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Delegations will find attached document SEC(2022) 323.

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EUROPEAN COMMISSION

Brussels, 17.8.2022
SEC(2022) 323 final

REGULATORY SCRUTINY BOARD OPINION

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Single Market emergency instrument and repealing Council Regulation (EC) 2679/98

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and2014/68/EU as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency

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EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / Single Market Emergency Instrument

Overall 2nd opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Natural disasters, human-made crises as well as measures taken in response to such situations, such as restrictions to the free movement of goods, services and persons may disrupt the proper functioning of the Single Market. Cooperation among Member States can strengthen the EU's resilience and crisis response.

The Single Market Emergency Instrument (SMEI) aims to minimise obstacles to the free movement of goods, services and persons in times of crisis and to avoid shortages of crisis-relevant goods and services. To this end, this initiative intends to equip the EU with a set of instruments for a rapid and effective response to any future crisis that might hamper the functioning of the Single Market.

(B) Summary of findings

The Board notes the substantial changes made to the draft report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations subject to the DG rectifying the following aspects:

(1) The report does not sufficiently identify, explore or distinguish between different types of crises that may impact the functioning of the Single Market.

(2) The report does not clearly set out the scope or recent uses of the Article 4(2) TEU national security exemption and as a result risks underestimating its significance in a crisis situation. It does not explain the hierarchy of emergency measures among the EU-level instruments and those that Member States themselves may introduce in a crisis situation on the basis of Article 4(2) TEU. The rationale, content and functioning of some options and measures are not sufficiently clear.

(3) The report does not sufficiently justify some of the obligatory measures proposed in the SMEI emergency mode from the subsidiarity and proportionality principles point of view.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) As the initiative is intended to provide an enabling framework for supporting a proper functioning of the Single Market in a crisis situation, the report should explore, analyse and discuss different crisis scenarios that may lead to disruptions in the free circulation of goods, services and persons in the EU. The current text of the report centres almost exclusively on the COVD-19 pandemic and the war in Ukraine while not sufficiently reflecting other recent crises with Single Market effects such as financial, natural disasters, terrorism or migration. In the absence of a broader analysis feeding into the problem definition, the report risks proposing solutions to the last crisis rather than building the Union's resilience, preparedness and rapid response to the next. Overall, the report should distinguish more clearly between structural problems (requiring long-term structural solutions) and emergency and crisis triggered situations that could require a coordinated action at the EU level. It should more clearly present as a problem driver the fact that the existing EU emergency instruments/mechanisms do not have Single Market in their focus rather than 'the lack of' appropriate bodies or instruments.

(2) Given the plethora of crisis-related instruments at the EU level and the possibility for Member States to invoke Article 4(2) TEU that provides for the Member States the right to take measures to maintain law and order and safeguard national security, the report should better explain and analyse with examples the hierarchy and interaction of these measures/instruments that would apply in a crisis situation. It should not underplay the significance of Article 4(2) TEU given the latter has been invoked by Member States in recent crises at some point, but instead seek to demonstrate how an effective SMEI with full Member State participation could potentially avoid the use of this Article of last resort. While the SMEI is meant to be built on early warnings, cooperation and coordination among Member States, potential conflicts between safeguarding national security and supporting a proper functioning of the Single Market cannot be excluded in the future. The report should discuss more thoroughly, including from a subsidiarity and proportionality perspective, how overlapping or conflicting measures at EU and Member State level will be avoided and potential conflicts resolved.

(3) The report should better present the rationale, content and functioning of some options and measures. It should bring out more clearly the practical functioning (including their financing) of the solidarity measures envisaged under policy option 3 ('Solidarity'), given that the main trust of this option seems to be about concentrating decision making at EU level. It should better justify why for building block 5 (transparency and administrative assistance during emergency) no alternative option than the most comprehensive legal framework (i.e., possibility to declare the notified national crisis measure incompatible) was considered, leaving no choice for the decision maker. It should better explain how the targets for strategic reserves will be set and whether (in particular smaller) Member States could cooperate in due time in achieving their respective targets, for instance by pooling certain measures to achieve synergies. It should also clarify how overlap or inefficient duplication of strategic reserves built up on the basis of different (national and EU level) objectives will be avoided, exploring targeted coordination mechanisms to this purpose. It should clarify the nature of the separate financial instrument that would be necessary for the most ambitious measures under building block 8 (crisis relevant supply chains).

(4) The report should explain how the digital by default principle will be applied in the measures envisaged under the SMEI instrument.

(5) Stakeholder views should be systematically presented in a more granular way, focusing on the types of stakeholders (e.g. Member States, SMEs) rather than only on the type of consultation.

The Impact Assessment does not present a preferred option. The Board notes an indication of the costs and benefits of the three identified options in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the (preferred) option(s) in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Single Market Emergency Instrument
Reference number	PLAN/2021/11161
Submitted to RSB on	29 July 2022
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions)		
Description	***Amount***	***Comments***
Direct benefits		
Access to the Single Market during times of crisis for citizens and businesses	Total amount not quantifiable but benefits generated by open borders and the free flow of goods, services and persons in times of crisis.	Benefits for citizens and businesses applicable for all policy options.
Support for the identified supply chains ensuring the functioning of the Single Market and better overall EU-level crisis response thanks to the availability of crisis-relevant products needed in the crisis response	Total amount not quantifiable but benefits generated better crisis response, thanks to better availability of crisis-relevant products and services.	Benefit for citizens and businesses applicable for all policy options but with a different order of magnitude depending on the effectiveness of the toolbox.
Repeal of the Strawberry Regulation	Simplification of the crisis framework.	As the Strawberry Regulation deals with emergency type of situations, there would be no costs savings for businesses and citizens with immediate effect.
Indirect benefits		
Social benefits in terms of improving living conditions and quality of life of citizens and saving lives, depending on the crisis.	Total amount not quantifiable, but benefits generated especially due to better availability of crisis-relevant products needed in the crisis response and less obstacles to the free movement of persons.	Benefits for citizens applicable for all policy options, but with a different order of magnitude depending on the availability of effective tools in the toolbox.
Administrative cost savings related to the 'one in, one out' approach *		
N/A		

*(1) Estimates are gross values relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in adjustment costs, administrative costs, regulatory charges, enforcement costs, etc.;); (4) Cost savings related to the 'one in, one out' approach are detailed in Tool #58 and #59 of the 'better regulation' toolbox. * if relevant.*

II. Overview of costs							
		Citizens/ Consumers		Businesses		Administrations (Member States)	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Actions applicable at all times	Direct adjustment costs	-	-	-	-	-	-
	Direct administrative costs	-	-	-	-	-	Costs of participation in Advisory Group estimated at ½ FTE per MS (all POs); costs of participation in trainings and drills organised by the Commission (PO2 and 3); costs of organising regular trainings for national experts (PO2 and 3)
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	-	-	-	-
Actions applicable in vigilance mode (see triggering mechanisms in section 5)[1]	Direct adjustment costs	-	-	-	-	-	Costs of gathering information on identified supply chains and monitoring them for a list of indicators (PO3); costs of participation in match-making; costs of constituting

[1] The recurrent costs in the context of vigilance are understood as ongoing costs incurred during the duration of a vigilance mode whereas one-off costs relate to single actions during a given activation of a vigilance mode. The assessment of costs will be done based on available evidence before triggering this mode certain as explained in section 5.

							strategic reserves (PO3)
	Direct administrative costs	-	-	-	-	-	-
	Direct regulatory fees and charges	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	-	-	-	-
Actions applicable in emergency mode (see triggering mechanisms in section 5)[2]	Direct adjustment costs	-	-	-	-	Costs of compliance with key principles of free movement (all POs)	Costs for encouraging economic operators to ramp up production (under PO2); costs of distribution of constituted strategic reserves (under PO3); costs for encouraging economic operators to ramp up production (under PO2); costs of distribution of constituted strategic reserves (under PO3)
	Direct administrative costs	-	-	Costs of complying with mandatory information requests (PO2 and 3)	-	Costs for issuing mandatory information requests (under PO2)	Costs for compliance with notification mechanism (all POs)
	Direct regulatory fees and charges	-	-	-	-	-	-

[2] The recurrent costs in the context of emergency are understood as ongoing costs incurred during the duration of a given emergency here as one-off costs relate to single actions during a given activation of a emergency mode. The assessment of costs will be done based on available evidence before triggering certain measures as explained in section 5.

	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	Opportunity costs linked to ramping up production (PO2 and 3); opportunity costs linked to accepting priority-rated orders (PO3)	-	-	-
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	Given that there are no immediate costs for businesses and citizens envisaged under this initiative and that the costs identified are incurred to businesses in exceptional circumstances (emergency and vigilance) the costs cannot be estimated for the 'one in, one out' approach. The assessment of impacts and related costs will be done based on available evidence before triggering certain measures as explained in section 5.					
	Indirect adjustment costs	N/A					
	Administrative costs (for offsetting)	N/A					

(1) Estimates (gross values) to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (adjustment costs, administrative costs, regulatory charges, enforcement costs, indirect costs;). (4) Administrative costs for offsetting as explained in Tool #58 and #59 of the 'better regulation' toolbox. The total adjustment costs should equal the sum of the adjustment costs presented in the upper part of the table (whenever they are quantifiable and/or can be monetised). Measures taken with a view to compensate adjustment costs to the greatest extent possible are presented in the section of the impact assessment report presenting the preferred option.

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels, 8 July 2022
RSB

Opinion

Title: Impact assessment / Single Market Emergency Instrument

Overall opinion: NEGATIVE

(A) Policy context

Natural disasters, human-made crises as well as measures taken in response to such situations, such as restrictions to the free movement of goods, services and persons may disrupt the proper functioning of the Single Market. Cooperation among Member States can strengthen the EU's resilience and crisis response.

The Single Market Emergency Instrument (SMEI) aims to minimise obstacles to the free movement of goods, services and persons in times of crisis and to avoid shortages of crisis-relevant goods and services. To this end, this initiative is intended to equip the EU with a set of instruments for a rapid and effective response to any future crisis that might hamper the functioning of the Single Market.

(B) Summary of findings

The Board notes the additional information provided in advance of the meeting and commitments to make changes to the report.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report does not provide a clear definition of a Single Market 'emergency'. It does not specify the criteria and decision-mechanisms for establishing and terminating an emergency. It does not clearly differentiate the basic SMEI measures and structures that will be implemented in the absence of a crisis from those that can only be activated once a Single Market 'emergency' is established. It does not clearly identify the decisional and analytical requirements and steps for taking emergency measures.

(2) The report does not provide a thorough assessment of the impacts of the policy options. It does not clearly differentiate the impacts that will result from the creation of the SMEI (and the directly applicable measures) from those that could materialise only if specific emergency measures are activated.

(3) The report is unclear about the policy choices and discretion open to policymakers on the basis of the analysis. It does not present alternative combinations of relevant policy options. The comparison of options is not linked to the analysis of impacts and does not sufficiently reflect the respect of the proportionality and subsidiarity principles.

(C) What to improve

(1) The report should clarify upfront that it deals only with problems that may appear during any kind of crisis clearly linked to the functioning of the Single Market. The problem definition should make a clear distinction between structural issues, such as dependence on critical raw materials or other non-diversifiable inputs, which are likely to require specific policy instruments, and clearly single market crisis-related challenges. It should clarify and substantiate with evidence to what extent global and external shortages of crisis-relevant goods alone critically affect the functioning of the Single Market and allow Article 114 to be used to justify related measures, such as strategic stockpiling and supply chain interventions (e.g. repurposing). It should also explain how precisely the SMEI will articulate with Member States' right to invoke Article 4(2) TEU in crises that they consider threaten their national security.

(2) The report should clarify upfront the definitions of Single Market 'vigilance' and Single Market 'emergency' and the overall gradual intervention approach envisaged. It should explain in detail the criteria, triggers, and process to activate and deactivate the 'vigilance' and 'emergency' modes and to move from one to another, who will take such decisions (Commission, Council or both), on the basis of what kind of analysis and alerts, and based on what type of decision-making instrument and voting procedure. Moreover, the report should explain how Single Market 'emergency' status would interact with the emergency status decided at the Member State level.

(3) The report should set out, analyse and compare a set of policy options that are feasible and politically relevant. It should explore policy options consisting of all or a selection of building blocks, representing different levels of ambition, different areas of action, different timings, or different triggers and decision process mechanisms for the instruments. The policy options should be framed to meet the expectations and recognise the constraints of stakeholders, Member States and Parliament.

(4) The report should better justify the selection of the nine building blocks. It should:

- explain how they were identified, whether there were other alternatives and how stakeholders' views were considered,
- explain the link between the building blocks and the remaining gaps in the Single Market legislation,
- clearly distinguish between those building blocks that will be in place permanently and those that could be activated only during an established crisis,
- present evidence (including experience from previous crises) that justifies as such the inclusion of the proposed far-reaching and intrusive interventions in the area of strategic reserves and supply chains and specify clearly the information needs required to justify regulatory interventions in these areas as well as assess the feasibility of such interventions,
- address the concerns shown by stakeholders, including from a subsidiarity and proportionality perspective as regards measures such as stockpiling, monitoring and enhancing the resilience of strategic supply chains, disclosure of information or accelerating Member States normal permitting procedures.

(5) The analysis of impacts should be strengthened. It should:

- specify unambiguously the evidence supporting the impact analysis and assess how robust the resulting conclusions are,
- acknowledge that for certain measures the necessary evidence will become available only in a crisis situation and will therefore need to be adequately reflected in the decision to activate such measures,
- assess the broader economic, international trade, competition and business impacts and present clearly the results of an SME test,
- explore and elaborate on the type of social and environmental impacts that the initiative could have,
- show a comprehensive overview of the administrative and adjustment costs (and savings) for businesses, citizens and national authorities to allow a realistic assessment of the magnitude of the expected administrative costs for businesses and citizens for the purpose of 'One-In, One-Out',
- clearly present the budgetary impacts of the initiative, including considering whether economic operators would be entitled to compensation in cases of revenue losses due to repurposing or EU prioritisation,
- specify which impacts will materialise once the instrument is adopted, and which only in a concrete crisis situation,
- improve the effectiveness analysis throughout (e.g. building up strategic reserves of critical goods only once an emergency is established might come too late and may plead rather for structural measures).

(6) The comparison of options should clearly flow from the analysis of the policy options. The report should justify the scores given to each policy option. On that basis the report should identify the most relevant or best performing combination of policy options and compare them in terms of effectiveness, efficiency and coherence to allow policy makers a complete and fully informed choice. This comparison should include a more developed assessment in terms of proportionality and respect of the subsidiarity principle.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Single Market Emergency Instrument
Reference number	PLAN/2021/11161
Submitted to RSB on	15 June 2022
Date of RSB meeting	06 July 2022

Electronically signed on 17/08/2022 14:55 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121