



EUROPEAN COMMISSION

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C(2023) 1648 final

Dear President,

The Commission would like to thank the Senát for its Opinion on the 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 {COM(2022) 459 final}; the 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 and 2014/68/EU as regard emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency {COM(2022) 462 final}; and the 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 {COM(2022) 461 final}.

These proposals, announced in the Commission Work Programme for 2022, form a package of measures designed to preserve the functioning of the Single Market in the event of future crises, to the benefit of citizens and businesses across the EU. The Single Market Emergency Instrument package aims to provide a structural answer to preserve the free movement of goods, people and services in crises. The experience from the past, including the COVID-19 pandemic, has shown that unilateral measures caused fragmentation, worsened the crisis and affected particularly SMEs. This showed the need for mechanisms allowing the EU to react fast and collectively and ensure that in a potential new crisis, the Single Market can remain open and goods of vital importance remain available to protect European citizens and to keep the economy running.

The Commission takes note of the concerns expressed by the Senát as regards the definitions, scope, the respective competences and roles of the Commission and the Member States, administrative burden on stakeholders, priority rated orders, fast track conformity assessment procedures and strategic reserves. In response to the more

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technical comments in the Opinion, the Commission would like to refer to the attached annex. The Commission is pleased to have the opportunity to provide a number of clarifications regarding its proposals and trusts that these will allay the concerns of the Senát.

Discussions between the Commission and the co-legislators concerning the proposal are now underway. The Commission remains hopeful that an agreement will be reached in the near future.

The Opinion of the Senát has been made available to the Commission's representatives in the ongoing negotiations of the co-legislators and will inform these discussions. The Commission will insist on the need to ensure that the rules are sufficiently effective and flexible, while avoiding any disproportionate burden on stakeholders.

The Commission hopes that the clarifications provided in this reply address the points raised by the Senát and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*

*Thierry Breton
Member of the Commission*

Annex

In preparing the proposals, the Commission has strived to ensure legal certainty by laying down clear definitions and criteria for all the concepts and mechanisms laid down in the proposed legal frameworks. The choice of the scope and the precise formulation of the definitions have been guided by the overarching objective to lay down a cross-cutting and flexible mechanism, allowing it to cater for a wide range of potential crisis scenarios, in order to preserve the functioning of the Single Market. The Single Market Emergency Instrument aims to cover those areas and sectors where there are currently no mechanisms for coordinated crisis-response at the EU level in place. Furthermore, the mechanisms set up by the proposed Single Market Emergency Instrument provide for the oversight by and the close involvement of the relevant competent national authorities at all stages of implementing the proposed rules.

The Commission has consistently strived to ensure that the implementation of the proposed rules would not entail a disproportionate burden for stakeholders, including economic operators. The close involvement of the national authorities at the stage of activation of vigilance and emergency modes as well as the implementation of the rules aims at ensuring this.

With respect to the proposed mechanism of priority rated orders, the Commission would like to point out that this constitutes only one of the specific tools which may be activated in the context of a Single Market emergency declared by the Council. Therefore, the application of this mechanism is not automatic, and all relevant data will have to be systematically weighed before the Commission will propose to the Council the activation of this mechanism, hence the decision is taken by the Member States. Moreover, this tool relies on the precept of 'comply or explain', underpinning the proportionality principle. Concretely, if, following an invitation by the Commission, an economic operator does not accept to voluntarily prioritise certain orders, the Commission may adopt an implementing act according to which the economic operator should either accept the priority rated order to explain within 10 day or explain why it is not possible or appropriate to do so. Furthermore, the implementing acts which the Commission may adopt under this mechanism are subject to systematic scrutiny by the representatives of the Member States.

Looking more closely at the architecture of the mechanism of priority rated orders, the Commission would like to point out that it provides for a multi-tiered system, which privileges the dialogue between the Commission and economic operators at each level. For example, in the first stage of the mechanism, an economic operator may simply be invited to prioritise certain orders. Only if the economic operator does not accept this, the Commission may initiate a detailed assessment of the circumstances of the case during which the economic operator as well as any parties demonstrably affected by the potential priority rated order would have the opportunity to state their positions. In exceptional circumstances, following such assessment, the Commission may address an implementing act, adopted by qualified majority by the Council, to the economic operator concerned, requiring it to either accept and prioritise the priority rated orders specified in the implementing act or explain why it is not possible or appropriate for that

operator to do so. Therefore, as the mechanism is currently proposed, economic operators cannot automatically and directly become subject to a priority rated order. In any event, the material scope of the provision on priority rated orders will be narrowly defined and determined on the basis of the list of crisis-relevant goods and services, which the Commission needs to adopt via implementing act following the activation of the emergency mode by the Council.

The proposed mechanism of priority rated orders thus provides for a number of safeguards to the benefit of economic operators, and also lists the principles which should guide the Commission in using this mechanism.

With respect to the cost of priority rated orders as well as the possible penalties associated with this mechanism, the Commission would like to point out firstly that the proposal provides that the priority rated order shall be placed at a fair and reasonable price. Secondly, with regards to the contractual liability and possible penalties for economic operators, the proposal provides for the exclusion of the contractual liability of economic operators which have accepted a priority rated order. This exclusion would be subject to the requirement for the contractual obligations to be governed by the law of a Member State and would be limited only to the violation of those contractual obligations necessary for compliance with the required prioritisation. Finally, with respect to the possible imposition of penalties, the proposal provides for such a possibility only in a limited number of instances, which cover the refusal to provide information on an existing third-country priority rated order, the failure to explain why the economic operator has not accepted a priority rated order and, in case a priority rated order has been accepted, the failure to comply with the accepted obligation. It should also be noted that the fines may be imposed in cases where the economic operator has acted intentionally or through gross negligence.

The Single Market Emergency Instrument package also brings forward amendments to 19 Union frameworks laying down harmonised rules for the design and placing on the market of products. The overall objective of these amendments is to provide for mechanisms which would ensure the availability of essential goods in cases of disruptions to the normal functioning of the Single Market. The selected frameworks are the ones which lay down the harmonised rules covering most of the consumer and industrial goods placed on the EU market. Additionally, the selected frameworks do not currently contain any provisions specifically laying down crisis-response measures.

The Commission would like to emphasise that the proposed crisis-response measures, including the fast-track conformity assessment procedures, do not provide for the possibility to derogate from the substantive safety requirements laid down by the harmonised Union frameworks. These measures are only limited to certain adjustments to the procedural requirements for assessing the compliance with the substantive requirements. Therefore, the application of the emergency procedures should not have a negative impact on the level of safety and the protection of the consumers and other users of such products. With respect to the interrogation by the Sénat on the follow-up actions with respect to goods placed on the market following a fast-track conformity assessment, the Commission would like to point out that in the first place, these follow-up

actions are to be specified by the competent national authority, which issues a temporary authorisation. Considering that they are able to fully assess the relevant aspects in each case, national authorities are responsible for specifying the procedural rules for assessing compliance and for the necessary follow-up actions. The proposal also provides for the possibility for the Commission to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to such products placed.

Finally, the Commission takes note of the comment by the Sénat concerning the provision on strategic reserves. The Commission would like to point out that the proposed mechanism places an emphasis on the continued dialogue between the Commission and the Member States. The objective is to ensure a coordinated approach towards the building of such strategic reserves. Firstly, the mechanism relies on an exchange of information between the Member States and the Commission regarding the stock of goods on their respective territories, including stocks held by economic operators, as well as any options for alternative supply. Particularly with a view of streamlining Member States' efforts, the Commission may draw up and regularly update a list of individual targets for the strategic reserves to be held by each Member State. These individual targets should also take into account the level of existing stocks of the economic operators and strategic reserves across the Union, and any information on economic operators' ongoing activities to increase their stocks. The mechanism leaves the responsibility to the Member States to determine the practical modalities governing the constitution of such reserves. In cases where the strategic reserves of a Member State continuously fall significantly short of the individual targets and economic operators on its territory are not able to compensate that shortfall, the Commission may assess the need to adopt an implementing act, requiring the Member State in question to build up its strategic reserves of the goods concerned by a set deadline. The provision lays down a list of findings, which the Commission needs to establish based on objective data in order to proceed with the adoption of such an implementing act. The objective of ensuring the most efficient use of reserves is also reflected in the provision which provides for the possibility for the Commission to recommend to the Member States to distribute the strategic reserves in a targeted way.
