the effectiveness of the general framework approach adopted in this Regulation, in particular the coherence and good articulation between this Regulation and other pieces of legislation and crisis	
	management structures, in particular the IPCR, HERA, UCPM and the Chips Act. PL (Drafting):	
	2. This report shall include an evaluation of the work of the advisory group under the	

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
	emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis management bodies.	
Article 45	DK (Drafting):	BE (Comments):
Repeal	2. This report shall include an evaluation of the work of the advisory group and the Commission under the emergency framework established by this Regulation, and its relation to the work of other relevant Union level crisis	The repeal of Regulation (EC) No 2679/98 must not affect the right to strike. The Monti clause should be included in a new paragraph 7a in Article 2 of the proposal (see previous comment on art.2) to guarantee the right to strike.
	management bodies.	DK (Comments):
		In order to ensure a full evaluation of the efficiency of the instrument, it is imperative that not only the advisory group, but also the Commission's work is evaluated.
		PL (Comments):
		We agree to repeal Regulation (EC) 2679/98 because, according to the evaluation of this Regulation, this mechanism is rarely used and the information exchange system is insufficient as it is too slow and outdated.
Council Regulation (EC) 2679/98 is repealed	PL (Drafting):	AT (Comments):
with effect from [date].	Council Regulation (EC) 2679/98 is repealed with effect from [date].	The so called "Strawberry Regulation" (Regulation (EC) No. 2679/98) states in Article
	References to the repealed Regulation shall be construed as references to this Regulation. ES (Drafting):	2 that the functioning of the internal market must in no way affect the exercise of fundamental rights and in particular the right to

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	Council Regulation (EC) 2679/98 is repealed with effect from [date].	strike. Only recital 36 of SMEI-Regulation states that this regulation respects fundamental rights, including "the right to collective bargaining and the right to take collective action as provided for in Article 28 of the Charter of Fundamental Rights" (and not in Article 26, as incorrectly stated by the EC). In particular, recital 36 of the proposal is not considered sufficient in this regard.
		A clear, legally secure exception for fundamental rights including the right to strike would be welcomed.
		ES (Comments):
		ES asks for the derogation of this article in order to keep in force the Council Regulation (EC) 2679/98.
		Firstly, it should be taken into consideration the differente nature of both regulations. While the objective of SMEI (art 1) is to "anticipate, prepare for and respond to impacts of crises on the Single Market" meaning in accordance with art 3 "an exceptional unexpected and sudden, natural or man-made event of extraordinary nature and scale that takes place inside or outside of the Union", in the case of the Council Regulation (EC) 2679/98 the objective are "obstacles to the free movement of goods among Member States which is attributable to a Member State" (art 1).

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
		Secondly, ES considers that the repealing of this Regulation entails the loss of a very flexible and agile instrument to denounce occasional disruptions of the free movement among Member States. It is a very useful instrument, which has not been contested by the Member States and that according to the evaluation made by the Commission in 2018 (twenty years after its entry into force) "the Regulation has [also shown] a deterrent effect and thus has exerted pressure on Member States' public authorities to address cases of disruptions in the physical movement of goods, and has therefore improved the management of obstacles under Article 4 of the Regulation".  Another different issue is the preservation of the right to strike (also included in art 2 of the Council Regulation (EC) 2679/98). We would like to see a clear reference of it in the SMEI text (whether as a recital or in the articles)
Article 46 Entry into force	PL (Drafting): Article 46 Entry into force and application	PT (Comments):  The entry into force 20 days after publication seems to be insufficient to comply with the implementation requirements foreseen in the SMEI proposal.
		PL (Comments):  Due to the complexity of solutions proposed in the regulation, the need to prepare national technical or administrative regulations to ensure

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
		the proper application of SMEI regulation and due to the specificity of the Polish legislative process, we need a period of at least 18 months of <i>vacatio legis</i> to prepare for application of this regulation.
		<b>IE</b> (Comments):  The period of twenty days for the Regulation to come into force does not seem adequate as new legislation and/or ICT infrastructure may be required.
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	LU (Drafting):  1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.  2. It shall apply from [date – twenty-four months after its entry into force].  PL (Drafting):  This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.  It shall apply from [18 months from the entry into force of this Regulation]	LV (Comments):  A longer period of entry into force would be needed (18 months) due to complexity of this proposal and necessary adjustments introduced at the national level.  BE (Comments):  The entry into force 20 days after publication may not be sufficient to comply with the implementation arrangements, as for the establishment of the advisory group (or rather steering committee – see previous comment on Art 4, repeated above in Art 34(2)) and the designation of the liaison office(s).  LU (Comments):  Member States need to take the necessary measures at national level to make sure the Regulation becomes effective. Therefore, a longer timeperiod for the entry into application is needed.

Commission proposal	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Drafting Suggestions	AT BE DK EE ES FI FR IE IT LU LV NL PL PT Comments
		We also strongly advise against deferred entries into force for different sections of the SMEI. For purposes of legal certainty and predictability, as well as coherence of the Regulation as one set of consistent rules, a single timeframe for the entry into application shall be retained.
This Regulation shall be binding in its entirety and directly applicable in all Member States.		FI (Comments): We understand that the Regulation should be applied as soon as possible. However, we see it important to give the Member States some time to carry out the implementation.
		PL (Comments): We agree to repeal Regulation (EC) 2679/98 because, according to the evaluation of this Regulation, this mechanism is rarely used and the information exchange system is insufficient as it is too slow and outdated.
Done at Brussels,		
For the European Parliament For the Council		
The President The President		