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IMPACT ASSESSMENT REPORT

Accompanying the document

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

for a Single Market Emergency Instrument

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

and DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2013/29/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU 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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GLOSSARY

Term or acronym	Meaning or definition
CFS	Centre for Strategic Futures, Singapore
CIFUS	Committee on Foreign Investment in the United States, US
CWP	Commission Work Programme
DPA	Defense Production Act, US
ECDC	European Centre for Disease Prevention and Control
EEN	Enterprise Europe Network
EFSCM	European Food Security Crisis preparedness and response Mechanism
ERCC	Emergency Response Coordination Centre
ESPA	Economic Security Promotion Act, Japan
FABS	Facilitating American-Built Semiconductors Act, US
FEPO	Future Economy Planning Office, Singapore
FIRB	Foreign Investment Review Board
GPA	Government Procurement Agreement, US
HERA	Health Emergency Preparedness and Response
IJA	Infrastructure Investment and Jobs Act, US
IMCO	European Parliament's Committee on Internal Market and Consumer Protection
IPCEI	Important Project of Common European Interest, EU
IPCR	Integrated Political Crisis Response
IPI	International Procurement Instrument
JOGMEC	State owned Japan Oil, Gas and Metals National Corporation, Japan
NDICI	Neighbourhood, Development, and International Cooperation Instrument - Global Europe, EU
NDS	National Defense Stockpile, US
NLF	New Legislative Framework
NSIA	National Security and Investment Act, UK
PPE	Personal Protective Equipment

RIE2025	Research Innovation Entrepreneurship Programme, Singapore
RSB	Regulatory Scrutiny Board
SCRI	Supply Chain Resilience Initiative, Australia
SMA	Southeast Asia Manufacturing Alliance, Singapore
SMET	Single Market Enforcement Task Force
SMIT	Single Market Information Tool
SMTD	Single Market Transparency Directive
TFEU	Treaty on the Functioning of the European Union
TRIS	Technical Regulation Information System
UCPM	Union Civil Protection Mechanism

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

A look back in history reveals that crises may pave the way to expeditious innovation, rapid advances in technology, policy, and/or procedures that in turn may offer benefits for societies, countries, and humanity¹. However, crises by their very nature disrupt citizens' lives as well as markets and the overall economy.

The Single Market is one of the EU's greatest assets and provides the backbone for the EU's economic growth and wellbeing. For this reason, the functioning of the Single Market needs to be guaranteed in times of emergency and crisis. While resilience of the Single Market is the prime responsibility of the European businesses, the free movement of goods, services and persons is the foundation of the Single Market and underpins a smooth functioning of supply chains, including the availability of services and goods.

In recent years, the world has been witnessing a sequence of crises from the COVID-19 pandemic to Russia's invasion of Ukraine. These will not be the last crises that the world will have to weather. In addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. Unfortunately, there is no crystal ball at hand to predict the exact time and form of the next crisis.

As recent crises have shown, a fully-operational Single Market and smooth cooperation of Member States on Single Market issues can considerably strengthen the EU's resilience and crisis response. Therefore, the Single Market Emergency Instrument, for which this Impact Assessment analyses different policy options, should provide a blueprint for an EU reaction on Single Market matters in a future crisis. It should take into account the lessons learned from past emergencies and extrapolate them to possible future emergencies.

This initiative will neither prevent nor solve any upcoming crises. Its aim is to act as a safety net for the functioning of the Single Market. It should provide a governance structure for the occasion that the smooth functioning of the Single Market is in jeopardy. In close cooperation with all Member States and other existing EU crisis instruments, SMEI should provide a targeted toolbox to ensure the functioning of the Single Market in any type of future crisis. It is likely that not all of the tools assessed in this Impact Assessment will be needed simultaneously. The idea is rather to brace the EU for the future and equip it with what may prove to be necessary in a given crisis situation affecting the Single Market.

The **European Council** in its Conclusions of 1-2 October 2020² stated that the EU will draw the lessons from the COVID-19 pandemic and address remaining fragmentation, barriers and weaknesses of the Single Market in facing emergency situations. In the Update of the Industrial Strategy Communication³, the Commission announced an instrument to ensure the free movement of persons, goods and services, as well as greater transparency and coordination in times of crisis. The initiative forms part of the Commission Work Programme for 2022⁴. The European Parliament welcomed the Commission's plan to present a Single Market Emergency Instrument and called on the Commission to develop it as a legally binding structural tool to ensure the free movement of

¹ <https://www.brookings.edu/research/sometimes-the-world-needs-a-crisis-turning-challenges-into-opportunities/>

² <https://www.consilium.europa.eu/media/45910/021020-euco-final-conclusions.pdf>.

³ COM(2021)350 final.

⁴ https://ec.europa.eu/info/publications/2022-commission-work-programme-key-documents_en.

persons, goods and services in case of future crises⁵. The initiative is expected to contribute to the achievement of the United Nations Sustainable Development Goals (SDGs), in particular SDG #1 No poverty, SDG #8 Decent work and economic growth, SDG #9 Industry, innovation and infrastructure, SDG #10 Reduced inequalities and SDG #16 Peace, justice and strong institutions (see Annex 3 for more details).

Legal context

A number of EU legal instruments lay down provisions which are relevant for the management of crises in general. On the other hand, certain EU frameworks and recently adopted Commission proposals lay down more targeted measures which focus on certain aspects of crisis management or are relevant for specific sectors. The Single Market Emergency Instrument will apply without prejudice to the provisions put forward by these targeted crisis management instruments, which are to be considered as *lex specialis*. A detailed overview of relevant existing and forthcoming instruments is included in Annex 9 (see part 2 of this Impact Assessment file). Financial services in particular are excluded from the scope of the initiative due to the existence of a dedicated crisis-relevant framework in this area. This also notably concerns the Commission Decision establishing the European Health Emergency Preparedness and Response Authority (HERA)⁶ and the Commission Proposal for a Regulation on serious cross-border threats to health⁷. The Single Market Emergency Instrument is thus intended to apply to non-medical goods and services which do not fall within the scope of the above-mentioned Proposals, which will be further elaborated below.

- ***Interplay with horizontal crisis response mechanisms***

The integrated political crisis response mechanism (IPCR)⁸ is among the horizontal crisis response mechanisms⁹. The Presidency of the Council of the EU uses the IPCR to facilitate information sharing and political coordination among the Member States in responding to complex crises. The IPCR was activated for the first time in October 2015 for the refugee and migration crisis. Since its activation, it has been instrumental in monitoring and supporting the response to the crisis, reporting to Coreper, the Council and the European Council. The IPCR has also been used to exercise the Union response to major crises caused by cyber-attacks, natural disasters, or hybrid threats. More recently, the IPCR mechanism has also been convened after the outbreak of the COVID-19 pandemic.

Another EU mechanism for general crisis response is the Union Civil Protection Mechanism and its Emergency Response Coordination Centre (ERCC)¹⁰. The ERCC is the Commission's central operational 24/7 hub for first emergency response, the establishment of strategic stockpiles at the EU level for emergency response ("rescEU"), disaster risk assessments, scenario building, disaster resilience goals, EU wide overview of natural and man-made disaster risks, other prevention and preparedness measures, such as training and exercises.

⁵ [European Parliament resolution of 17 February 2022 on tackling non-tariff and non-tax barriers in the single market \(2021/2043\(INI\)\)](#).

⁶ C(2021)6712 final.

⁷ COM(2020)727 final.

⁸ <https://www.consilium.europa.eu/en/policies/ipcr-response-to-crises/>.

⁹ It was formally set up by Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response, on the basis of previously existing arrangements.

¹⁰ Laid down by the Decision (EU) 1313/2013 governing the functioning of the Union Civil Protection Mechanism.

- ***Interplay with measures targeting specific aspects of crisis management***

The above-mentioned horizontal crisis response mechanisms are supplemented by other more targeted measures, focusing on specific aspects of the Single Market such as the free movement of goods, common rules on exports or public procurement.

One such framework is the Regulation (EC) No. 2679/98 setting up a response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation')¹¹. This Regulation provides for a mechanism of notification as well as a system of information exchange between the Member States and the Commission. (See sections 8.1 and 8.2 for more details.)

The Regulation on common rules for exports¹² allows the Commission to subject certain categories of products to an extra-EU export surveillance or to an extra-EU export authorisation. The Commission was subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance¹³ on this basis.

Other economic measures include negotiated procedure and occasional joint procurement by the Commission on behalf of the Member States¹⁴.

- ***Interplay with sector-specific crisis measures***

Certain EU frameworks lay down more targeted measures which focus only on certain specific aspects of crisis management or only concern certain specific sectors.

The Commission communication "Contingency plan for ensuring food supply and food security"¹⁵ draws lessons learnt during the COVID-19 pandemic and previous crises with the objective to step up coordination and crisis management including preparedness. To this end, the contingency plan puts forward key principles to be followed to ensure food supply and food security in the event of future crises. To ensure the implementation of the contingency plan and the key principles therein, the Commission in parallel established the European Food Security Crisis preparedness and response Mechanism (EFSCM), a group composed of Member States and non-EU countries representatives as well as of food supply chain stakeholders chaired by the Commission to strengthen coordination, exchange data and practices. The EFSCM was convened for the first time in March 2022 to discuss the impacts of the energy and input price increases and the consequences of Russia's invasion of Ukraine for food security and supply. The market observatories and the civil dialogue groups are other fora that ensure transparency and the flow of information in the agri-food sector.

The Commission communication "Contingency plan for transport"¹⁶ has the objective to ensure crisis preparedness and business continuity in the transport sector. The plan establishes a "crisis manual" that includes a toolbox consisting of 10 actions aimed at mitigating any negative impact on the transport sector, passengers and the internal market in the event of a crisis. These include among others measures rendering EU transport laws fit for crisis situations, ensuring adequate support for

¹¹ Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, *OJ L 337, 12.12.1998, p. 8.*

¹² Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015.

¹³ Commission Implementing Regulation (EU) 2021/2071 of 25 November 2021.

¹⁴ They can be adopted on the basis of 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.

¹⁵ COM(2021)689 final.

¹⁶ COM(2022)211 final.

the transport sector, ensuring free movement of goods, services and people, sharing of transport information, testing transport contingency in real-life situations etc.¹⁷

Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products¹⁸ (CMO Regulation) as well as the sister CMO Regulation for fisheries¹⁹ provide the legal basis for collecting relevant information from Member States to improve market transparency²⁰.

Regulation (EU) 2021/953 establishing the EU Digital COVID Certificate²¹ sets out a common framework for the issuance, verification and acceptance of interoperable certificates for COVID-19 vaccination, test or recovery certificates to facilitate free movement of EU citizens and their family members during the COVID-19 pandemic. Furthermore, based on a Commission proposal, the Council adopted specific recommendations on the coordinated approach to the restriction of free movement in response to COVID-19 pandemic²².

Finally, the Commission Decision of 16 September 2021 established the Health Emergency Preparedness and Response Authority²³ for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.

- ***Interplay with ongoing initiatives***

In parallel, a number of initiatives, which have been recently proposed and are currently being discussed, concern aspects relevant for the crisis response and preparedness. These initiatives however have a limited scope covering specific types of crisis scenarios and are not intended to set up a general horizontal crisis-management framework. To the extent these initiatives include a sectoral crisis response and preparedness framework, that framework will take precedence over the Single Market Emergency Instrument as *lex specialis*.

The Commission proposal for a Regulation on serious cross-border threats to health, repealing Decision No 1082/2013/EU (the 'Cross-border Health Threats Decision')²⁴ aims at strengthening the EU's health security framework, and reinforcing the crisis preparedness and response role of key EU agencies with respect to serious cross-border health threats. It would strengthen the

¹⁷ Additional measures include: managing refugee flows and repatriating stranded passengers and transport workers, ensuring minimum connectivity and passenger protection, strengthening transport policy coordination through the Network of National Transport Contact Points, strengthening cybersecurity and cooperation with international partners.

¹⁸ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, *OJ L 347*, 20.12.2013, p. 671.

¹⁹ Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000. *OJ L 354*, 28.12.2013, p. 1.

²⁰ Following Russia's invasion of Ukraine, the obligation for Member States to provide monthly notifications of cereal stocks has been included in an amendment to Commission Implementing Regulation (EU) 2017/1185 of 20 April 2017 laying down rules for the application of Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards notifications to the Commission of information and documents and amending and repealing several Commission Regulations, *OJ L 171*, 4.7.2017, p. 113.

²¹ Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, *OJ L 211*, 15.6.2021, p. 1.

²² Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, *OJ L 337*, 14.10.2020, p. 3 and its subsequent updates.

²³ C(2021)6712 final.

²⁴ COM(2020)727 final.

preparedness and response planning and reinforce epidemiological surveillance and monitoring, improve data reporting, strengthen EU interventions.

The Commission proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level²⁵ provides for crisis response tools such as joint procurement, mandatory information requests for businesses about their production capacities, and repurposing production lines in case of public health crises once a public health emergency would be declared. The declaration of an EU emergency situation would trigger increased coordination and allow for the development, stockpiling and procurement of crisis-relevant products. The proposal covers medical countermeasures and medicinal products for human use but not medical services.

The Commission proposal for the European Chips Act²⁶ aims to strengthen Europe's semiconductor ecosystem. One important pillar of this strategy is to set up a mechanism for coordinated monitoring and response to shortages in the supply of semiconductors, aiming to anticipate and swiftly respond to any future supply chain disruptions, through a dedicated emergency toolbox, together with Member States and international partners.

The Commission proposal for a Data Act²⁷ will allow public sector bodies to access data held by the private sector that is necessary for exceptional circumstances, particularly to implement a legal mandate if data are not otherwise available or in case of a public emergency (i.e. exceptional situation negatively affecting the population of the Union, a Member State or part of it, with a risk of serious and lasting repercussions on living conditions or economic stability, or the substantial degradation of economic assets in the Union or the relevant Member State(s)).

The Commission proposal to amend the Schengen Borders Code²⁸ aims to provide a common response at the internal borders in situations of threats affecting a majority of Member States. The proposal will also put in place procedural safeguards in case of unilateral reintroductions of internal border controls and provide for the application of mitigating measures and specific safeguards for cross-border regions in cases where internal border controls are reintroduced. The proposal promotes increased use of effective alternative measures to address the identified threats to internal security or public policy instead of internal border controls, for instance increased checks by police or other authorities in border regions, subject to certain conditions. The proposal also includes the possibility for the Council to quickly adopt binding rules setting out temporary travel restrictions for third country nationals at the external borders in case of a threat to public health. It also clarifies which measures Member States can take to manage the EU's external borders effectively in a situation where migrants are instrumentalised by third countries for political purposes.

The Commission proposal for a revision of the Financial Regulation, scheduled for adoption by the Commission in the course of 2022, adapts the applicable procurement rules in crisis management situations to allow an EU institution or body to procure on behalf of Member States or to act as a central purchasing body in order to donate or resell supplies and services to Member States, as well as to launch joint procurement procedures despite the EU institutions not acquiring services and supplies for themselves. It also updates the definition of a crisis to include public health emergency situations and provides for triggering the crisis provisions in line with applicable internal procedures.

²⁵ COM(2021)577 final.

²⁶ COM(2022)46 final.

²⁷ COM (2022)68 final.

²⁸ COM (2021)891 final.

The proposal for a Directive on the resilience of critical entities adopted by the Commission in December 2020²⁹ has the objective to enhance the resilience of entities providing services that are essential for the maintenance of vital societal functions or economic activities the EU. With this initiative, the aim is to create a comprehensive framework to support Member States in ensuring that critical entities providing essential services are able to prevent, protect against, respond to, resist, mitigate, absorb, accommodate and recover from disruptive incidents such as natural hazards, accidents or terrorism. The Directive will cover eleven key sectors, including energy, transport, banking and health.

2. PROBLEM DEFINITION

2.1 What is/are the problems?

The purpose of the initiative is to provide immediate solutions to ensure that the Single Market works as it should during crises.

Recent crises have demonstrated how fragile the Single Market can be in case of unforeseen disruptions and at the same time, how much the European economy and all its stakeholders rely on a well-functioning Single Market. The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to the appearance of obstacles to free movement within the Single Market, thus disrupting its normal functioning. On the other hand, a crisis can amplify the shortages of crisis-relevant goods and services if the Single Market is fragmented and is not functioning. This is why this Impact Assessment focusses on two separate but interrelated problems: obstacles to free movement and shortages of crisis-relevant goods and services.

While this problem definition draws a great deal upon the lessons learnt from the COVID-19 crisis, it is only one example highlighting the possible negative consequences for the Single Market that may arise in case of crisis situations. The scope of this initiative is not to provide solutions to overcome a future crisis as a whole, but rather to enable a swift and flexible response to Single Market impacts of a crisis. Against this background, the main problems identified and addressed by this Impact Assessment are described below.

2.1.1 Obstacles to free movement of goods, services and persons in times of crisis

The proper functioning of the Single Market can be disrupted in a crisis situation, either by forces of nature or by national regulatory responses such as restrictions on free movement of goods, services and persons, which can have legitimate objectives such as protecting public health. Supply chains can swiftly become interrupted, companies face difficulties in sourcing, supplying or selling goods and services. The access of consumers to key products and services then becomes disrupted. Additionally to public health and security risks, citizens, and in particular vulnerable groups, are also confronted with strong negative economic impacts.

On what concerns the **free movement of goods**, cross-border delivery of goods was typically permitted during the COVID-19 crisis. Nonetheless, the increased border checks created delays and costs for cross-border transport of goods. Cross-border intra-EU trade in goods declined substantially during the first wave of the pandemic, contracting by a third in April 2020, but then recovered to nearly normal levels over the summer of 2020³⁰.

²⁹ COM(2020)829 final.

³⁰ Study by IMCO Committee "[The impact of COVID-19 on the internal market](#)".

More specifically, during the COVID-19 crisis, the vast majority of Member States (amounting to 19 Member States) introduced different types of export restrictions and other restrictions distorting the Single Market for goods. Examples of such measures included suspension of exports of agricultural and food products and export bans for COVID-related material including personal protective equipment. A new intra-EU export restriction on agricultural products of strategic importance was introduced by Hungary in the context of Russia's invasion of Ukraine. These obstacles to the free movement of goods have also contributed to the problem of supply shortages, as discussed in the following sub-section.

Most restrictions of the free movement of goods were lifted, often following bilateral contacts between the Commission and the Member States in question. However, addressing the patchwork of restrictions required a lot of ad hoc solutions including political level intervention and was lengthy due to a lack of transparency, cooperation and solidarity between Member States.

For what concerns **free movement of services and persons**, the key relevant restrictive measures adopted by some Member States to protect public health and on the basis of the precautionary principle were: 1) intra-EU travel bans (including entry and exit bans and bans on non-essential travel)³¹, 2) temporary reintroduction of border controls in order to better enforce travel restrictions, and 3) the requirements for certain cross-border travellers to undergo quarantine and/or testing when crossing the borders.

Following the introduction of entry/exit bans and related travel restrictions and the reintroduction of internal border controls, there was a strong negative effect on free movement of goods, services and persons. There were significant truck build-ups and long waiting times on a number of internal borders. For example, after the introduction of new restrictions by Germany on 14 February 2021 including testing requirements for truck drivers, there were traffic jams of up to 25 km on the Czech-German border³² and there were queues of up to 40 km long in Italy ahead of the Brenner pass into Austria³³.

Measures applicable at the internal borders have severely disrupted labour mobility in the Single Market. This has particularly affected almost 2 million cross-border workers³⁴. Consequently, there has been a shortage of seasonal agriculture sector workers in many Member States, including Italy, Spain and Germany, whose economic model depend on such labour. Engineers could not service breakdowns in industrial machines across the border due to quarantine requirements³⁵. Many countries are heavily reliant on cross-border workforce, e.g. in Luxembourg 45% of the work force was commuting from neighbouring countries across the border in 2019³⁶.

Barriers affecting transport workers/transport service providers also have a major impact on the flow of goods across the Single Market. Restrictions on free movement of persons coupled with the reintroduction of internal border controls led to disruptions of movement of trucks across borders

³¹ Special Report 13/2022 of the European Court of Auditors of 13 June 2022 "Free movement in the EU during the COVID-19 pandemic".

³² According to press reports: <https://www.dpa-international.com/topic/lorries-queue-german-czech-border-entry-bans-cause-headache-urn%3Anewsml%3Adpa.com%3A20090101%3A210215-99-450723>.

³³ According to press reports: https://www.ansa.it/nuova_europa/en/news/sections/news/2021/02/15/covid-40-km-queue-of-trucks-between-brixen-and-brenner_dabde036-b65e-428d-a4da-017fad1bf982.html.

³⁴ European Parliament, Briefing - Single market and the pandemic: Impacts, EU action and recovery [Single market and the pandemic \(europa.eu\)](#), June 2020, p. 5.

³⁵ Information exchange with BusinessEurope, 2020.

³⁶ Report "State of Health in the EU Luxembourg Country Health Profile" 2019, p. 9.

and therefore posed risks of disruption in manufacturing supply chains, in addition to direct costs due to perishable fresh food being stuck in traffic.

Overall, these events have exposed the EU's economy to an unprecedented and sustained shock, with the EU economy contracting by 6.3% over the course of 2020³⁷. The impact is further demonstrated by intra-EU trade falling by 24% during the second and third quarter of 2020³⁸. While a large part of the contraction in GDP was due to local restrictions, the contraction in the intra-EU trade was likely in substantial part caused by the obstacles to free movement.

In the context of global megatrends such as climate change and pressure on democratic models of governance and values as identified by Strategic Foresight reports³⁹, other potential crises could also lead to Member States introducing restrictions on free movement. Such crises could include natural disasters, technological disasters, geopolitical threats, migration crises, terrorist attacks, financial crises, another pandemic, or a crisis of a completely unpredictable nature.

In the case of a natural disaster, such as a volcano eruption, a flood or an earthquake, items needed in the first response could be of particular necessity and export restrictions could be introduced by Member States for such items. In the case of a technological disaster, such as a nuclear accident, export restrictions could similarly be introduced by Member States for items needed in the first response or helpful to mitigate the effects of the disaster. Furthermore, it is possible that restrictions on free movement of persons could be introduced in order to cordon off the area of disaster. In such a case, ensuring the freedom of movement for key personnel in managing the disaster at stake would be of particular importance.

In the case of terrorist attack, for example an attack on a major port, the most important consequence could be the introduction of restrictions on free movement of persons. As a second order effect, an interruption in the functioning of a major port could lead to supply chain bottlenecks, which could amplify any existing shortages. A migration crisis in itself is unlikely to lead to restrictions to free movement, as in recent experience the actions taken by Member States in this context focused on the reintroduction of border controls.

Another pandemic could likely lead to similar effects on the Single Market in the absence of a solution, i.e. reappearance of restrictions for free movement of persons and of export restrictions. Effects of geopolitical instability could include trade sanctions and other disruptions of supply which may result in shortages of specific products, which could lead to export restrictions in the Single Market.

Financial crises are unlikely by themselves leading to restrictions of free movement, as financial services are outside of the scope of the initiative. There could be other crises of completely unpredictable nature that could lead to appearance of free movement restrictions and the need to coordinate.

The two problems considered by this Impact Assessment are interrelated, as obstacles to free movement can lead to or exacerbate shortages of crisis-relevant products and vice versa. However, as shortages of crisis-relevant products can also have a number of other drivers, we consider the two problems separately.

³⁷ Annual Single Market Report 2021, SWD(2021)351 final, p. 1.

³⁸ Annual Single Market Report 2021, SWD(2021)351 final – Figure 1, p. 9.

³⁹ 2021 Strategic Foresight report, https://ec.europa.eu/info/sites/default/files/strategic_foresight_report_2021_en.pdf.

2.1.2 Shortages of crisis-relevant goods and services

Shortages of crisis-relevant goods and services in times of crisis

A shortage could be defined as an imbalance between supply and demand affecting not only prices but also quantities⁴⁰. While structural problems require long-term structural solutions, the focus of this initiative is on the shortages of crisis-relevant goods and services in situations of emergency, which can be severely amplified during a crisis by a non-functioning Single Market. This could be due to Member States competing against each other in securing the availability of such products in separate and uncoordinated public procurement procedures. This could also be due to the Member States imposing uncoordinated and contradictory national measures such as export restrictions. Or this could be because the relevant Single Market legislation does not allow to place crisis-relevant products on the market with the appropriate urgency.

During the COVID-19 crisis, while most companies and supply chains showed a high degree of resilience and adaptability, sudden supply and demand shocks for crisis-relevant products have led to acute shortages of such products. There was an unprecedented surge in demand for certain types of personal protective equipment (PPE), especially during the first wave of the pandemic. With the exception of a few specific legal frameworks, the New Legal Framework does not foresee any emergency procedures for placing products on the market. Tremendous ad hoc efforts by the Commission, the Member States and industry eventually led to a significant increase in production capacity for PPE in the EU.

Shortages of crisis-relevant products can also lead to degraded quality of products. According to the market surveillance authorities for PPE, due to a surge of deployment of masks on the market to meet the high demand during the first wave of the pandemic, between 60 and 80% of face masks checked by them failed their test⁴¹. The data recorded in the Safety Gate/RAPEX Rapid Alert System for dangerous non-food products confirms this: in 2020, 171 measures were reported against face masks that did not fulfil the minimum health and safety requirements. For the year 2021 this amounted to 147 cases (in 2020, 7% of the alerts on Safety Gate concerned protective masks, in 2021 this was 6%). Yet, low quality products, especially for PPE, defeat their purpose because they put people at risk rather than protecting them.

Additionally, in the context of a crisis response, intra-EU export restrictions can have the effect of limiting supplies and disrupting supply chains of goods that are critical for the crisis response, thereby having a detrimental effect not only on the functioning of the Single Market but also on the well-being of citizens and the effectiveness of the overall EU crisis response.

During the COVID-19 crisis, there was a risk of Member States competing against each other by launching separate public procurement procedures for the same crisis-relevant products. The Commission together with the Member States launched joint public procurement for various medical goods relying on the Emergency Support Instrument. At the moment of drafting this Impact Assessment, outside of the field of civil protection, there is no structured framework for making use of joint public procurement allowing the Commission or other EU institutions to procure goods on behalf of the Member States on its own, or to procure flexibly at the time of crisis.

⁴⁰ [Detecting and Analysing Supply Chain Disruptions, DocsRoom - European Commission \(europa.eu\)](#).

⁴¹ EUPCN, ADCO PPE, presentation 9 June 2021.

In the context of global megatrends such as climate change or geopolitical instability, a number of different types of crisis can lead to the situations where shortages of crisis-relevant products are amplified by the non-functioning Single Market.

In the case of a natural disaster, for example an earthquake, joint procurement and accelerated placing of products on the market could be needed for ensuring the availability of products and services needed in the first response, in addition to ensuring free movement. Similarly, in the case of a nuclear accident or another technological disaster, there could be shortages of items needed to respond to the disaster, in which case joint procurement and/or accelerated placing of products on the market could be needed, as well as potentially more far-reaching solutions on ensuring the availability of supply of such products.

In the case of a terrorist attack on a key transportation route the result could be a significant transportation bottleneck, leading to a critical shortage of products.

While specific medical countermeasures would be covered by the relevant instruments, another pandemic could lead to an unpredictable shortage of products needed to combat that specific pandemic, which could require solutions to tackle such a shortage. Effects of geopolitical instability could include disastrous disruptions of supply of crisis-relevant products and services, which may require very far-reaching solutions to ensure the availability of supply. There could be other crises of completely unpredictable nature resulting in deep shortages of crisis-relevant products.

Structural supply chain constraints that could lead to or aggravate shortages during a given crisis

The EU gains resilience from world markets being open and integrated in global value chains. The ongoing monitoring of Critical Raw Materials and two rounds of In-depth Reviews of Strategic Dependencies⁴² have substantially contributed to a deeper understanding of the EU's supply chains vulnerabilities that could entail shortages of goods or services in a crisis situation. Such structural issues require more long-term solutions reinforcing the EU open strategic autonomy, for example in fields such as raw materials, semiconductors and energy. Yet, disruptions can affect specific crisis-relevant products and inputs that are particularly critical for the good functioning of society and the EU economy during an emergency. While an emergency by itself can lead to a shortage of crisis-relevant goods and services, in an emergency any existing structural problem is likely to be amplified – as it happened during the COVID-19 crisis for semiconductors, and with Russia's invasion of Ukraine for energy and a number of raw materials. Russia's invasion of Ukraine and the related sanctions and countersanctions have put pressure on global supply chains, including in the agri-food sector and inputs such as fertilisers, animal feed and energy, with farmers being confronted with higher prices for basic inputs. This has also led to restrictions affecting the functioning of the Single Market.

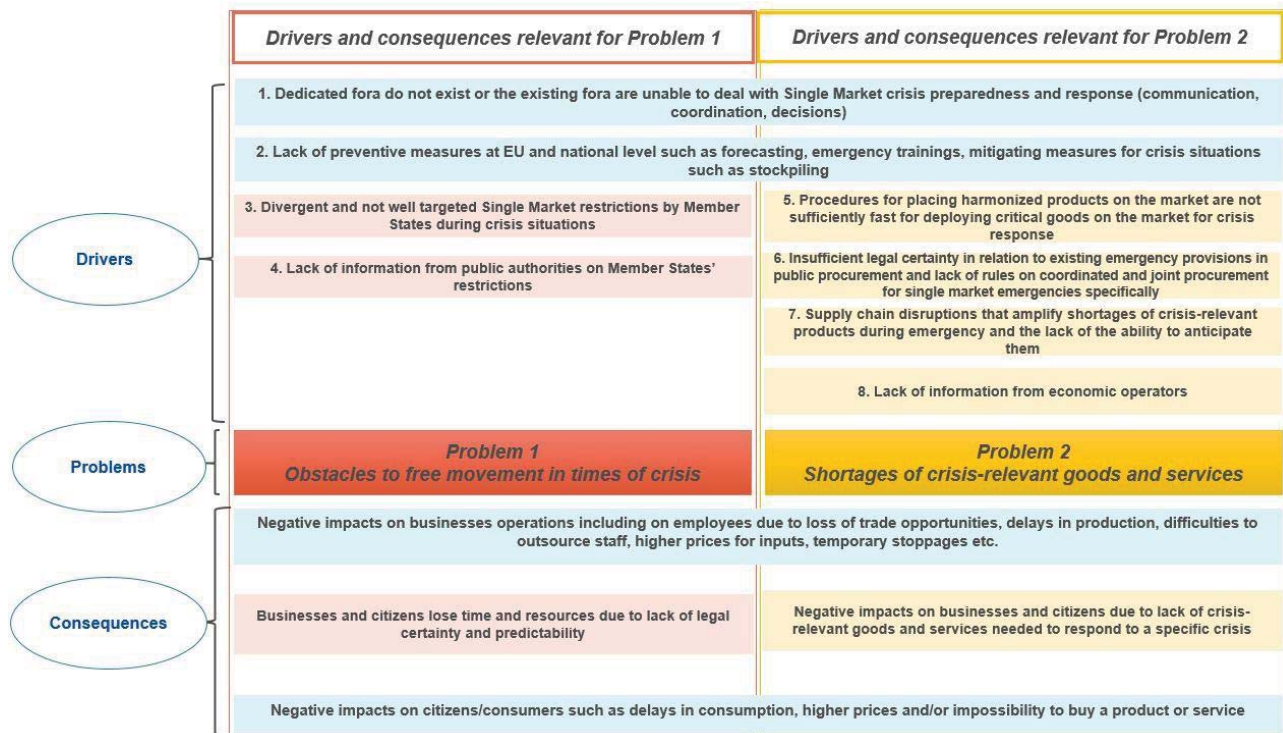
Some of these vulnerabilities have de facto shown their ability to affect the Single Market. Overall, in the course of 2021 and 2022, there has been mounting evidence across countries and industrial ecosystems about supply chains distress, and in particular about specific supply shortages. For instance, the share of firms reporting shortages in equipment in the third quarter of 2021 was 57.8% in the motor industry and 52.2% for electrical equipment⁴³. Respondents to the public consultation

⁴² SWD(2021)352 and SWD(2022)41. In particular, they have shed light on the strategic dependencies, especially on China, affecting the energy intensive industries (critical raw materials in general, rare earth and magnesium, chemicals), health (active pharmaceutical ingredients), renewable energy (e.g. permanent magnets, photovoltaic panels and technologies) and digital (e.g. semiconductors, cloud services, cybersecurity technologies) industries.

⁴³ Annual Single Market Report 2022, SWD(2022)40 final.

pointed to difficulties when wishing to purchase goods, such as the product not being available for purchase, the product being available with a very high price increase or with a very high delay in delivery time. This has moreover led to upward pressure on prices, mainly observed in industry sectors, but also in certain services sectors. Many of these shortages have structural origins, yet the impacts of such shortages during an emergency might have severe disruptive effects on the availability of crisis-relevant products and might require quick corrective actions to support the functioning of the Single Market.

2.2 What are the problem drivers?



The links between problems, problem drivers and consequences are illustrated in the problem tree graph above. The drivers and consequences related to problem 1 are marked in pink, those related to problem 2 are marked in light yellow and those related to both are in light blue. As explained in Section 2.1, the two problems are interrelated as obstacles to free movement in times of crisis can in themselves lead to or exacerbate shortages of crisis-relevant goods and services and vice versa.

- Dedicated fora do not exist or the existing fora are unable to deal with Single Market vigilance and crisis response (communication, coordination, decisions)*

There are various mechanisms and groups at the EU level dealing with crisis vigilance and response; from the Integrated Political Crisis Response (IPCR) mechanism for crisis coordination in the Council, the Union Civil Protection Mechanism (UCPM) and its Emergency Response Coordination Centre (ERCC) for first emergency response coordination with Member States and other Participating States in the UCPM to sector specific expert bodies such as the European Food Security Crisis preparedness and response Mechanism (EFSCM) or other sectoral expert groups, such as for example the national transport contact points network, which discuss crisis-related matters when warranted. However, the existing fora either have not been designed for information sharing, coordination and cooperation on the Single Market impacts of crises or do not allow

discussing cross-cutting or interconnected Single Market impacts of the crises in several areas together. Under the currently applicable EU legal frameworks, the Member States are obliged to exchange crisis-relevant information between themselves only in the area of civil protection.

The COVID-19 pandemic, in particular during its early stages, showed that Member States are prone to act on their own, although confronted with the same threat. There is no explicit legal obligation for Member States to consult or inform each other about their crisis measures in general⁴⁴.

IPCR focused at the start of its activation under the Croatian Presidency on the health aspects, and only later started to take into account the effects of COVID-19 on other policy areas, such as border management and transport. Whereas the IPCR is providing for communication and coordination between the Member States at the times of crisis, assisted by the Commission, it has not been designed to address and resolve the impacts of the crises on the Single Market, such as availability of crisis-relevant goods and services. This follows in part from Article 222 TFEU, the legal basis for the Council Implementing Decision on IPCR, which focuses on humanitarian, civil protection and defence matters. Also, although allowed to intervene in the event of natural and man-made disasters, such interventions are limited to the Member States whose political authorities have requested the involvement of the IPCR. The requirement of request by the political authorities of all concerned Member States before being able to discuss the crisis concerned in the IPCR is not likely to allow the IPCR in its current form to get involved in a timely manner, where a Single Market emergency would occur. Due to its high level of political representation, it is also not able to go into much technical detail in its discussions and does not allow for live coordination at a technical level.

Therefore, while IPCR proved to be a useful tool that contributed to the EU's crisis response during COVID-19, the existing EU emergency instruments/mechanisms overall do not have the Single Market in their focus and do not represent a pre-agreed and formalised institutional answer to a health crisis or another crisis involving cross-cutting restrictions of free movement and/or shortages of crisis-relevant goods and services.

Finally, there would also be instances of bilateral or regional cooperation between the Member States aiming at coordination and cooperation between the participating Member States, but they would not cover the whole Single Market.

2. Lack of preventive measures at EU and national level such as forecasting, emergency trainings, mitigations measures for crisis situations such as stockpiling

Several Member States operate a specific monitoring system used through their own crisis management tools/contingency plans to gather information from economic operators and assess the situation to reduce negative impacts of a crisis on businesses. Crisis management systems at Member State level are setting up monitoring systems targeting vital service providers and strategic supply chains for crisis-relevant products. Member States have designated critical sectors and industrial ecosystems (such as energy, health, transport, agri-food, cybersecurity) that require a more acute monitoring. Such sectors must be involved in the collection of targeted information and

⁴⁴ The Single Market Transparency Directive sets up a TRIS system, which requires Member States to notify draft restrictions of free movement of goods and information society services. Such notification is followed by a three months standstill period during which other Member States and the Commission may provide written comments on the notified measures. In case of any comments that standstill period is prolonged by another three months. In case of important reasons, Member States may ask under the urgency procedure the Commission to allow them within 10 days to waive the 3+3 months standstill period and peer review and adopt the measures.

develop strategic plans in order to avoid supply chain disruptions. Data are collected through business associations to identify, to the extent possible, interruptions in the free movement of goods, services and people and shortages of crisis-relevant goods and services affecting the Single Market thanks to a better knowledge of the market. For example, the current market information systems in Spain have made it possible to detect market crisis situations caused by high market availabilities (stocks and/or productions) together with significant price reductions. Business associations gather information from companies on a sectoral basis, for sharing information with and having a dialogue with public authorities. SMEs and micro-enterprises also participate in the monitoring system as well as economic observatories. Spain develops a system of declarations of stock levels for certain agricultural goods. However, only several Member States confirmed the existence of such monitoring, which is scattered across the EU and lacks coherence. Furthermore, the findings stemming from monitoring at national level may not reach the Commission and/or other Member States and may not be collectively discussed with a view to inform possible action.

At the EU level, there is a lack of formal preventive tools such as forecasting or strategic reserves in view of addressing possible supply chain shortages in the Single Market during crises. Before the COVID-19 pandemic, there was no structured monitoring tool that could provide reliable, up-to-date quantitative information on the situation of supply chains (in particular the balance between demand and supply) for critical equipment during the pandemic. The Clearing House for medical equipment was therefore created as an ad hoc solution. The Commission has thereafter sought to address the lack of reliable and standardised data, intelligence gathering and monitoring of medical countermeasures specifically in the framework of proposed instruments linked to HERA.

In certain areas including agricultural products, EU legislation⁴⁵ provides the legal basis for collecting relevant information from Member States to ensure market transparency. This monitoring supports forecasting and serves to inform possible mitigation measures. Measures to improve the EU's ability to anticipate or prevent shortages are or may be discussed in formal and/or informal fora such as sectoral expert groups or ad hoc work streams. For instance, the Chief Economist Network working group recently set up by the Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs with the Member States has been discussing analytical methods useful for detecting and analysing supply chain disruptions, as well as a Shortages Alert System based on official statistics concerning the price evolution for goods and stakeholders' expectations about factors affecting the supply and demand of products. However, while these discussions are extremely valuable to build a common understanding of the relevant market developments and to fine-tune the methodology for assessing these developments, they can hardly go beyond an informal exchange of information and cannot trigger a coordination of the possible policy responses. In addition, the Commission has been regularly monitoring relevant developments in the area of critical raw materials specifically⁴⁶, which could provide inspiration for monitoring also beyond the raw materials area.

There is no appropriate Early Warning System whereby the Member States could notify information to the Commission on shortages of goods or services that result from Single Market impacts of an emergency situation or about any developments that would lead to those. The Early Warning System of the Strawberry Regulation⁴⁷ allows for notification of free movement obstacles

⁴⁵ See e.g. Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products (Common Market Organisation or CMO regulation).

⁴⁶ https://ec.europa.eu/growth/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en.

⁴⁷ Council Regulation (EC) No 2679/98 of 7 December 1998 on the functioning of the internal market in relation to the free movement of goods among the Member States, *OJ L 337, 12.12.1998, p. 8*.

between two Member States to the Commission but is rarely used. Member States may in principle raise any free movement obstacles for discussion in the Single Market Enforcement Task Force. However, its' scope is not focused on enforcement matters for crisis management. The Early Warning and Response System operated by DG ECHO is designated for early warning concerning natural disasters that might need to be followed up by humanitarian assistance and civil protection measures. The mechanism for early warnings proposed in Article 15 of the Chips Act for Europe proposal concerns semiconductors, their parts and the raw materials that are needed for their production. The Early Warning System contained in the proposal for the Cross-border health threats Regulation proposal concerns threats to public health, not shortages of goods and services at the time of public health emergencies.

As far as stockpiling or strategic reserves are concerned, apart from emergency oil/gas reserves and reserves in the field of civil protection⁴⁸, there are currently no EU-level measures or initiatives. While strategic reserves are a way to address short-term supply chain disruptions or imbalances, the interest in strategic reserves has increased due to the unstable geopolitical situation brought forward by Russia's invasion of Ukraine as well as other factors including Europe's dependency on third countries for certain goods. For example, in the area of security of supply for energy, Russia's invasion of Ukraine has aggravated the situation and driven energy prices to unprecedented levels. This situation prompted the Commission to present a legislative proposal requiring underground gas storage across the EU to be filled in at least 80% of their storage capacity by 1 November 2022 (rising to 90% in subsequent years)⁴⁹.

By way of example, international like-minded partners including USA, Japan and Switzerland already dispose of strategic reserves arrangements and can rely on legal instruments allowing for the adoption of additional measures in this respect (e.g. the US Defense Production Act or Japan's JOGMEC, see Annex 8 for an overview).

When it comes to preventive measures by the industry, many companies have adapted their supply chain "thinking" and introduced mitigating measures following Russia's invasion of Ukraine. For instance, according to a survey of its members carried out by VDMA, the German umbrella association representing the mechanical engineering industry, more than 80% of respondents have changed or considered changing their procurement principles or opted for increased stockholding further to Russia's invasion⁵⁰.

According to a survey of Member States carried out by the Commission in May 2022, the picture is mixed when it comes to preventive measures in place at national level. The survey looked at crisis preparedness measures already in place in the Member States and in particular, the presence (or absence) of national monitoring systems and strategic storage or stockpiling systems of goods of key importance. As regards monitoring, several Member States have implemented risk assessment mechanisms in designated critical sectors and strengthened the exchange of information between stakeholders in such sectors and national competent authorities. Regarding strategic reserves, most Member States do not have stockpiling systems in place. However, certain Member States have

⁴⁸ The rescEU strategic reserves at the EU level for capacities in the area of emergency response (response teams with equipment and/or critical items/goods for first response operations). Such capacities are currently available or under development in line with Article 12 of Decision 1313/2013 in the areas of forest fire fighting, emergency health, chemical, biological, radiological and nuclear incidents, transport and logistics, shelter and energy supply. For example, in direct response to the COVID-19 pandemic, specific stockpiles of medical countermeasures have been set up under rescEU in a number of Member States.

⁴⁹ COM(2022) 135 final.

⁵⁰ Results of the 14th VDMA Flash Survey Mechanical Engineering, from 5 to 6 April 2022.

established systems, such as Finland and specifically its National Emergency Supply Agency. Recent initiatives or fora in this area include Estonia's Stockpiling Agency, operating since July 2021, the creation by the Spanish National Security Council of the Strategic Reserve based on Industrial Production Capacities in October 2020, and the Polish Government Programme of Strategic Reserves created in December 2020. Other Member States have set up strategic stocks for specific products (e.g. gas, basic food and drinking water, protective equipment or medicinal products). Russia's invasion of Ukraine, meanwhile, has prompted more Member States to initiate plans including dedicated task forces to manage supply chain disruptions through similar measures.

3. Divergent and not well targeted Single Market restrictions by Member States during crisis situations

Neither primary EU law, nor any of the secondary EU law instruments with the exception of the legislation concerning financial services, lay down crisis-specific provisions for the purpose of ensuing coordination of the measures that the Member States may adopt in response to the disruptions to the functioning of the Single Market.

Over the course of recent crises, Member States have been introducing restrictions affecting the functioning of the Single Market that were not well targeted to the issues. The approach taken by Member States in terms of restrictions was also often heterogeneous and uncoordinated.

Specifically during the COVID-19 pandemic, restrictions on free movement and internal border controls have been reintroduced repeatedly to protect public health and on the basis of the precautionary principle, while at the same time having a negative impact on the economy. On several occasions, Member States acted on their own without consulting or even, in some cases, informing other Member States, even when confronted with the same threat⁵¹.

In the public consultation, 23 of 24 respondents, the majority being business associations, stated that they were negatively affected by the restrictions on free movement of persons, cross-border service provision or export of goods, with many affected to a great extent. Stakeholders repeatedly explained the difficulties resulting from uncoordinated and not well targeted restrictions. The biggest issue put forward as problematic by the stakeholders in the area of transport was the uncoordinated response as well as frequent changing of rules⁵². A number of Chambers of Commerce reported⁵³ difficulties faced by cross-border businesses due to the differences in duration of quarantines, frequency of tests and definitions of key categories of persons benefiting from facilitating measures between Member States. They called for a unified and coordinated approach.

Recommendations adopted at EU level may be used to incite the emergence of a coordinated approach among the Member States regarding restrictive measures adopted in response to crisis situations. However, the effectiveness of such recommendations is limited due to the fact that they are non-binding legal instruments and there are no legal means to enforce them.

4. Lack of information from public authorities on Member States' restrictions

Stakeholders and Member States can receive some information on draft crisis measures of other Member States via the TRIS system that is operated under the Single Market Transparency

⁵¹ Impact assessment on amending Schengen Borders Code, SWD(2021)462, pp.28-29.

⁵² Summary report for the public consultation on the Contingency plan for transport, p.6.

⁵³ Letter from Eurochambres, 16 February 2021.

Directive⁵⁴. The Directive provides also for an urgency procedure according to which in urgent situations, due to serious and unforeseeable circumstances, an EU country may adopt a technical regulation without respecting the standstill period.

Member States⁵⁵ are obliged under the Schengen Borders Code⁵⁶ to notify the reintroduction of internal border controls. Whilst the Commission cannot veto any such decision of the Member States, it may issue an opinion on the necessity and proportionality of such checks. The adoption of such an opinion is without prejudice to the powers of the Commission to launch infringement procedures. The European Court of Auditors stated that the Commission did not sufficiently monitor Member States who did not comply with the existing notification obligations⁵⁷, did not issue opinions on disproportionality of the national measures on the reintroduction of internal border controls and did not start infringement proceedings even if the information received from the Member States on the reintroduction of such border controls was not sufficient to demonstrate proportionality of the taken measures for the fight against COVID-19⁵⁸.

Regarding restrictions to the free movement of persons, Member States are not obliged to notify to the Commission measures affecting the free movement of persons under Directive 2004/38/EC (the Free Movement Directive). According to the functioning of the Directive, restrictions to free movement for reasons of public policy, public security or public health apply based on an individual assessment and are subject to judicial control.

Administrative assistance including points of contact that provide information and assistance to citizens and businesses is provided by national authorities based on differing national legislation implementing the Services Directive⁵⁹ and on the Single Digital Gateway Regulation⁶⁰. However, the provision of crisis-specific administrative assistance with fulfilment of additional formalities and procedures is not guaranteed by one single contact point in each of the Member States. There are also linguistic barriers for the economic operators for accessing information from each of the host Member States where they carry out their economic activities and this brings an additional administrative burden.

In the experience of the COVID-19 crisis, the repeated lifting and reintroduction of free movement restrictions and of internal border controls led to a situation where, despite the Commission's efforts to coordinate Member States measures, the rules were not known in a timely manner, were sometimes difficult to access or unclear (see also problem driver 3).

⁵⁴ Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, *OJ L 241*, 17.9.2015, p. 1.

⁵⁵ This obligation applies to the EU Member States which have lifted controls at internal borders, EEA countries and Switzerland.

⁵⁶ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders, *OJ L 77*, 23.3.2016, p. 1.

⁵⁷ The European Court of Auditors was able to identify based on its own research several cases where Member States did not notify reintroductions of internal border controls in 2020 and 2021, see p.21 of the Special Report.

⁵⁸ See the Special Report of the European Court of Auditors, p. 25.

⁵⁹ Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, *OJ L 376*, 27.12.2006, p. 36.

⁶⁰ Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012, *OJ L 295*, 21.11.2018, p. 1.

The lack of reliable, timely and widely accessible information about national restrictions during the COVID-19 pandemic has been repeatedly highlighted by business representatives as a key challenge affecting economic activities⁶¹. A number of Chambers of Commerce reported difficulties to find information on the different measures affecting free movement put in place in different Member States⁶², lack of clarity of rules and lack of legal certainty, administrative and practical burden to comply with the rules and the need to ensure mutual recognition of tests⁶³.

The cross-border regions also experienced many difficulties related to constant changes. In 2020, the Euregio Meuse-Rhine region alone received 416,000 questions from citizens and businesses⁶⁴. According to Eurostar *'The clarity and reciprocity of border restrictions, and their joint implementation, is essential [...] [B]order restriction rules have been changing and updating on a virtually daily basis. The result has been confusion for passengers, staff and within governments. Frequently governments' own information (e.g. embassy websites) has failed to keep up and had been partial, inaccurate or missing entirely. The overwhelming majority of passengers are trying to be responsible but if the rules are not clear and simple, they struggle to comply. Eurostar staff and border forces are put in the difficult position to have to interpret rules and regularly fail to provide answers with confidence.'*⁶⁵

The stakeholders in the area of transport, especially businesses, experienced problems with cross-border operations due to lack of clear and up-to-date information on the national measures as well as due to regular testing requirements imposed on transport workers without easy access to testing facilities, or specific language requirements for tests, as well as unavailability of auxiliary services due to closures or lack of personnel⁶⁶. This challenge was mitigated by the implementation of the Green Lanes system, which recommended exempting transport workers from all restrictions and facilitating the movement of goods and the border crossing thereof. The ensuing legal uncertainty has been particularly problematic for SMEs, who may not have the resources to source relevant information quickly. SMEs have reported difficulties keeping track of fragmented and constantly changing rules and restrictions, such as those impacting service provision, for which relevant information has been hard to find for non-national service providers⁶⁷.

5. Procedures for placing harmonized products on the market are not sufficiently fast for deploying critical goods on the market for crisis response

EU product safety rules, especially those aligned to the so-called New Legislative Framework⁶⁸, are aimed at ensuring the safety of products that are placed on the Single Market by laying down a harmonised set of requirements, conformity assessment procedures and market surveillance

⁶¹ Feedback from BusinessEurope and SMEUnited during public hearing by the European Parliament's Committee on the Internal Market and Consumer Protection on "Impact of restrictions imposed during the COVID-19 crisis on the free movement of professionals and way forward".

⁶² Consultation meeting with the Association of German Chambers of Commerce and Industry (DIHK) Board Europe, 9 December 2021.

⁶³ Letter from Eurochambres, 16 February 2021.

⁶⁴ See letter from Marion Dammann, President of the High Rhine Commission, Head of Lörrach District Authority (D), and Stephan Attiger, Vice-President of the High Rhine Commission, Administrator of the Canton of Aargau (CH) ARES(2020)4394367, as reported in <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021SC0462>.

⁶⁵ Written contribution submitted to the Commission.

⁶⁶ Summary report for the public consultation on the Contingency plan for transport, p.6.

⁶⁷ Feedback from BusinessEurope and SMEUnited during public hearing by the European Parliament's Committee on the Internal Market and Consumer Protection on "Impact of restrictions imposed during the COVID-19 crisis on the free movement of professionals and way forward".

⁶⁸ [New legislative framework \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021SC0462).

procedures for each respective product category. The vast majority of industrial products in the EU are subject to harmonised rules provided by the New Legislative Framework (NLF). The NLF sets out the essential requirements products have to follow, formulated in a general manner to ensure that legislation remains technology neutral and fosters innovation. It is up to manufacturers to ensure that their products comply with the essential requirements. Harmonised standards are intended to facilitate this process and provide a presumption of conformity with the essential requirements. The NLF also foresees horizontal rules on market surveillance.

Currently about 40 pieces of sectoral product legislation follow this regulatory model. The aim of these rules is to ensure the free movement of goods on the Single Market while ensuring a high level of protection. In particular, many products that proved to be essential during the Covid-19 pandemic, such as Personal Protective Equipment (PPE), are regulated according to these rules. Other potentially critical products such as machinery, radio equipment or pressure equipment are equally governed by frameworks aligned to this regulatory model.

With the exception of a few specific legal frameworks such as the new Regulation on Medical devices⁶⁹, the NLF does not foresee any emergency procedures for placing products on the market. This is why during the pandemic, the Commission adopted the Recommendation on PPE and Medical Devices⁷⁰ in order to provide with the possibility for the national authorities to rely on specific derogatory procedures for the conformity assessment of crisis-relevant products and therefore ensuring the swifter placing of such products on the market.

The evaluation study of the NLF has found that the basic principles of the NLF have proven to function well during the COVID-19 pandemic. Yet, especially business stakeholders involved with PPE and medical devices noted that *“it took too long for new market entrants to familiarise themselves with the legislation and go through the procedures necessary to place products important in the fight against COVID-19, such as PPE and medical devices, on the Union market”*.

One national authority highlighted the need to *“to establish procedures for any crisis, urgency or other special situations”* within the conformity assessment system⁷¹. While the issues could be eventually resolved, much time was lost trying to find ad hoc solutions.

In addition, for some legal frameworks (e.g. Machinery, Radio Equipment Directive) the use of a harmonised standard may imply that a manufacturer can do a self-declaration of conformity without having to have recourse to third party conformity assessment body. In some cases, the overall time to conduct the full procedure involving a third party conformity assessment body may be several weeks or months. In cases where the relevant harmonised standards are not available, manufacturers would not be able to use this possibility and would have to undergo the lengthier third party assessment by a notified body. This can delay market access for critical products in times of crisis. Furthermore, as the experience has shown during the COVID-19 pandemic, restrictive measures taken at national level such as lockdowns could have an impact on the availability of such third party assessment bodies. In those cases where the testing facilities had to remain closed due to pandemic-related restrictions, the immediate result was that significant backlogs in the conformity assessment of products were accumulating. These backlogs concerned also the crisis-relevant products, which added additional strain on the already strained supply chains.

⁶⁹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, *OJ L 117*, 5.5.2017, p. 1.

⁷⁰ Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

⁷¹ NLF evaluation study, p. 103.

6. Insufficient legal certainty in relation to existing emergency provisions in public procurement and lack of rules on coordinated and joint procurement for single market emergencies specifically

The EU legal framework for public procurement by individual Member States contains a number of provisions that foresee flexibilities for emergencies when there is an urgent need to procure goods or services quickly. In case of urgency, public buyers have several possibilities, such as substantially reducing deadlines to accelerate open or restricted procedures, or if necessary opting for negotiated procedures without publication. In case of extreme urgency, direct awards to preselected economic operators might be allowed. Public buyers may have to look for alternative and possibly innovative solutions. However, while the overall legal framework therefore appears fit for purpose, Member States may be hesitant to use the flexibilities provided for, out of concerns for possible non-compliance with the applicable rules and potential court cases challenging the use of emergency procurement rules.

To complement public procurement by national level buyers, during the COVID-19 crisis, the Commission together with the Member States launched joint public procurement for various medical goods relying on the Emergency Support Instrument. This proved an effective way to procure necessary products, needed for preserving life, health and human dignity during natural or man-made disasters. In addition, the possibility to procure goods for the needs of civil protection exists under the rescEU mechanism. However, there is currently no structured framework for making use of joint public procurement outside of the field of civil protection or medical countermeasures, allowing the Commission or other EU institutions to procure goods on behalf of the Member States on its own, or to procure flexibly at the time of crisis substantially reducing deadlines to accelerate open or restricted procedures, or if necessary opting for negotiated procedures without publication where necessary. Member States may procure any crisis-relevant goods or services individually, without any obligation to coordinate such procurement procedures between themselves and with the Commission. Several Member States observed in their replies to the Member States questionnaire administrative obstacles to public procurement that constrained a rapid and flexible process of crisis measures. Latvia noted in its reply that this had a limiting effect on compiling national strategic reserves. The upcoming revision of the Financial Regulation is intended to introduce crisis procurement provisions to the Financial Regulation. The proposal is expected to become applicable in four years' time and its emergency procurement provisions will apply only in case of declaration of crisis under the Financial Regulation. The crisis definition of the draft revision of the Financial Regulation as it stands is not adapted to Single Market emergency situations, therefore the proposed emergency procurement provisions cannot provide a solution for the purposes of the Single Market emergencies even after their entry into force.

7. Supply chain disruptions that amplify shortages of crisis-relevant products during emergency and the lack of the ability to anticipate them

Supply chain disruptions can stem from a wide variety of causes. Some of these causes are structural and therefore require more long-term solutions reinforcing the EU open strategic autonomy, for example in fields such as raw materials, semiconductors and energy. However supply chain disruptions can lead to or amplify shortages of crisis-relevant products.

The COVID-19 pandemic disrupted global supply chains in unprecedented ways, inter alia by fundamentally changing consumption patterns during the lockdown thereby impacting demand, or by forcing shutdowns of factories in manufacturing hubs globally.

Further to a sharp increase in global demand in the second half of 2020, supply side bottlenecks became evident, most notably: (i) logistic disruptions in the transport sector (mainly container shipping) that struggled to cater for the surge in merchandise trade in post-lockdown reopening, thus exacerbating pre-existing challenges in this regard (ii) microprocessors, a highly cyclical industry faced with a surge in demand, and (iii) a host of commodities, such as metals, wood, energy and others, where a combination of supply disruptions and spiralling demand pushed up prices to all-time highs. Backlogs continued to drag on or even exacerbate throughout 2021 and beyond, leading to shortages especially in the manufacturing sector, with negative effects (on production capacity and consequently, outputs) across various industrial ecosystems⁷². The supply disruptions disproportionately impacted insular regions that are heavily dependent on imports (including basic goods) and limited connectivity modes (air and maritime).

Supply chains have become increasingly complex as they span across a variety of suppliers and geographical areas, in an attempt to maximise the comparative advantage at each stage of the production process. These business models or practices, which are highly efficient in normal times, may be vulnerable in times of unexpected events, since any unexpected pressure can paralyse entire supply chains. They have exacerbated shortages further during the COVID-19 pandemic⁷³.

Russia's invasion of Ukraine and resulting sanctions and trade restrictions have put further strain on supply chains. This is having an impact on the supply of food products (including animal food) in the Single Market that has led to price increases and to sudden changes in product composition (e.g. to replace sunflower oil), which also triggered the need for emergency amendment to legal provisions on labelling in the Single Market. Even before the invasion, commodity markets displayed significant price increases, affecting agricultural markets due to higher fertiliser and energy costs. In addition to driving up prices and leading to possible shortages in the medium and longer term, this situation also affects how Member States operate within the EU Single Market: in March 2022, Hungary notified to the Commission measures concerning the intra-EU export of agricultural products of strategic importance for feed and food security of supply. The Hungarian measures include a notification obligation concerning exports, giving the State the right to pre-empt exports or purchase such products.

Furthermore, there is a high reliance on Russia and (to a lesser extent) Belarus and Ukraine for a range of other products including raw materials, such as wood, rare earths and noble gases, as well as fertilisers and related inputs and rubber. Imports have been severely affected, not the least in view of import bans in relation to Russia. While alternative sources generally exist, those may not be available, or are available at higher prices.

China's recent zero-Covid policy that imposed a lockdown on millions of workers across the country brings about additional disruptions, notably as regards logistics. These measures are expected to translate into further challenges (delays in deliveries, higher prices and risk of shortages) for global supply chains and with major spill over effects on the availability of goods in the Single Market.

In response to these challenges, industry has been forced to look for alternative sources of supply. For instance, according to VDMA's survey in April 2022, following Russia's invasion of Ukraine,

⁷² European Economic Forecast 2021, European economy institutional paper 160, DG ECFIN (November 2021).

⁷³ Magableh G. M. (2021). "Supply Chains and the COVID-19 Pandemic: A Comprehensive Framework." European Management Review, p.10.

82% of respondents have implemented or considered a broader supplier network and 42% have implemented or considered alternative routes or logistics⁷⁴.

There is a lack of EU-level measures to identify, anticipate and monitor such supply chain disruptions that can have an impact on the availability of crisis-relevant products during an emergency. There are also no effective measures to tackle such shortages during an emergency. This can lead to or amplify further the shortages of crisis-relevant products during an emergency, thus hampering the EU-level crisis response.

8. *Lack of information from economic operators*

Data is essential for driving better delivery of policy and for improving the quality of policy outcomes. Increasingly, the data used in evidence-based policymaking is held by companies, often very large ones but also smaller ones active in specific supply chains. Public sector bodies typically acquire such data from the private sector by setting reporting obligations, launching public procurement, or encouraging voluntary data-sharing collaborations. In some cases, national authorities may not possess relevant firm-level information, or their national rules on information collection may prevent them from sharing it with the Commission or with other Member States (either at all or in a sufficiently timely/disaggregated fashion). Another factor limiting the availability of information is the challenge faced by economic operators themselves to obtain relevant data within their supply chains e.g. in case problems arise that would require accessing information from suppliers further down in the supply chain, in view of developing solutions within the industry. This is typically observed in increasingly complex and globalised supply chains, with business models relying on multiple suppliers along the chain from production to delivery to end consumers.

All in all, existing mechanisms for obtaining and sharing information from economic operators show limitations, such as being incomplete or too slow. This concerns in the first place emergency situations and the products deemed essential for such situations. The COVID-19 pandemic has confirmed the difficulties in the timely acquisition of data necessary for crisis management by governments at national, regional, and local levels⁷⁵ as well as by European institutions. These were not able to obtain the necessary information from economic operators for taking optimal crisis response measures to respond to shortages of crisis-relevant goods. In particular, economic operators refused to provide information on their production capacities, number of manufacturing facilities and their stocks of crisis-relevant goods, consumables, intermediate products and raw materials, which are necessary for the production of such goods, referring to business secrets and contractual terms that prohibit them to reveal such information. The example of vaccines production during the COVID-19 pandemic is a case in point: the Commission compiled data on production capacity (by adding up notified exports to third countries and EU deliveries) based on a proxy assuming that companies were producing vaccines at full capacity during the crisis, which did not reflect the actual potential.

None of the recently proposed initiatives, such as the proposals for the Council Regulation on the emergency framework regarding medical countermeasures, the Data Act and the Chips Act, which contain provisions on mandatory information requests, provide for targeted information requests for emergencies where the functioning of the Single Market is severely disrupted (outside of

⁷⁴ Results of the 14th VDMA Flash Survey Mechanical Engineering, from 5 to 6 April 2022.

⁷⁵ De Nigris, S. *et al.* (2020). *Artificial Intelligence and digital transformation: early lessons from the COVID-19 crisis*; several EU and international case studies available in a Data & Policy special collection dedicated to *Telco Big Data Analytics for COVID-19*, see [here](#); Science Academies of the Group of Seven (G7) (2021). *Statement on Data for international health emergencies: governance, operations and skills*.

specifically on medical countermeasures and semiconductors). Furthermore, when such mechanisms exist at national level, they are not coordinated with the other Member States nor mirrored at EU level.

However, it is difficult for the EU and Member State level authorities to take fully targeted action, such as procurement action, at the time of crisis to remedy shortages of crisis-relevant goods or their components, without having accurate information at their disposal. For example such information could point to specific additional sources of disruptions of the supply of crisis-relevant goods (e.g. availability of testing services, of packaging etc.) or to the potential risk of spillover effects to other sectors/goods/services (e.g. if the raw materials used for the manufacturing of product A are also used in product B, an increase in the demand and the production of product A has the potential to put the production of product B under strain). Similar challenges are observed when it comes to obtaining necessary information for the purpose of ensuring correct application and enforcement of Single Market rules, including in times of crisis.

2.3 How likely is the problem to persist?

Recent experience has shown that in a tightly interconnected global economy certain disruptions in some parts of the world can quickly spread and produce spill over-effects, including in the Single Market. Furthermore, such crisis could be of different nature, thus requiring a more nuanced response, tailored to the specificities of each scenario. Currently there is no horizontal framework allowing to cater for the possible disruptions to the proper functioning of the Single Market that might arise during a crisis, no matter its nature. Even if a number of ongoing initiatives aim to lay down such crisis-relevant provisions and mechanisms in certain specific sectors, those initiatives would not be able to capture crisis scenarios, which fall beyond their scope or would not be able to fully capture in a comprehensive manner disruptions, which even partly fall outside their scope. This in turn will likely hamper EU's ability to anticipate and to address fragmentation in the Single Market and to remedy the disruptions in the supply chains of critical goods and services.

Notwithstanding the ongoing initiatives laying down certain sectorial crisis relevant provisions, if and when a new crisis strikes, the EU will still lack dedicated fora where all the cross-sectorial issues affecting the Single Market can be discussed and coordinated in a coherent and holistic manner. If such a mechanism continues to lack, Member States are likely to introduce heterogeneous restrictions again. In the absence of transparency of such measures, problems related to lack of timely and clear information are likely to reoccur. Inability to anticipate supply shortages as well as a lack of information from economic operators and a lack of vigilance measures would kneecap the EU's response. The EU crisis response itself could be hindered by a lack of streamlined rules on the availability of critical products as well as by an insufficient legal certainty and a lack of provisions on joint or coordinated procurement.

3. WHY SHOULD THE EU ACT?

3.1 Legal basis

Within the context of a crisis, the Single Market can be impacted both by the appearance of the specific disruptions and shortages inherent to the said crisis, as well as by the possible intra-EU restrictions to the free movement of goods, services and persons, which may emerge in an attempt to address the said crisis. The general objective of the initiative is to lay down the mechanisms and procedures, which would allow to prepare for and to address potential crises and disruptions to the proper functioning of the Single Market. Such measures are also aimed to minimise the intra-EU obstacles to the free movement in times of crisis. More specifically, in the case of a crisis, the

measures have to be taken to address any identified shortages and to safeguard the availability of crisis-critical goods and services across the entire EU.

A number of measures, considered within the context of this initiative (e.g. derogation to certain notification procedures or for procedures on the conformity assessment of certain products) derogate or complement existing EU harmonisation legislation, based on the general internal market legal basis (Article 114 of the Treaty on the Functioning of the European Union (TFEU)). In addition, other measures which are considered, such as the ramping up of production capacities, the speeding up of permitting, priority rated orders as well as the accumulation and distribution of strategic reserves also aim to ensure a coherent response to future crises and to avoid the fragmentation of the Single Market. 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 EU level aimed to ensure the availability of crisis-relevant products, such as strategic reserves or priority rated orders, may prove to be indispensable for the restoration of the normal functioning of the Single Market.

Pursuant to Article 4(2) of the Treaty on European Union (TFEU), the Member States retain the competence to take all measures within the context of “*their essential State functions, including ensuring the territorial integrity of the State, maintaining law and order and safeguarding national security...* [And]... *national security remains the sole responsibility of each Member State.*” It is an article of last resort that can be used by Member States in a crisis.

In principle, uncoordinated individual crisis response measures have the potential to further exacerbate the crisis if they were to add additional obstacles to the smooth functioning of the Single Market and may in those circumstances put additional strain on the supply chains of crisis-relevant goods and services. However, it is likely that there could be only limited overlap between the measures which can be adopted under the Single Market Emergency Instrument and the measures adopted by the Member States pursuant to Article 4(2) TFEU due to the fact that the two mechanisms have a different material scope with Article 4(2) TFEU focused on the preservation of the territorial integrity, the maintenance of law and order and safeguarding the national security, while the Single Market Emergency Instrument primarily concerns restrictions to free movement with impact on the Single Market. Nevertheless, potential conflicts between safeguarding national security and supporting the proper functioning of the Single Market cannot be excluded in the future.

In order to establish a clear delineation between Article 4(2) TFEU and other instruments, in recent legislative procedures, e.g. Revised Directive on Security of Network and Information Systems (NIS2), in the context of inter-institutional negotiations a specific caveat has been included to ensure that the specific instrument concerned is without prejudice to the Member States’ rights and responsibilities stemming from this Article⁷⁶. Therefore, an analogous provision will be included in SMEI which will act as a general framework without prejudice to specific rights and responsibilities of Member States in the context of Article 4(2), which will take precedence.

⁷⁶ Specifically, the compromise proposal for the Directive on measures for a high common level of cybersecurity across the Union (NIS2 Directive) includes in Article 2(3) a provision: “This Directive is without prejudice to the Member States’ responsibilities to safeguard national security or their power to safeguard other essential State functions, including ensuring the territorial integrity of the State and maintaining law and order.”, see <https://data.consilium.europa.eu/doc/document/ST-10193-2022-INIT/x/pdf>. An analogous provision is likely to be included in the context of the Directive on the resilience of critical entities, proposed by the Commission in December 2020, COM(2020)829 final, for which a political agreement was achieved in June 2022.

Furthermore, while Member States could potentially take measures pursuant Article 4(2) that could have an impact on the Single Market, an effective Single Market Emergency Instrument with full Member States' participation would ensure a coordinated crisis response and mutual trust and would therefore diminish the effects of a crisis, which could decrease the need for the potential introduction of last resort measures under this Article.

3.2 Subsidiarity: Necessity of EU action

The economic activities across the Single Market are deeply integrated. Interaction between companies, service providers, clients, consumers and workers located in different Member States that rely on their free movement rights, is increasingly common. The experience of the past crisis has shown that often the distribution of production capacities across the EU is uneven (e.g. with the production lines of certain products primarily located in a few Member States such as PPE). In parallel, in the case of a crisis, the demand for crisis-relevant goods or services across the EU territory may also be uneven. The objective of ensuring the smooth and undisrupted functioning of the Single Market cannot be achieved by means of unilateral national measures. Moreover, even if measures adopted by the Member States individually may be able to address to a certain extent the deficiencies resulting from a crisis at the national level, they are in fact more likely to further exacerbate the said crisis across the EU by adding further obstacles to the free movement and/or additional strain on products already impacted by shortages.

3.3 Subsidiarity: Added value of EU action

The introduction of rules which govern the functioning of the Single Market is a competence shared between the EU and the Member States. A significant number of EU frameworks governing various aspects are already in place and they contribute to the smooth operation of the Single Market by laying down coherent sets of rules which apply across all the territories of the Member States.

However, the existing EU frameworks generally lay down rules concerning the day-to-day functioning of the Single Market, outside of any specific crisis scenarios. This being said, some proposals which have been recently adopted by the Commission contain certain crisis-relevant provisions. However, there is currently no horizontal set of rules and mechanisms which address aspects such as the contingency planning, the crisis monitoring and the crisis response measures, which would apply in a coherent manner across economic sectors and across the entire Single Market.

The emergency instrument would only be deployed with the objective of ensuring a coordinated approach to respond to crises that have important cross-border effects and threaten the functioning of the Single Market, and where no EU instrument already exists or where the existing instruments do not lay down crisis-relevant provisions. Putting in place contingency and vigilance measures across the Single Market can facilitate the coordination of the response measures in the case of a crisis. Furthermore, such measures can be complemented by effective and efficient coordination and cooperation amongst the Commission and Member States during the crisis in order to ensure that the most appropriate measures to address the crisis are taken.

The options below foresee a toolbox of targeted EU-level measures that would be proportionately used in response to a specific crisis. Prior risk assessment, based on a well-defined set of criteria and involving closely the Member States, will be systematically conducted before specific measures are deployed at EU level. The various tools may be activated and deployed by themselves or in different combinations depending on the specific emergency circumstances.

The Single Market Emergency Instrument is not intended to lay down a detailed set of EU level provisions which should be exclusively relied upon in the case of crisis. Instead, the instrument is intended to lay down and ensure the coherent application of possible combinations between provisions taken at EU level together with rules on the coordination of the measures taken at the level of the Member States. In this respect, the emergency measures which may be taken at EU level on the basis of the Single Market Emergency Instrument would be coordinated with and complement the emergency response measures adopted by the Member States. In order to allow for such coordination and complementarity, the Single Market Emergency Instrument would set out specific measures which the Member States should refrain from imposing once a Single Market emergency has been activated at EU level.

In this context, the EU added value of this instrument would be to lay down the mechanisms for a swift and structured way of communication between the Commission and Member States, coordination and information exchange when the Single Market is put under strain, and to be able to take necessary measures in a transparent way – speeding up existing mechanisms as well as adding new targeted tools for emergency situations. It would also ensure transparency across the internal market, ensuring that businesses and citizens that rely on their free movement rights have at their disposal appropriate information about the applicable measures across all the Member States. This will increase legal certainty allowing them to take informed decisions.

A further advantage of action in this domain would be to equip the EU with the resilience tools needed to sustain the competitiveness of the EU industry in a geopolitical context in which our international competitors can already rely on legal instruments allowing for a structured monitoring of supply chain disruptions and for the adoption of possible response measures such as strategic reserves (e.g. the US Defense Production Act or Japan's JOGMEC, see Annex 8 for an overview).

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objective

The general objective of SMEI is to enhance the Single Market's vigilance for, response to and its smooth functioning in times of crisis. To this end, SMEI will equip the EU with a well-calibrated crisis toolbox that permits a rapid and effective response to any future crisis that threatens to hamper the functioning of the Single Market, complementing other existing EU mechanisms, including through better coordination, transparency and speed. The objective is to strengthen the functioning of the Single Market and provide quick and practical solutions to issues of free movement of goods, services and persons and of supply in times of crisis.

4.2 Specific objectives

This initiative pursues two specific objectives (SOs).

SO1: Minimise obstacles to free movement of goods, services and persons in times of crisis

The specific objective 1 is to minimise obstacles to free movement of goods, services and persons in times of crisis by providing a toolbox of solutions to ensure a well-coordinated EU-level vigilance and response to crises affecting the Single Market. To this end, it is expected to provide a toolbox of solutions consisting of vigilance, coordination and transparency measures assuring more aligned and targeted Member State responses and providing needed transparency when it comes to obstacles to free movement.

SO2: Address shortages and safeguard availability of crisis-relevant goods and services

This specific objective aims at facilitating quick and practical solutions to issues of supply in times of crisis. To this end, it is expected to provide adequate vigilance, coordination and transparency mechanisms for a targeted policy response and for all Single Market players by enabling information exchange and close cooperation with industry/stakeholders for identifying crisis-relevant supply chain bottlenecks and capacity needs and taking further action when necessary to ensure the availability of crisis-relevant goods and services in an emergency.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1 What is the baseline from which options are assessed?

The potential impacts of the policy options are measured against the current dynamic baseline scenario that consists of no additional EU actions, meaning no change to the currently existing or proposed regulatory framework and existing mechanisms and tools for crisis management. The baseline scenario is not the current state but the state that would dynamically develop without any additional EU action.

Currently, there is no single forum, with a horizontal mandate and a clearly defined role, which would gather and discuss the cross-sectorial concerns, disruptions and crisis-response measures. Several Member States operate public information systems on the market situation (production, stocks, exports, prices, etc.) that enables the effects of possible crises in the markets to be analysed and quantified, and have organised meetings with sectoral representative organisations. However existing examples bilateral or regional cooperation between the Member States do not cover the whole Single Market neither geographically, nor in terms of the sectors covered.

In terms of communication of crisis-response measures, at EU level the Commission put in place the interactive tool Re-open EU which aims to provide the information that citizens need to plan their travel. Member States' competent authorities inform citizens and businesses generally about their crisis measures via official websites of institutions, media (press conferences) and social networks. Dedicated web pages were created to provide detailed information about specific sectors to inform about measures by ecosystems and upcoming meetings within the EU institutions. Some Member States have also set up information hotlines to provide business with administrative assistance in view of implemented measures such as loans guaranteed by the state. In the case of technical regulations, stakeholders and Member States would be able to receive some information on draft crisis measures of (other) Member States via the TRIS system that is operated under the Single Market Transparency Directive. The Member States are obliged to notify the reintroduction of internal border controls under the Schengen Borders Code, but the follow-up is limited. As regards free movement of persons, there is no notification obligation for measures such as entry and exit bans.

There is currently no obligation for the Member States to establish single contact points for the provision of crisis-specific administrative assistance with fulfilment of additional formalities and procedures. Furthermore, there are no specific provisions addressing the language regime for contacts with the national contact points, which may be already set up or which alleviate the administrative burden for requestors.

There is currently no obligation for the Member States to exchange crisis-relevant information outside the areas of civil protection and medical countermeasures. The Member States could exchange some crisis-relevant information on ad hoc basis via the IPCR and the Single Market Enforcement Task Force. Some regions would hold at the crisis time regular meetings between the crisis management authorities to share challenges and best practices and there would also be some

instances of bilateral exchange of information between the Member States. Their obligations of exchanging information with the Commission, would be limited to the fragmented notification obligations under the Single Market Transparency Directive, Services Directive and the Schengen Borders Code.

With respect to specific monitoring systems for crisis management purposes, several Member States operate specific monitoring systems used through their own crisis management tools/contingency plans to gather information from economic operators and assess the situation to reduce negative impacts of a crisis on businesses. However, such monitoring is not systematically done across all the Member States and there are no provisions at EU level rendering such monitoring mandatory. Furthermore, the Member States, which perform such monitoring are not required to inform the Commission and the other Member States.

There is no horizontal Early Warning System whereby the Member States could notify information to the Commission on identified shortages of goods or services that result from Single Market impacts of an emergency situation or about any developments that would lead to those.

Preparatory actions exist in specific areas such as civil protection or specific sectors, depending on national practices and/or EU level initiatives. However, there are no tailored preparatory tools in view of the broader Single Market impacts of possible future crises.

There are no EU-level mechanisms organising the collaboration with private sector stakeholders for the purposes of information gathering in view of the anticipation of future crises. When such mechanisms exist at national level they are not coordinated nor mirrored at EU level.

With the exception of the legislation concerning financial services, neither primary, nor secondary EU law contain crisis-specific provisions specifically targeting emergencies affective the proper functioning of the Single Market. The standard rules for placing products on the market embedded in the EU harmonised product framework do not provide for crisis-response procedures. More specifically, the sectorial harmonised product legislations in general do not provide for the possibilities to use fast-track conformity assessment procedures for crisis-relevant products. Additionally, the sectorial legal frameworks for harmonised products generally do not provide the possibility for the Commission to adopt technical specifications in cases where no harmonised standards are available, which has the potential to accelerate the placing on the market of products by providing the manufacturers with the possibility to rely on simplified and swifter conformity assessment procedures.

For public procurement the baseline scenario consists of the inability of the Commission, outside the areas of civil protection and medical counter-measures, to procure on behalf of the Member States during the crisis or otherwise. The Joint procurement provision of the Public Procurement Directive requires the Member States to negotiate between themselves what the procedure of such joint procurement by the Member States would be and to put in place a joint undertaking or a joint purchasing body for each instance of joint procurement.

There are no specific arrangements for distribution of crisis-relevant goods at the time of dire shortages, ramping up the production lines of crisis-relevant products, speeding up permitting procedures and accepting and prioritising orders of crisis-relevant products by economic operators, apart from the potential rescEU strategic reserves in the area of civil protection/emergency response. The Commission currently does not have a possibility to oblige the economic operators or their representatives to reply to targeted crisis-related information requests. It may, however, rely on the EEN/cluster survey on the impact of supply chain disruptions and the information received by

the Industrial Forum or from other sources. It appears from the study carried out by DG CNECT for the impact assessment of the Data Act that the legal possibilities of the Member States authorities to issue such information requests during the crisis and to share the received information with other Member States and the Commission differ largely and the overall legal framework is fragmented.

5.2 Setup of the instrument

The policy options described below provide a flexible toolbox of measures which allows the selection of the most appropriate measures depending on the type and nature of the crisis.

The toolbox is built around eight building blocks which are described in detail in Section 5.3. The building blocks were identified on the basis of the mapping of problem drivers as well as the analysis of the gaps in terms of coverage of the relevant sector-specific crisis legislation with the objective to address all the problem drivers and all the identified gaps (see Table 1 in section 5.3). All building blocks are necessary in order to ensure the coverage of all problem drivers.

The options establish: 1) a **governance body** and a framework for 2) **contingency planning**, 3) **Single Market vigilance** and 4) **Single Market emergency** measures that would function along a gradual approach, which can be illustrated by a “traffic lights approach” presented below.

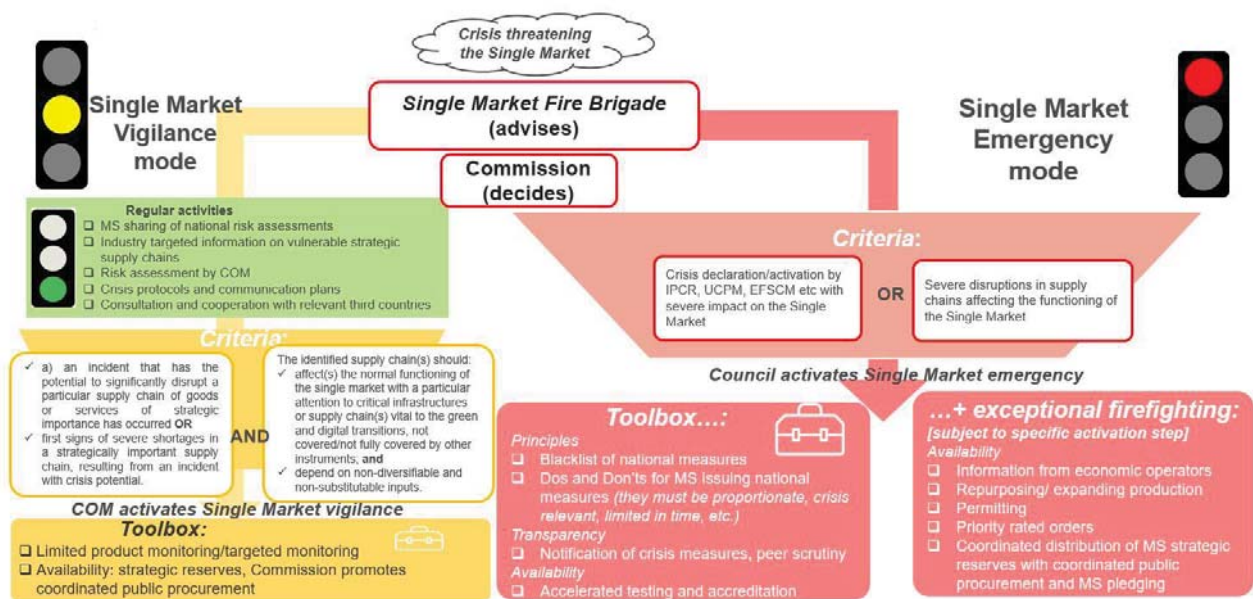
The **definition**⁷⁷ of a Single Market emergency at the moment of drafting this Impact Assessment is foreseen as follows: ‘*Single Market emergency*’ means a wide-ranging impact on the Single Market in at least two Member States of a natural or man-made crisis⁷⁸ taking place inside or outside the Single Market, that severely disrupts or threatens to severely disrupt the functioning of the Single Market or puts its supply chains that are indispensable for the normal functioning of society and have a limited substitution and diversification potential at risk.’ This definition caters for any future emergency while putting a clear focus on its effects on the Single Market and it is wide enough to cover “any” product and service since future crises are unknown today. In practice the instrument will not deal with “every” product and service, but only with those relevant for the crisis.

Other relevant definitions for the purpose of the instrument may be:

- ‘*goods and services of strategic importance*’ means goods and services are necessary for maintaining economic activities in the Single Market in strategically important areas of the economy and are considered as reference during the vigilance mode;
- ‘*strategically important areas of the economy*’ means those areas with critical importance to the EU and its Member States’ strategic interests such as security, safety, public order, health and the green and digital transformation, including critical infrastructure, critical technologies and inputs which are essential for safeguarding such interests, the disruption, failure, loss or destruction of which would have a significant impact in a Member State or the Union;
- ‘*crisis-relevant goods and services*’ means goods and services that are indispensable to safeguard or restore the functioning of the Single Market during a Single Market emergency or for responding to such emergency;

⁷⁷ The definitions and the activation criteria provided in this section are without prejudice to the final legal text of the proposal.

⁷⁸ ‘A natural or man-made crisis’ means an unexpected event with large scale and exceptional impact that gives rise to severe wide-ranging negative consequences in the Member States.



1) Governance body

A central governance body observes the state of the Single Market along a traffic light approach to ensure *adequate coordination and advises* the Commission on the appropriate measures for preventing or addressing the impact of a crisis on the Single Market. It is composed of the Commission and one representative from each Member State and is chaired by the Commission. The governance body has as observers representatives of other crisis-relevant instruments. Industry is consulted on a need basis with the possibility to set up ad hoc industry subgroups depending on the products/services/supply chains identified. It will *propose the activation and the scope* of the Single Market vigilance and emergency modes and analyse the relevant information gathered by the Member States or the Commission by voluntary or mandatory means, including from the economic operators, depending on the chosen policy option (**building block 1**)⁷⁹.

2) Contingency planning

In normal times (“green light”), where no sudden event is likely to have or is already having severe disruptive effects on the Single Market, market forces ensure the functioning of the businesses and of the Single Market. The economic operators, the Member States or the Commission may, depending on the policy option retained, assess the risks to supply chains of goods and services of strategic importance (e.g. goods and services that are necessary for maintaining economic activities in the Single Market in

⁷⁹ During the vigilance mode, the governance body could assist the Commission in the following tasks: providing an advisory opinion on the activation and scope of the vigilance mode; gathering foresight, data analysis and market intelligence, as well as fostering continuous exchanges of information between the Commission and Member States to build a common analysis; performing risk assessment at EU level to anticipate and prevent disruptions; analysing aggregated data received by other crisis-relevant bodies at EU level, such as the European Semiconductors Board, the HERA Board and any crisis-relevant emanation of the Council; issuing a repository of national and EU crisis measures. In case of a Single Market emergency, the governance body could assist the Commission in the following tasks: analysing crisis-relevant information gathered by Member States or the Commission; providing an advisory opinion on the activation and scope of the emergency framework, as well as on the possibility to prolong it, once it is activated; advising on the implementation of the emergency measures chosen for emergency response at EU level; performing a peer scrutiny of national crisis measures; facilitating exchanges and sharing of information, including with other crisis-relevant structures at EU level.

strategically important areas of the economy) if such risk assessment has not been undertaken by industry (**building block 2**).

Depending on the policy option chosen, the Commission could make the relevant elements of the risk assessment available to the representative organisations of economic operators in order to assist them in carrying out their own risk assessments and take measures to ensure their resilience against the identified risks. Furthermore, the Commission, assisted by the governance body, could develop in the risk assessment a list of early warning indicators to identify factors that may disrupt, compromise or negatively affect the supply of goods and services of strategic importance and make publicly available such list. An early warning system may be set up by which the Member States' contact points will alert the Commission and the other Member States about incidents that have the potential to significantly disrupt the functioning of the Single Market and its supply chains of services and goods. In determining the significance or the seriousness of the disruption, pre-determined parameters may be taken into account such as the number of economic operators' affected, geographical area or duration of the disruption.

If the Member States become aware of a risk of severe disruptions of the Single Market, they shall alert the Commission. Upon this alert, or where the Commission learns of a risk of severe shortages including from international partners, it will convene an extraordinary meeting of the SMEI governance body and enter in dialogue with stakeholders, in particular the industry, to identify and prepare effective crisis response measures concerning the identified disruptions.

The SMEI governance body will discuss the severity of the disruption and whether it may be appropriate, necessary and proportionate to activate the vigilance mode based on a pre-defined set of criteria such as:

- a) an incident that has the potential to significantly disrupt a particular supply chain of goods or services of strategic importance has occurred

Or

- b) it appears from the information gathered by the Commission and the governance body that there are first signs of severe shortages such as atypically high increases of prices in a particular supply chain of goods or services of strategic importance, resulting from an incident with a crisis potential.

These criteria will apply with respect to goods or services of strategic importance, vital to the green and digital transition, which are dependent on non-diversifiable and non-substitutable inputs and not covered by any of sector-specific EU legal frameworks laying down crisis-response measures.

If the Commission, assisted by the SMEI governance body, has established that the criteria above are fulfilled, it will activate the Single Market vigilance mode ("yellow light") by means of implementing acts for maximum six months with possibility to prolong or deactivate. The Commission implementing act, which will be subject to the examination comitology procedure in accordance with Article 5 or Regulation (EU) 182/2011 would be the most appropriate activation mean, in line with the similar mechanism (i.e. monitoring of crisis-relevant medical countermeasures) in the Commission Proposal for an Emergency framework for medical countermeasures.

3) Single Market vigilance



This component would consist of a framework for impacts of incidents that have not yet escalated into a full-blown Single Market emergency and includes a set of vigilance measures such as information gathering and industry stockpiling and/or Member States strategic reserves.

Information gathering concerns identified supply chains of goods and services of strategic importance and the measures could vary from guidance for businesses, to recommendations to Member States, to obligations to Member States to monitor shortages affecting the functioning of the Single Market as regards the companies that operate in their territory in those supply chains and the possibility for the Commission to coordinate such monitoring.

The measures related to industry stockpiling/ Member States strategic reserves, depending on the policy option retained, could be 1) guidance for industry stockpiling without public procurement, 2) recommendations to the Member States for building up strategic reserves with focus on Member States facilitating the role of the industry in ensuring resilience with providing guidance on the use of public procurement or 3) obligations to Member States to build up, maintain or reduce their strategic reserves in order to meet the targets for strategic reserves (for selected goods of strategic importance) pre-identified by the Commission by means of implementing acts. On the latter, strategic reserves are activated upon the condition that: i) there is evidence that industry's stockpiling is insufficient or inexistent, ii) alternative supply sources do not work or are insufficient and iii) assessment of risks and impacts by the Commission and the governance body indicates a need for building up strategic reserves. When the vigilance mode has been activated by an implementing act, the Commission will identify among the goods of strategic importance identified by that act the goods for which building a reserve may be necessary and inform the Member States. It can request Member States by means of an implementing act to provide the information on their levels of strategic reserves. The Commission, assisted by the governance body, will coordinate and streamline efforts of Member States to build up and maintain strategic reserves by promoting coordinated public procurement (in particular allowing smaller Member States to pool their resources) and the exchange of information and cooperation between Member States, including by facilitating public-private cooperation and with the objective to avoid overlap or duplication of reserves. Where the building of strategic reserves can be rendered more effective by streamlining among Member States, the Commission, based on the opinion of the governance body, may draw up and regularly update by means of implementing acts the list of individual targets for those strategic reserves that the Member States should maintain, taking into account factors such as the probability and impact of shortages and risks identified during the risk assessment, the level of existing stocks and strategic reserves across the Union and the costs of building and maintaining such strategic reserves. The Member States will regularly inform the Commission about the current state of their strategic reserves and of any excess stocks. The Commission will facilitate the cooperation between those Member States which have already reached their targets and others. Where strategic reserves of a Member State continuously fall short of the targets, the Commission may adopt a decision requiring the said Member State to build up its strategic reserve by a set deadline. Such a decision would only be taken if either the Commission considers it indispensable or 14 Member States ask the Commission to issue such a binding target decision (**see building block 3**).

Where the Commission becomes aware of severe disruptions leading to severe shortages affecting the functioning of the Single Market in the presence of concrete and reliable evidence, it shall assess whether the criteria for activating the emergency mode are met:

- a crisis, which has already triggered the application of at least one of the relevant EU crisis-response mechanisms, has produced a severe impact on the Single Market

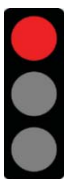
Or

- there are indications that a severe disruption in supply chains affects the functioning of the Single Market, which disruption will be assessed by the Commission in consultation with the governance body based on the following indicators:
 - an estimation of the number of economic operators and/or users relying on the disrupted supply chain for the provision of the goods or services concerned;
 - the dependency of other sectors from the disrupted supply chain on the goods or services concerned;
 - the impacts in terms of degree and duration, on economic and societal activities, the environment and public safety;
 - the market share of the affected economic operator(s);
 - the geographic area that could be affected, including any cross-border impacts;the importance of the affected economic operator in maintaining a sufficient level of supply of the goods or of the services, taking into account the availability of alternative means for the provision of those goods or services;
- the absence of substitute goods or inputs and or services.

Examples of other relevant EU crisis response mechanisms could include IPCR, UCPM or EFSCM etc.

If the criteria above are met and in consultation with the governance body, the Commission will propose the activation of the Single Market emergency by means of Council implementing act, which is to be adopted via the qualified majority voting procedure (15 out of 27 Member States representing at least 65% of the total EU population) and would be justified by the magnitude of the crisis / importance of the decision (2 days following the Commission proposal to activate). The emergency stage will be activated for six months with the possibility to be renewed for another six months or terminated before.

4) Single Market emergency



The activation of the Single Market emergency will immediately unlock a number of possible emergency measures (**see building blocks 4-8**) which include measures to facilitate free movement, improve transparency, speed up the placing of crisis-relevant products on the market during emergency, public procurement or exceptional measures impacting crisis-relevant supply chains, specifically:

- distribution of crisis-relevant goods at the time of dire shortages;
- ramping up the production lines of crisis-relevant products;
- speeding up permitting procedures;
- accepting and prioritising orders of crisis-relevant products by economic operators ('priority rated orders');
- obtaining information from economic operators.

On this last category of measures, there is a variety of policy approaches from guidance, recommendations and obligations to economic operators and to Member States. The latter would require an additional activation by means of a Commission implementing act adopted in examination procedure (maximum 14 days or accelerated), and on duly justified grounds of urgency in urgency procedure (5 days, immediately applicable). The activation of such measures

would be underpinned by the assessment of impacts carried out by the Commission and the SMEI governance body, and:

- will be activated only after unsatisfactory results of consultation and response by industry;
- will be activated upon the advice of the SMEI governance body after careful examination of monitoring data and consultation with all relevant expertise;
- will relate to clearly identified crisis-relevant goods and services.

The information provided by economic operators will be safeguarded through the obligation for the Commission for ensuring the confidentiality and trade secrets protection.

For the coordinated distribution of strategic reserves, the Commission, taking into consideration the opinion provided by the governance body, may recommend to the Member States, where possible, to distribute the strategic reserves in a targeted way in areas where they are most needed, having regard to the need not to aggravate the Single Market disruption further and the principles of necessity, proportionality and solidarity and establishing the most efficient use of reserves with a view to ending the Single Market emergency.

As regards priority rated orders of crisis-relevant products by economic operators, the Commission may invite economic operators in crisis-relevant supply chains to accept and prioritise certain orders of inputs for the production of crisis-relevant goods or orders for the production of crisis-relevant goods as final products. In situations where the economic operators refuse to accept to prioritise such orders and yet the Commission or 14 Member States considers such prioritisation indispensable, the Commission may take recourse to obliging the economic operators to accept such priority rated orders by means of a Commission decision. Such decision shall be taken in accordance with applicable Union legal obligations, having regard to the circumstances of the case, including the principles of necessity and proportionality. The decision shall in particular have regard for the legitimate interests of the economic operator concerned and the cost and effort required for any change in production sequence. In its decision, the Commission shall state the legal basis of the priority rated order, fix the time-limit within which the order is to be performed in the absence of contestation by the economic operator addressed, and, where applicable, specify the product and quantity, and state the penalties for non-compliance with the obligation. The priority rated order shall be placed at fair and reasonable price. Where an economic operator accepts and prioritises a priority rated order, it shall not be liable for any breach of contractual obligations that is required to comply with the priority rated orders.

5.3 Building blocks

On the basis of the mapping of problem drivers as well as the analysis of the gaps in terms of coverage of the relevant sector-specific crisis legislation, we identified the measures that could form part of the toolbox with the objective to address all the problem drivers and all the identified gaps. We then defined eight building blocks on the basis of these measures, grouping the measures into blocks that would apply in different modes (at all times, in vigilance mode and in emergency mode) and further by topic/problem driver:

1. governance, coordination and cooperation
2. crisis contingency planning
3. Single Market vigilance (including elements of public procurement and constitution of strategic reserves)
4. key principles and supportive measures for facilitating free movement during emergency
5. transparency and administrative assistance during emergency
6. speeding up the placing of crisis-relevant products on the market during emergency

7. public procurement during emergency
8. measures impacting crisis-relevant supply chains during emergency (including distribution of strategic reserves, ramping up and repurposing of production, priority-rated orders, speeding up permitting, information requests)

Building blocks 1 and 2 would apply at all times (“green light”). Building block 3 would apply in the Single Market vigilance mode (“yellow light”). Finally, building blocks 4-8 would all only apply in the Single Market emergency mode (“red light”). The correspondence between problem drivers, problems, gaps and building blocks is presented in the table below:

Table 1. Correspondence between problem drivers, gaps and building blocks

Problem drivers	Gaps	Solutions = building blocks
1. Dedicated fora do not exist or the existing fora are unable to deal with single market vigilance and crisis response (communication, coordination, decisions)	1. Lack of a clearly identified forum with a broad horizontal mandate for discussion among sectorial experts inevitably delays the response time in case of crisis 2. Lack of an existing fora at EU level covering all aspects relating to the functioning of the Single Market 3. Lack of requirements for the Member States to exchange any crisis-relevant information between themselves, with the exception of civil protection	1. governance, coordination and cooperation
2. Lack of preventive measures at EU and national level such as forecasting, emergency trainings, mitigations measures for crisis situations such as stockpiling	1. Scattered or non-existent monitoring at Member States level 2. Lack of tailored preparatory tools in view of the broader Single Market impacts of possible future crises 3. The findings stemming from monitoring at national level may not reach the Commission and/or other Member States and may not be collectively discussed 4. Lack of formal preventive tools at the EU level such as forecasting or strategic reserves in view of anticipating or tackling possible supply chain shortages in the Single Market during crises	2. crisis contingency planning 3. Single Market vigilance
3. Divergent and not well targeted Single Market restrictions by Member States during crisis situations	1. Lack of existing EU-level mechanisms (neither at the level of primary law, nor at the level of secondary law) for crisis management due to disruptions of the functioning of the Single Market 2. Limited effectiveness of EU-level recommendations, which may be issued in a crisis context due to their non-binding nature	4. key principles and supportive measures for facilitating free movement during emergency
4. Lack of information from public authorities on MS restrictions	1. Lack of clear and coherent rules regarding the administrative assistance including points of contact that provide information and assistance to citizens and businesses at national level, resulting in linguistic barriers and additional administrative burden for economic operators 2. Length of the delays provided for in the TRIS system operated under the Single Market Transparency Directive (SMTD), which may not be sufficiently adapted to crisis scenarios 3. Follow-up to reintroduction of internal border controls under the Schengen Borders Code, which cannot be vetoed by the Commission, is limited. There is no notification obligation for measures restricting free movement of persons such as entry and exit bans	5. transparency and administrative assistance during emergency
5. Procedures for placing harmonized products on the market are not sufficiently fast for deploying critical goods on the market for crisis response	1. Lack of legally binding fast-track conformity assessment procedures allowing for a swifter placing of harmonised crisis-relevant products on the market during emergency 2. Lack of mechanisms allowing to swiftly lay down detailed technical specifications for crisis-relevant products	6. speeding up the placing of crisis-relevant products on the market during emergency
6. Insufficient legal certainty in relation to existing emergency provisions in public procurement and lack of rules on coordinated and joint procurement for single	1. Member States may procure any crisis-relevant goods or services individually, without any obligation to coordinate such procurement action between themselves 2. Outside of rescEU mechanism in the area of civil protection, the Commission currently has no mechanism at its disposal to procure on behalf of the Member States 3. The Joint procurement provision of the Public Procurement Directive requires the Member States to	3. Single Market vigilance 7. public procurement during emergency

market emergencies specifically	negotiate between themselves what the procedure of such joint procurement by the Member States would be and to put in place a joint undertaking or a joint purchasing body for each instance of joint procurement	
7. Supply chain disruptions that amplify shortages of crisis-relevant products during emergency and the lack of the ability to anticipate them	<ol style="list-style-type: none"> 1. Lack of appropriate Early Warning System whereby the Member States could notify information to the Commission on shortages of goods or services that result from Single Market impacts of an emergency situation or about any developments that would lead to those 2. Lack of formal preventive tools at the EU level such as forecasting or strategic reserves in view of anticipating or tackling possible supply chain shortages in the Single Market during crises 3. Lack of specific EU-level arrangements for distribution of crisis-relevant goods at the time of established shortages, ramping up the production lines of crisis-relevant products, speeding up permitting procedures and accepting and prioritising orders of crisis-relevant products by economic operators 	<ol style="list-style-type: none"> 2. crisis contingency planning 3. Single Market vigilance 8. measures impacting crisis-relevant supply chains during emergency
8. Lack of information from economic operators	<ol style="list-style-type: none"> 1. Lack of mechanisms for collaboration between the private sector and public authorities in each the Member States and lack of a coordinated mechanism for such a collaboration at the EU level 	<ol style="list-style-type: none"> 8. measures impacting crisis-relevant supply chains during emergency

In the following Table 2 we set out a description of the contents of each building block, including the alternative policy approaches that could be chosen for each building block. Beside the baseline scenario or ‘doing nothing’, we assess for each building block an approach focused on non-legislative measures additional to the baseline scenario, a hybrid approach combining legislative and non-legislative measures and a third approach proposing a legislative framework with a broader range of crisis management measures. The approaches should not be seen as self-standing options, but policy alternatives considered in preparation of policy options.

Table 2 below presents an overview of approaches per building block. A very detailed overview of approaches per building block is presented for further reference in Annex 5. These approaches for each building block are analysed in detail in Annex 6 in order to define realistic policy options, which represent combinations of different approaches selected for each building block. These newly defined Policy Options reflect different levels of political ambition and different levels of support of stakeholders. These Policy Options are then analysed in detail in section 6.

TABLE 2. OVERVIEW OF POLICY APPROACHES PER BUILDING BLOCK

<i>Building blocks</i>	<i>Policy approach 1: Soft law</i>	<i>Policy approach 2: Targeted legal solutions combined with soft law</i>	<i>Policy approach 3: Comprehensive legal framework combined with some soft law</i>	<i>Mode when the building block applies.</i>
1. Governance, coordination, cooperation	<p>Informal network of experts set up by DG GROW as the technical-level.</p> <p>Recommendation to MS to exchange crisis-relevant information.</p>	<p>Advisory Group set up by the SMEI regulation to serve as the technical-level forum.</p> <p>Obligation of the MS to share between themselves and with the Commission within the expert group and the Council crisis-relevant information, in anticipation of the crises and during crisis.</p>	<p>High Level Board with high-level MS representatives, chaired by COM supported by dedicated technical sub-groups.</p> <p>Obligation of the MS to share any crisis-relevant information in the HLB with other MS and the Commission. HLB shares information with IPCR and other crisis-relevant EU-level bodies.</p> <p>Obligation of the Commission to share information that it has obtained from the economic operators via mandatory information requests with the High Level Board.</p>	Applies at all times
<p>2. Crisis contingency planning</p> <ul style="list-style-type: none"> - <i>Regular assessment of risks</i> - <i>Emergency trainings and drills of relevant national experts</i> - <i>Crisis protocols</i> - <i>Compendium of crisis response measures</i> 	<p>New guidance where necessary for the functioning of the Single Market in times of crises on:</p> <ul style="list-style-type: none"> ✓ voluntary assessment of risks to supply chains of goods and services on regular basis ✓ crisis-relevant training and drills for national experts <p>Compendium of crisis response measures, prepared and maintained by the</p>	<p>Recommendation to the MSs:</p> <ul style="list-style-type: none"> ✓ to assess risks to supply chains of goods and services of strategic importance on a regular basis ✓ to train and organise drills in crisis vigilance and crisis communication to relevant national experts <p>Compendium of crisis response measures, prepared and maintained by the MS and the Commission in the Advisory Group.</p>	<p>Recommendation to the MS to assess risks of supply chains of goods and services of strategic importance on a regular basis.</p> <p>Obligation of the Commission to:</p> <ul style="list-style-type: none"> ✓ operate in cooperation with the MS an early warning system ✓ devise in cooperation with the Member States crisis protocols and the framework for crisis communication to be applied during vigilance and emergency modes 	Applies at all times

	<p>informal network of experts.</p>		<ul style="list-style-type: none"> ✓ provide training on crisis coordination and cooperation and information exchange for national experts. ✓ conduct stress tests, simulations and in-action and after-action reviews of the national crisis protocols and communication plans with Member States <p>Obligation to MS to train their relevant crisis management staff regularly.</p> <p>Compendium of crisis response measures, prepared and maintained by the Commission for the High Level Board.</p>	
<p>3. Single Market vigilance</p>	<p>Guidance on voluntary stepped-up information gathering concerning identified strategic supply chains.</p> <p>New guidance to economic operators on mitigating measures, including strategic storage or stockpiling of goods of strategic</p> <p>Guidance on the use of the negotiated procedure under the Public Procurement Directive for compiling any relevant MS level strategic reserves.</p>	<p>Recommendation to the MS on information gathering concerning identified strategic supply chains and obstacles to free movement.</p> <p>Industry stakeholders in the relevant supply chain(s) to be invited by MS to provide targeted information factors impacting the availability of such goods and services.</p> <p>The Commission would actively promote matchmaking among companies in the identified supply chains.</p> <p>Recommendations to the MS on mitigating measures, and stockpiling of goods of strategic importance.</p> <p>Guidance on the use of the negotiated procedure under the Public Procurement Directive for compiling any relevant MS level strategic reserves.</p>	<p><i>Subject to the activation of the Single Market vigilance mode by means of Commission implementing act:</i></p> <p>The obligation of the MS to monitor identified supply chains of goods and services of strategic importance with the Commission coordinating such monitoring.</p> <p>The Commission would actively promote matchmaking among companies in the identified supply chains.</p> <p>The Commission would step up the monitoring of relevant free movement obstacles.</p> <p>Obligation of the Commission to draw up and regularly update the list with targets for strategic reserves to be constituted by Member States for the selected supply chains of goods and services of strategic</p>	<p>Vigilance mode</p>

			<p>importance.</p> <p>The Commission will issue Recommendations requesting MS to build up, maintain or reduce their strategic reserves in order to meet the targets.</p> <p>The Commission will coordinate and streamline efforts of MS to build up and maintain strategic reserves.</p> <p><i>Subject to additional trigger by means of Commission implementing acts (during the activation of the Single Market vigilance) upon the condition that i) there is evidence that industry's stockpiling is insufficient or inexistent, ii) alternative supply sources do not work or are insufficient and iii) impact assessment by the Commission and governance body indicates a need for building up strategic reserves.</i></p> <p>Where the strategic reserves of MS fall significantly short of the targets, the Commission can oblige the MS to build up strategic reserves for selected goods of strategic importance that would correspond to such targets.</p> <p>MS would rely on the provisions of the Procurement Directive for carrying out any necessary individual or coordinated procurement for building up their strategic reserves.</p>	
4. Key principles and supportive measures for facilitating free movement	New guidance or Recommendations on free movement of crisis-relevant workers, service providers,	Reinforcing key principles of free movement of crisis-relevant workers, service providers, goods in binding rules (identifying restrictions of free movement incompatible with the Single Market in a	Providing for a comprehensive set of rules supporting free movement of goods and persons (including workers, posted workers, service providers), especially crisis-relevant goods and persons in times of crisis in	Emergency mode

during emergency	persons and goods.	particular crisis situation, black lists of such measures and providing supportive measures) Recommendation to Member States on free movement of persons (including workers and service providers) and goods.	binding rules.	
5. Transparency and administrative assistance during emergency - <i>Notification of national crisis measures</i> - <i>Information and assistance in relation to national crisis measures</i>	Member States share national crisis measures voluntarily with COM ⁸⁰ and other MS. Recommendation to the Member States to provide administrative assistance to businesses, workers, services providers, consumers and citizens for fulfilment of any crisis-related formalities and procedures.	<i>Binding simplified</i> fast-track notification mechanism of any free movement restrictions ⁸¹ + flash peer review of draft notified measures in the EG ⁸² .	Binding full-fledged fast-track notification mechanism ⁸³ + flash peer review of draft notified measures + possibility to declare the notified national crisis measures incompatible with EU law <i>by COM Decision</i> ⁸⁴ and to request the Member State in question to refrain from adopting the draft measures or to abolish the adopted measures.	Emergency mode
6. Speeding up the placing of crisis-relevant goods on the market	Guidance on ✓ increasing availability of products and ✓ prioritizing market surveillance and controls	Targeted amendments of existing Single Market harmonisation legislation ✓ enabling national market surveillance authorities to authorise the placing on the market of critical products while conformity assessment is ongoing. ✓ possibility for the Commission to	Targeted amendments of existing Single Market harmonisation legislation for products ✓ derogating from existing conformity assessment procedures during a specific timeframe ✓ possibility to use normal European standards for harmonised/non-	Emergency mode

⁸⁰ COM may in principle start normal infringement proceedings if any notified crisis measure is incompatible with EU law.

⁸¹ Not applicable to the reintroduction of internal border controls under the Schengen Borders Code as there is a separate notification obligation.

⁸² Besides the flash peer review comments, COM may in principle start normal infringement proceedings if any notified crisis measure is incompatible with EU law.

⁸³ Not applicable to the reintroduction of internal border controls under the Schengen Borders Code as there is a separate notification obligation.

⁸⁴ The possibility for the Commission is an option and not an obligation. It is always without prejudice to other tools such infringement procedures, administrative and political letters etc.

		<p>adopt technical specifications for harmonised/non-harmonised products where no harmonised standard exists.</p> <ul style="list-style-type: none"> ✓ obligations to MS to prioritise market surveillance for crisis-relevant products. 	<p>harmonised products in the absence of European standards.</p> <ul style="list-style-type: none"> ✓ obligation to prioritise market surveillance for crisis-relevant products. 	
7. Public procurement during emergency	<p>New guidance on public procurement:</p> <ul style="list-style-type: none"> ✓ the use of emergency provisions of public procurement ✓ voluntary coordination of public procurement action by individual Member States during the crisis 	<p>New provision on coordinated procurement/common purchasing by the Commission for some or all MS, if requested by the MS⁸⁵, with MS budget whereby the Commission draws up the proposal for framework agreement organising in detail the joint procurement to be signed by the participating Member States. Such procurement would exclude any joint/coordinated procurement by the same MS that does not involve the Commission at the same time.</p> <p>New provision obliging the Member States to coordinate with and consult other MS and the Commission prior to engaging in individual procurement action of crisis-relevant products during the crisis.</p> <p>New guidance:</p> <ul style="list-style-type: none"> ✓ the use of emergency provisions of public procurement ✓ the use of occasional joint procurement by the Member States under the Procurement Directives 	<p>Targeted amendments of the Procurement Directives allowing Member States to derogate from existing public procurement procedures/suspend the application of the Procurement Directives for procurement of crisis-relevant products during a specific timeframe during the crisis.</p> <p>New provision on coordinated procurement/common purchasing by the Commission for some or all MS, which would exclude any procurement by any MS jointly or individually at the same time⁸⁶. It could allow the Commission to derogate from several steps of normal procurement procedures under the Financial Regulation.</p>	Emergency mode
8. Measures impacting crisis-relevant supply chains	Guidance on distribution of possibly previously	<i>The use of below measures is subject to the individual activation of these measures</i>	<i>The use of below measures is subject to individual activation of the measures during</i>	Emergency

⁸⁵ If the emergency procurement provisions of the proposal for the Regulation revising the Financial Regulation will not be adopted by the time SMEI is adopted.

⁸⁶ If the emergency procurement provisions of the proposal for the Regulation revising the Financial Regulation will not be adopted by the time SMEI is adopted.

<p>during emergency</p> <ul style="list-style-type: none"> - <i>Distribution of crisis-relevant goods at the time of dire shortages</i> - <i>Ramping up the production lines of crisis-relevant products</i> - <i>Speeding up permitting procedures</i> - <i>Accepting and prioritising orders of crisis-relevant products by economic operators</i> - <i>Obtaining information from economic operators</i> 	<p>stockpiled products relevant for a certain type of crisis.</p> <p>Guidance on ways how the MS could encourage the economic operators to ramp up their production capacity of crisis-relevant products during the crisis.</p> <p>Guidance on speeding up permitting procedures to ramp up the production capacity for products relevant for the specific type of crisis.</p> <p>Guidance on the ways how the MS could encourage the economic operators to accept and prioritise orders of crisis-relevant products.</p> <p>Recommendation to the economic operators to share crisis-relevant info.</p>	<p><i>during the activation of the Single Market emergency mode⁸⁷:</i></p> <p><i>Measures would be envisaged only where the industry is unable or unwilling to provide effective solutions without reasonable justification, further to guidance by the Commission.</i></p> <p>Recommendation to the MS on distribution of possibly previously stockpiled products relevant for a certain type of crisis.</p> <p>Empowering the MS to oblige the economic operators to ramp up their production capacity of crisis-relevant products during the crisis.</p> <p>Recommendation to the MS on speeding up permitting procedures during the crisis.</p> <p>Recommendation to the Member States to encourage the economic operators to accept and prioritise orders of crisis-relevant products.</p> <p>Providing for harmonised rules for mandatory information requests for targeted crisis-relevant information by the MS to economic operators in crisis-</p>	<p><i>the activation of the Single Market emergency mode:</i></p> <p><i>Measures would be envisaged only where the industry is unable or unwilling to provide effective solutions without reasonable justification, further to guidance by the Commission.</i></p> <p>Obligation of the Member States to distribute possibly previously stockpiled products relevant for a certain type of crisis when the reserves have been financed by the EU.</p> <p>Empowering the Commission to oblige the economic operators to ramp up their production capacity of crisis-relevant goods (e.g. repurposing their production lines or creating new production lines)⁸⁸.</p> <p>Obliging the MS to speed up permitting procedures during the crisis by means of legislation in order to ramp up the production capacity for products relevant for the specific type of crisis.</p> <p>Obligation of the economic operators to accept and prioritise orders of EU authorities of crisis-relevant products.</p> <p>Commission empowered to issue</p>	<p>mode</p>
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⁸⁷ Additional activation by means of Commission implementing act (at the advice of the governance body) at the time or after activation for the emergency mode.

⁸⁸ In case this measure is retained, such an empowerment for the Commission would imply a need for a special financial instrument (based on the model of Emergency Support Instrument which was activated during the COVID-19 crisis to help the EU address the pandemic, in particular to secure the COVID-19 vaccines) to reimburse the economic operators for their costs in such a scenario.

		<p>relevant supply chains as to their production capacities, current supply chain disruptions + data necessary for assessment of the nature and magnitude of the supply chain disruptions.</p>	<p>mandatory requests of crisis-relevant information to economic operators in crisis-relevant supply chains, based on the lists of contacts or relevant ad hoc information provided by the Member States, as to their production capacities, current supply chain disruptions + data necessary for assessment of the nature and magnitude of the supply.</p>	
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The Single Market Emergency Instrument initiative would take the form of a Proposal for a Regulation of the European Parliament and of the Council. Considering that in the case of provisions laid down in a Regulation, there is no need for the Member States to transpose them into their respective national legislation, this specific legal instrument would allow to ensure that the provisions are applied in a consistent manner.

The proposed Regulation would bring targeted amendments to a series of sectorial harmonised product legal frameworks in order to introduce in each specific framework derogatory procedures which would be applied once the Single Market emergency mode has been activated.

With respect to other frameworks such as the Single Market Transparency Directive or the Services Directive, the proposed Regulation will introduce complementary procedures, which are to be applied in the emergency mode and will clarify the relationship between the relevant legal frameworks but without amending the respective legal frameworks.

Digital by default rule will apply for all measures as relevant. Specifically, secure, interoperable solutions will be used for the exchange of information between Member States and the Commission foreseen under building block 1. Equally, communication protocols and the framework for crisis communication, as well as the early warning system foreseen under building block 2 would be based on interoperable digital solutions, building on already existing technical solutions. These solutions, in particular the exchange of information tool, would also form basis for an interoperable digital solution to be used for coordinated monitoring foreseen in the vigilance mode in building block 3. Fast-track notification mechanism foreseen under building block 5 would be interoperable with existing notification IT tool(s) as it would be an extension of such tool(s). Finally, for information requests from companies an electronic tool would be used which would ensure once-only principle and reuse of data and would be user-centric to minimise the administrative burden for companies.

5.4 Policy options

The approaches for each building block are analysed in detail in Annex 6 in order to define realistic policy options, which represent combinations of different approaches selected for each building block. The options reflect different levels of political ambition and different levels of support of stakeholders. For some of the building blocks, the choice of the preferred policy approach is straightforward taking into account the feedback from stakeholders, proportionality and subsidiarity of measures. For others, in particular for far-reaching measures, the views of stakeholders including Member States and businesses differ, hence the different approaches for these blocks have been included in the different policy options. The overview of the composition of the policy options resulting from the analysis in Annex 6 is presented in the table below. These policy options will be analysed in detail in section 6.

Policy Option 1 consists of common elements between all three Options for blocks 1, 4, 5, 6, 7 and of soft-law measures relying on recommendations for blocks 2, 3 and 8, representing the lower level of ambition and aiming to ensure full **transparency**. Policy Option 2 introduces more ambitious elements in blocks 2 and 8 relying on actions by Member States, aiming for increased **cooperation**. Policy Option 3 introduces binding measures for Member States under blocks 3 and 8 in order to go beyond cooperation and ensure a maximum of **solidarity**.

Table 3. Overview of the composition of the policy options

Mode	Building blocks	Policy Option 1 TRANSPARENCY	Policy Option 2 COOPERATION	Policy Option 3 SOLIDARITY
All times	1. governance, coordination and cooperation	<i>Approach 2</i> Formal Advisory Group as the technical-level forum and obligation of the MS to share information within the group in anticipation and during the crisis		
All times	2. crisis contingency planning	<i>Approach 2</i> Recommendation to the Member States for risk assessment, training and drills & compendium of crisis response measures	<i>Approach 3</i> - Recommendation to MS for risk assessment & compendium of crisis response measures and - Obligation to the Commission for Union level risk assessment - Obligation to MS to train their relevant crisis management staff regularly	
Vigilance	3. Single Market vigilance	<i>Approach 2</i> - Recommendation to the Member States on information gathering concerning identified strategic supply chains - Recommendations to the Member States for building up strategic reserves of goods of strategic importance		<i>Approach 3</i> - Obligation to Member States to gather information concerning identified strategic supply chains and share that information with the Commission - Obligation of the Commission to draw up and regularly update, by means of implementing acts, a list with targets for strategic reserves to be constituted by Member States for the selected supply chains of goods and services of strategic importance, by means of recommendation Subject to additional trigger: - Obligations to Member States to build up strategic reserves for selected goods of strategic importance if the Member States

			strategic reserves fall significantly short of the targets	
Emergency	4. key principles and supportive measures for facilitating free movement during emergency	<i>Approach 2</i> Reinforcing key principles of free movement of goods, services and persons in binding rules where appropriate for effective crisis management		
Emergency	5. transparency and administrative assistance during emergency	<i>Approach 3</i> Binding full-fledged fast-track notification mechanism, flash peer review and possibility to declare the notified measures incompatible with EU law; contact points and electronic platform		
Emergency	6. speeding up the placing of crisis-relevant products on the market during emergency	<i>Approach 2</i> Targeted amendments of existing Single Market harmonisation legislation: faster placing of crisis-relevant products on the market; Commission can adopt technical specifications; MS prioritise market surveillance for crisis-relevant products		
Emergency	7. public procurement during emergency	<i>Approach 2</i> New provision on coordinated procurement/common purchasing by the Commission for some or all Member States		
Emergency	8. measures impacting crisis-relevant supply chains during emergency mode	<i>Approach 1</i> Guidance on ramping up production capacity; speeding up permitting procedures; accepting and prioritising orders of crisis relevant goods Recommendations to businesses to share crisis-relevant information	<i>Approach 2</i> Recommendations to MS for the distribution of possibly previously stockpiled products; speeding up permitting procedures; encouraging economic operators to accept and prioritise orders Subject to additional activation: Empowering MS to oblige economic operators to ramp up production capacity and to address binding information requests to economic operators	<i>Approach 3</i> Subject to additional activation: Obligations to MS to distribute products previously stockpiled; speeding up permitting procedures, Obligations to businesses to accept and prioritise orders; ramp up production capacity and provide crisis-relevant information

5.5 Options discarded at an early stage

Discarded policy approaches

Annex 6 provides a list of discarded policy approaches for different building blocks. They were discarded due to their lack of effectiveness in meeting the policy objectives and/or the lack of support of stakeholders. The policy options retained for the assessment are composed of the retained policy approaches and are framed to recognize the constraints of stakeholders while meeting the expectations of Member States and the European Parliament.

Discarded options on legal instrument

It is foreseen that the proposal will use the Commission implementing act to activate vigilance mode and individual measures, and the Council implementing act to activate emergency mode.

With respect to the Single Market vigilance mode, two mechanisms were considered for its activation: activation by means of Council implementing act or by means of a Commission implementing act. Similarly, with respect to the Single Market emergency mode, both the possibility to activate it by means of a Council implementing act or by means of a Commission implementing act were considered.

Procedurally, there is also a difference between two types of implementing acts. Specifically, Commission implementing acts are subject to procedures for control by the Member States of the Commission's exercise of implementing powers ('Comitology procedures') as laid down by Regulation (EU) No 182/2011⁸⁹. While different comitology procedures have been set up, each providing for specific procedural requirements, the common thread for all of them is that they provide for the requirement to consult a dedicated committee set up by the basic act, which is composed by representatives of the Member States. The objective of the Single Market Emergency Instrument is to provide a framework which enables the swift adoption of response measures in case of an emergency affecting the functioning of the Single Market. In that respect, any procedural delays should be as short as possible in order to provide for the necessary flexibility and reaction time necessary in times of crisis.

For what concerns the emergency mode, given the broad-ranging effects that it produces for the Member States, the political significance of the transition to the Single Market emergency mode and the range of the measures that may be taken by the Commission during that mode, it should be exceptionally activated by means of Council implementing acts that are adopted at the proposal of the Commission. Therefore, in the case of the activation of the Single Market emergency mode, due to its broad-ranging effects and political significance, the use of Council implementing acts would be more appropriate. Similarly, the Commission proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level⁹⁰ provides that the public health emergency framework is to be activated by means of Council implementing decisions. In that respect, it would appear appropriate to ensure a similar approach with respect to the activation of the two complementary emergency frameworks (namely the Single Market Emergency Instrument and the emergency framework regarding medical countermeasures).

Conversely, due to its essentially preventive nature, the Single Market vigilance mode may be activated by means of a Commission implementing act. Similarly, the activation of the Mechanism for monitoring crisis-relevant medical countermeasures under the Proposal for framework of measures for ensuring the supply of crisis-relevant medical countermeasures is also done by means of a Commission implementing act.

⁸⁹ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, *OJL 55, 28.2.2011, p. 13*.

⁹⁰ COM(2021)577 final.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The following assessment provides a qualitative analysis of the impacts generated by each policy option, based on the evidence gathered from multiple sources. Whenever possible, it also provides a quantitative analysis of benefits and costs relating to the main economic and social impacts. The cost/benefit analysis, however, is not fully comprehensive due to data gaps and limitations as so far no other crisis-coordination and management tool of horizontal nature exists at EU level. The quantification of costs and benefits is based on a number of assumptions coming from other existing impact assessment studies and reports and expert knowledge of the Commission officials. The aim of this assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation⁹¹. Given that for certain measures the necessary evidence will become available only in a crisis situation (unknown today), the assessment provides a qualitative assessment of the type of impacts to be expected for different stakeholders groups. This is also the reason why the instrument foresees the need for the assessment before activating certain measures in the decision mechanisms (as explained in section 5.2, setup of the instrument).

1. POLICY OPTION 1

Economic Impacts

Impact on companies

The toolbox of measures under Policy Option 1 is expected to bring **economic benefits** for companies, in particular during an emergency, due to better EU-level crisis response leading to less obstacles to free movement and better availability of crisis-relevant products. These measures do not impose any compliance costs on companies as all of the measures that could have cost implications for companies (e.g. information requests or stockpiling) are voluntary. This voluntary nature means that businesses will only decide to go ahead with these measures when they perceive that the benefits of doing so will outweigh the costs.

In terms of measures with immediate effect (block 1 and block 2), during an emergency, thanks to better coordination of national measures and cooperation between the Member States within the governance body and with other crisis relevant mechanisms, it is expected that there will be an overall better crisis response benefiting companies. In their responses to the call for evidence and the public consultation, business stakeholders stressed that the initiative should ensure cooperation, coordination and exchange of information and should focus on crisis response. Some of the industry associations pointed out in their position papers that *SMEI should primarily ensure cooperation, coordination and exchange of information* (Business Europe). Also, the European Trade Union Confederation (ETUC) asked for a Single Market Emergency Instrument that will *address the lack of coordination and cooperation between the Member States*. Business stakeholders supported the instrument's role to ensure exchange of information. During the stakeholder workshop, 69% of respondents (mainly public authorities and business associations) were in favour of mandatory exchange of gathered information by Member States in a dedicated forum.

The measures contained in the crisis contingency planning building block 2 will bring economic benefits to companies in the longer term, if the emergency mode is activated, thanks to better foresight and anticipation to manage a Single Market emergency when it strikes. There are no direct compliance and administrative costs for companies. In the public consultation, regular risk assessment by the industry was supported by 22 out of 24 respondents and by the Member States

⁹¹ More details on data gaps and limitations are presented in Annex 4.

was supported by 22 out of 24 respondents. Emergency training and drills were supported by 22 out of 24 respondents. Business stakeholders expressed support for risk assessment by public authorities (BusinessEurope) and emergency simulation exercises (SMEUnited).

During the vigilance mode, under Policy Option 1 the measures foreseen in the Single Market vigilance (block 3) are voluntary (providing information on supply chains and participating in match-making). In terms of benefits, promotion of match-making among companies in the identified supply chains is expected to result in certain benefit for companies. In the longer perspective, if a crisis materialises, measures taken by Member States on information gathering on supply chains and on constituting strategic reserves in the vigilance mode could result in better availability of crisis-relevant goods, which could benefit companies in terms of better EU-wide crisis response; however these benefits would be limited due to being dependent on the uptake of recommendations by Member States. Any costs for companies will be incurred based on their own assessment of costs and benefits. In the public consultation, 14 out of 24 respondents supported a targeted monitoring mechanism (above referred to as targeted information gathering) of identified supply chains to anticipate shortages. Some business stakeholders were in favour of voluntary or mandatory mechanisms to anticipate future shortages (for example SMEUnited, Europen, VDMA, ETUC), whereas others considered that this was not in line with the principles of proportionality and necessity (BusinessEurope, ERT, and Dansk Industri).

On the question of a strategic storage or stockpiling system for goods of strategic importance in the public consultation, 19 respondents out of 21 were generally supportive of such a measure, whether done on the industry, Member States or EU level. There were a number of divergent suggestions on how to determine such goods of strategic importance, both in terms of methodology and in terms of specific goods.

During the emergency mode, certain blocks (4-7) and measures could be activated depending on the type of crisis. The impacts will therefore strongly depend on the types of measures activated and sectors concerned. Therefore, the analysis below focuses on the type of expected impacts.

During an emergency, facilitation of free movement by means of key principles and related measures and better information (transparency) will have a very positive impact on companies due to the improved legal certainty and improved free movement of goods, services and persons, resulting in higher turnover, less delays in production, less difficulties in outsourcing staff, lower prices for inputs and less temporary stoppages (blocks 4 and 5).

In general, companies support key principles and supportive measures for facilitating free movement during emergency (block 4) and transparency and administrative assistance during emergency (block 5). 21 out of 21 respondents to the public consultation supported providing key principles concerning crisis measures restricting the free movement of certain categories of goods as well as persons, workers and professionals. 19 out of 21 respondents supported setting out key principles to identify a blacklist of national measures restricting the free movement of goods, services and persons incompatible with the particular crisis situation. Business stakeholders widely supported measures to ensure free movement, singling out the needs of cross-border workers, critical occupations and supporting solutions such as key principles and blacklists. Specifically, in their position papers the European Organization for Packaging and the Environment (EUROPEN) was in favour of key principles to identify incompatible national restrictions, the German Mechanical Engineering Industry Association (VDMA) stated that a blacklist of measures could be useful. Stakeholders have largely supported actions regarding information sharing and/or notifications of national crisis measures as a solution to crisis situations. 20 out of 22 public consultation respondents (mostly business associations) were in favour of specific mandatory

notification mechanisms followed by flash peer review. 21 out of 22 respondents expressed support both for EU-level and national level contact points, as well as for publishing the summary of the national crisis measures on a dedicated EU website. In the stakeholder workshop, the majority of participants supported obligatory notifications and disseminating information via electronic platform and a single point of contact in the EU, with less support for voluntary options. Business stakeholders stressed the need to address difficulties to access information and the need for Member States to share information about national measures, supported notification mechanism and called for a dedicated information interface and hotline. Eurocommerce stated that overall, access to timely (real-time), comprehensive and clearly structured information has been a huge problem.

Economic benefits for companies are also foreseen for the measures related to speeding up the placing of crisis-relevant products on the market during emergency (block 6). Through these measures, the companies would benefit due to being able to anticipate revenues from commercialising their crisis-relevant products earlier than in normal circumstances by deploying them on the market before finalising the conformity assessment and due to being able to meet the increased demand, thus increasing their overall turnover. The risk of non-compliant products would be mitigated by the increased market surveillance. Streamlining EU product rules (such as mandatory conformity assessment and standards) and prioritising products' controls for a limited time, to enable a swift deployment of products of potential relevance to a crisis on the market was considered as an efficient solution by 14 out of 17 respondents in the public consultation. Businesses associations BusinessEurope, SMEUnited, VDMA and Dansk Industri support the idea to facilitate procedures for placing crisis relevant products on the market.

For the public procurement (block 7), the possibility for the Commission to lead joint public procurement on behalf of Member States will affect the market and there may be some companies that will be beneficiaries of such procurement and therefore would have a higher turnover, while other companies may have less business opportunities. This may in particular favour larger companies who may be better placed to participate in larger tenders. The overall impact on the companies is expected to be beneficial, due to the fact that overall there would be a better EU-wide crisis response due to better availability of crisis-relevant products and less fragmentation in the market. Business stakeholders were in favour of guidance on public procurement (Eurochambres) and did not see the need to modify the rules (BusinessEurope, Dansk Industri). In the stakeholder workshop, joint procurement by the Commission on behalf of the Member States was supported by 53% and guidance on emergency procurement in Member States by 49% of participants.

For the measures impacting crisis-relevant supply chains during emergency (block 8), under Policy Option 1, all the measures are of voluntary nature and limited to recommendations and guidance. Companies may acquire indirect economic benefits which will depend on the uptake of the guidance by the Member States and companies. Such indirect benefits are harvested by improving the functioning of the Single Market during emergencies and resolving the crisis faster thanks to adequate availability and allocation of crisis-relevant goods to tackle the crisis at stake. However, there is likely to be only a very limited take-up of such measures and the benefits for the Single Market and for companies are expected to be very limited under this Policy Option.

Respondents to the public consultation considered that ramping up production capacity, e.g. by repurposing or extending existing production lines on a voluntary basis was efficient (13 out of 17 respondents). Business stakeholders considered that recommendations would be sufficient (Eurochambres), stressing that businesses are best placed to manage their own supply chains (ERT, VDMA). Business association (SMEUnited) supported the possibility to oblige companies to prioritise orders in times of crisis and ramp up production without specifying the means (on voluntary or mandatory basis). The latter was also supported by Eurochambres upon the condition

that is implemented by means of recommendation. In the stakeholder workshop, recommendations gathered more support than obligatory solutions, with recommendation to businesses to ramp up production capacity of crisis-relevant products was supported by 73% and recommendation to businesses to prioritise orders of crisis-relevant products by 63% gathering particular support.

Business stakeholders called for the information to be disclosed on voluntary basis and insisted that industry should not be burdened by excessive requirements, with BusinessEurope, ERT, European and others objecting to disclosure of business confidential information, and even stronger in the context of monitoring. In the stakeholder workshop, in terms of obtaining information from businesses, participants were in favour to encourage voluntary sharing (75%).

As the measures under Policy Option 1 for block 8 are voluntary, limited to recommendations and guidance, they would not imply any cost for companies as the decisions on their implementation would be left to companies.

Impact on SMEs

Under Policy Option 1, SMEs are likely to be specifically affected by the measures under building blocks 3-8. SMEs will benefit from promotion of match-making (block 3). SMEs are particularly affected by the obstacles to the free movement and the lack of transparency of measures as their activities could be easily disrupted by restrictions especially in cross-border regions. Therefore the positive impacts of easing free movement (block 4) are expected to be especially pronounced for SMEs. They will particularly benefit from better transparency (block 5). SMEs will benefit from the possibility to place products faster on the market (block 6). Finally, SMEs may be somewhat affected by the joint procurement, however the precise effect is impossible to predict as it will depend on the nature of the crisis. Nevertheless it is possible that due to the larger overall size of tenders, SMEs may have less opportunities to win such a tender (block 7). Under Policy Option 1, it is not expected that SMEs would be impacted by voluntary measures such as information requests or stockpiling or prioritising orders (block 8) as companies will be able to decide on their own if they are willing to participate in these measures. Overall, no costs for SMEs are therefore expected under Policy Option 1.

In its position paper, SMEUnited expressed support for measures such EU and national single points of information, facilitation of free movement of workers and acceleration of conformity assessment procedures during crises.

Impact on competitiveness

Under Policy Option 1, there would be better transparency and legal certainty as well as lower costs for EU companies due to easing of free movement and measures to ensure transparency (blocks 4 and 5). This would have a positive impact on international competitiveness of EU companies. Since blocks 2, 3 and 8 are voluntary, they would allow the companies to opt in or opt out in line with their preferences, thus there would not be an impact on competitiveness from these blocks.

Impact on competition

Under Policy Option 1, competition is likely to be directly affected by measures under building blocks 4, 5, 6 and 7. Easing free movement of goods, services and persons by definition increases trade in the Single Market due to increasing the number of companies competing, and thereby improves competition (block 4). Better information leading to improved legal certainty and predictability similarly positively affects competition (block 5). The possibility to place products on the market faster may increase the amount of products on the market, therefore the impact on competition is expected to be positive. The risk that some crisis-relevant goods might be non-compliant would be mitigated due to the increased market surveillance of such goods, although this

might mean less resources for checks of other goods (block 6). The possibility to launch joint public procurement may have different effects on the competition, as some companies may be beneficiaries whereas others may have less possibility to win a tender. The precise effect is impossible to predict as it will depend on the nature of the crisis (block 7). Finally, the measures on supply chains will only be voluntary under this option, therefore it is unlikely that they would have a significant effect on competition (block 8). Overall, the effect on competition is expected to be positive.

Impact on international trade

Crisis measures with high international trade and competition impacts have been kept outside of the scope of SMEI since they belong to the realm of EU exclusive competence (emergency state aid framework, export authorisation schemes).

Under Policy Option 1, international trade may be affected in particular by blocks 4, 5, 6 and 7. Easing free movement will in general improve the functioning of the Single Market, which may lead to better trade opportunities, thus increasing international trade as more products and services can be produced and consumed in the Single Market and therefore sold to or bought from international partners (block 4). Better legal clarity and predictability is also likely to encourage trade, including international trade (block 5). Speeding up the placing of crisis-relevant products on the market is likely to stimulate trade, including for exporters to the Single Market, thus boosting international trade (block 6). The possibility to launch joint public procurement may have different effects on international trade, as some companies may be beneficiaries whereas others may have less possibility to win a tender. The precise effect is impossible to predict as it will depend on the nature of the crisis (block 7). Finally, the measures on supply chains will only be voluntary under this option, therefore it is unlikely that they would have a significant effect on international trade (block 8). Overall, the effect on international trade is expected to be positive.

Impact on Member States (public authorities)

In terms of measures with immediate effect (block 1 and block 2), this option will entail some direct costs for the Member States related to participation in the SMEI Advisory Group, which are estimated at ½ FTE annually (block 1). Travel expenses would be reimbursed by the Commission similar to existing expert groups. The costs of the exchange of information fall largely on the Member States. Their magnitude depends on the extent to which they have information available already in a suitable format. In that case, additional costs for the transmission are likely to be low. Otherwise additional efforts are needed, but these depend on the nature of the information required in a concrete crisis and cannot be estimated in the abstract.

Since under Policy Option 1, the measures in block 2 are based on guidance, the costs will depend on the MS willingness to follow it in terms of voluntary risk assessment and organising training and drills. Further elaboration on these costs is included under Policy Option 2 where such measures are binding.

The public consultation results indicated that the majority of the national authorities responsible for the Single Market believes that a new dedicated forum for coordination and information exchange is necessary to ensure effective coordination and information exchange on obstacles to free movement. Most Member States have voiced their support for mechanisms to ensure greater transparency and coordination during a crisis (for example BG, DK, DE, EE, IE, FI, LV, MT, NL, PL, SE, SI, letter of nine Member States of 3 June 2022). In their replies to the Member States questionnaire, Member States recognised the need to ensure an effective partnership between Member States (national public and private entities) and the Commission (notably through the participation in several Committees, Steering Groups, Expert Groups, Taskforces, European

Clusters, and in SME Envoys Network) when it comes to information sharing. In light of future crises, most Member States having responded to the Member States questionnaire agree that preparedness measures such as risk assessments concerning the availability of non-medical goods and critical raw materials are indispensable; strategic storage or stockpiling of such goods and critical raw materials should be undertaken. They acknowledge that in most cases, national authorities are best prepared to take the above-mentioned measures.

For the vigilance mode, the measures for Member States are voluntary. There could be costs of gathering information on identified supply chains and obstacles to free movement, costs of participation in promotion of match-making, costs for voluntarily constituting strategic reserves for crisis-relevant goods but these costs will depend on the uptake of the recommendations by public authorities. The costs depend on voluntary actions ultimately taken by the Member States when the Single Market vigilance mode is activated. Such costs are expected to be similar to business as usual as most of the Member States that have replied to the targeted questionnaire indicated that they have national level activities to monitor the market with early warning systems in place.

In the stakeholder workshop, guidance to Member States on voluntary targeted monitoring of identified strategic supply chains for shortages was supported by 61%. However, some Member States, such as DK, emphasise that gathering information would potentially require a great deal of work and coordination. This would imply in their view significant burdens for public authorities and businesses subjected to reporting requirements, and also entail risks around forced disclosure of sensitive business information. Member States have pointed out in their replies to the Member States questionnaire that the private sector could be further involved in management of stockpiles.

For the emergency mode, the costs will be subject to the activation of the emergency mode and will depend on which building blocks will be relevant to the specific crisis.

For key principles and supportive measures for facilitating free movement, there would be compliance costs for Member States. The aim of these key principles is to ensure that the new restrictions introduced with Member States are compatible with the functioning of the Single Market, therefore Member States will need to make sure that their new measures are compliant. However these will form part of the normal activity of Member States in terms of developing new rules (block 4).

Member States have widely supported measures to ensure free movement of persons, goods and services (for example BE, BG, DK, IE, EE, FI, LU, NL, PL, PT, RO, SE, letter of nine Member States of 3 June 2022).

For transparency and administrative assistance during emergency (block 5), the costs for a notification mechanism are slightly higher than current costs for the Single Market Transparency Directive and the costs of the notification mechanism under the Service Directive, due to the wider obligation on the Member States to notify any free movement restrictions. Based on the data in the impact assessment on the Services Directive notification proposal, the average time spent to comply with the notification procedure is 12 hours per notification. This leads to administrative costs of €385.20 per notification, assuming the EU average of hourly earnings for civil servants holding a university degree of €32.10. There would be also costs for setting up national contact points, which could be estimated at approximately 1.5 FTE per Member State.

Some Member States have warned about the difficulties of introducing a new notification obligation and/or the need to build on the existing mechanisms (for example joint letter of 11 March 2022 and individually DK, IE, FI, SE), while stressing the importance of ensuring transparency for citizens

and businesses with regards to measures taken across Member States (joint letter of 11 March 2022) and calling for an online platform providing standardised information on measures (BE, LV, PL). In its replies to the Member States questionnaire, LV recommends setting up a dedicated platform where all the necessary information would be available in times of crisis: a webpage for up-to-date information, like the existing Re-open EU platform that provides information on travel and health measures.

For speeding up the placing of crisis-relevant products on the market during emergency (block 6), no additional costs are expected – familiarising with the new technical specification developed by the Commission and prioritising market surveillance would fall under business as usual.

Regarding the costs for the Member States for the public procurement during emergency (block 7), the costs under this policy option are similar to the costs for setting up Commission-led procurement of COVID-19 vaccines, which are considered business as usual.

When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance (joint letter of 11 March 2022, also AT, FR, DE).

For measures impacting crisis-relevant supply chains during emergency (block 8), in case of following the Commission recommendations, there could be costs for distribution of voluntarily constituted strategic reserves; costs for encouraging economic operators to ramp up their production capacities, encouraging them to accept and prioritise orders of crisis-relevant goods and of speeding up permitting procedures. As these costs are voluntary, they are expected to be of limited magnitude.

A number of Member States have voiced concern about including in the scope of the initiative measures to address difficulties in supply chains, also drawing attention to the need to follow strictly the principles of necessity and proportionality of measures and to avoid the related administrative burden. On the other hand, Member States such as PL, RO, EL, AT, LU have spoken in favour of addressing crisis preparedness and supply chains disruptions.

Most Member States agree in their replies to the Member States questionnaire that in light of a future crisis, tools that allow to increase the availability of non-medical goods and critical raw materials (speeding up permitting procedure, targeted mandatory information requests to businesses on their stocks and production capacities, priority rated orders) should be taken. They acknowledge that in most cases, national authorities are best prepared to take such measures.

They also point out in their replies to the Member States questionnaire that the private sector could be further involved in management of stockpiles and the continuity of supply chains. Supply chain-wise, the private sector should have the capacity to switch production from their day-to-day items to key items in times of crisis. Meanwhile, the public sector would continue the coordination efforts, knowing they can rely on the private sector. The public sector may need to finance the additional capacities of the private sector.

Impact on the Commission (budgetary implications)

Under Policy Option 1, for a number of building blocks, guidance or recommendations will be developed by the Commission. We assume that this forms part of normal functioning of the Commission and therefore no additional costs are attributed to these activities.

Under Policy Option 1, the **immediate budgetary implications** for the Commission would be limited to administrative costs for the functioning of the Advisory Group, including reimbursement of travel expenses for experts (recurrent). This is estimated at 30.000 EUR annually, which is based on a standard budget for a meeting with 27 MS experts of 15.000 EUR. The organisation of the meetings would require ½ AD FTE that could be added through reallocation of staff. There would be also one-time costs for creating a compendium of crisis responses, which would be done by existing Commission resources.

In vigilance mode, there could be costs for promotion of match-making between companies. Matchmaking between companies in identified strategic supply chains would be primarily coordinated by the Commission, requiring up to 2 AD FTE totalling an estimated 314.000 EUR/year. Possible involvement of Member States in matchmaking activities may entail more limited resources for the Commission due to cost savings, involving up to 1 FTE at approximately 157.000 EUR/year. Additionally there would be a need of 1 AD FTE for organising and running the Advisory Group meetings that could be added through reallocation of staff.

In emergency mode, the use of different blocks would depend on the nature of the emergency.

For the organisation of the meetings of the Advisory Group (block 1) in the emergency mode which have higher recurrence, 1.5 AD FTE are needed that could be added through reallocation of staff during the time the emergency mode is activated.

For key principles and supportive measures for facilitating free movement (block 4), no costs are expected for the Commission in addition to its normal activities of monitoring and enforcement.

For transparency and administrative assistance during emergency (block 5), there would be costs of analysing notifications and of follow-up. Based on the impact assessment report on the Services Directive notification proposal, on average, the assessment of a notification by a Commission staff member will take 2-3 hours. In case comments or questions addressed to the Member State concerned are to be prepared, it is estimated that this will lead to an additional 5 hours of work per notification. This option will impact the Commission in that it will lead to additional work stemming from the comments received from stakeholders who will be granted access to the notifications to be considered. Another element could be the possible increase of notifications from those Member States currently not completely fulfilling the obligation under the Services Directive. For restrictions affecting the free movement of persons, we calculate additional resources of 2 AD officials. Further to this increase in workload, there is likely to be an impact on the translation costs. Additionally, there could be costs linked to setting up an electronic platform for disseminating crisis-related information, which are similar to the costs for the Re-open EU platform, estimated at 600.000 EUR per annum.

For speeding up the placing of crisis-relevant products on the market (block 6), there could be costs for the Commission for developing and adopting technical specifications, when and if applicable depending on the nature of the crisis, which are considered to be a normal activity.

For public procurement during emergency (block 7), the costs are similar to the costs for setting up Commission-led procurement of COVID-19 vaccines, which are considered business as usual.

For measures impacting crisis-relevant supply chains during emergency (block 8), under this Policy Option, the Commission will develop a number of recommendations and guidance, however the costs of developing such documents are considered business as usual.

Social Impacts

There are strong links between the functioning of the Single Market and the achievement of the EU green and digital twin transition objectives in particular, and of society more generally.

Specifically, measures easing free movement of goods, services and products will have a significant impact on workers because they will lead to securing employment due to higher cross-border trade and less disruptions in economic activity. As a consequence, there will be less bankruptcies and less redundancies, which will lead to the reduction in poverty. Easing free movement of persons will have a significant social impact on cross-border workers and their communities, by providing better opportunities to maintain their social connections. Outermost regions can be disproportionately affected by obstacles to free movement, worsening the economic and social situation of vulnerable communities, therefore less obstacles to free movement will result in better social outcomes for outermost regions (particularly relevant for blocks 4 and 5).

Measures to ensure better availability of crisis-relevant products and services will result in direct social benefits as they will improve crisis-specific response of the EU, thereby contributing to better quality of life of citizens. However due to the voluntary nature of the measures in blocks 2, 3 and 8, the ability to ensure the availability of such crisis-relevant products in a situation of last resort would be severely limited, in particular when it comes to guidance on constituting and distributing strategic reserves, as well as guidance on speeding up permitting procedures, ramping up production, priority-rated orders, and requesting information from economic operators. Therefore the toolbox would only ensure a certain degree of social benefit.

Environmental impacts

The initiative overall is likely to lead to increased economic activity (compared to the baseline) due to the better functioning Single Market, which may lead to impacts on the environment associated with increased economic activity. The only measure in the toolbox that may have specific environmental impacts is speeding up permitting procedures, as issuing permits in an expedited manner with simplified requirements may potentially lead to less scrutiny of environmental impacts. Under Policy Option 1, only guidance to Member States is foreseen in this area, therefore the expected environmental impact is very limited (block 8). Overall, the Option is therefore consistent with ‘do no significant harm’ principle.

1. POLICY OPTION 2

The differences of Policy Option 2 compared to Policy Option 1 are in blocks 2 and 8. In block 2, crisis contingency planning, there will be an obligation for the Commission to conduct a regular Union-level risk assessment for supply chains of strategic goods and services; to operate together with Member States an Early Warning System for alerts and incidents; to develop crisis protocols; to organise training and drills for national experts. In block 8 (measures impacting crisis relevant supply chains that could be activated during the emergency mode), in addition to voluntary measures, there would be a legal empowerment for Member States to 1) address binding information requests to economic operators in crisis-relevant supply chains as to their production capacities, current supply chain disruptions and related data; to 2) oblige the economic operators to ramp up their production capacities of crisis-relevant products, with the possibility to offer targeted and necessary financial support in compliance with state aid rules. The assessment below focuses on these new elements in comparison with Policy Option 1.

Economic Impacts

Impact on companies

The toolbox of measures under Policy Option 2 is expected to bring further **economic benefits** for companies, in particular during an emergency, due to significantly better EU-level crisis response leading to less obstacles to free movement and better availability of crisis-relevant products.

In terms of measures with immediate effect, due to the fact that there would be a Union-wide risk assessment conducted by the Commission and related crisis contingency measures, there would be better foresight and anticipation to manage a Single Market emergency when it strikes. There are no compliance and administrative costs for companies.

In the public consultation, regular risk assessment by the Commission was supported by 23 out of 24. Business stakeholders expressed support for risk assessment by public authorities (BusinessEurope).

During the vigilance mode, there would be no changes compared to Policy Option 1.

During the emergency mode, the possibility to implement measures in block 8 would be subject to the activation of the emergency mode. Furthermore, there would be additional activation by a Commission implementing act for individual measures of obligatory nature.

For the legal empowerment for Member States to address binding information requests to companies, this could lead to costs for companies. However as such information requests would be limited to cases of utmost necessity and only if the companies have refused to provide such information voluntarily at an earlier stage, it is expected that such requests would be relatively rare and of limited scope. In terms of costs related to mandatory information requests to companies, the costs are similar to those indicated by the impact assessment on the Single Market Information Tool (SMIT) proposal (option 4)⁹². For a company affected by a mandatory info request the impact assessment estimated the one-off administrative costs to be approximately 0.29 million EUR. Since the measure will be used in the emergence mode and only if Member States decide to use their

⁹² [Impact assessment of the SMIT proposal, SWD\(2017\)217](#). The European Commission withdrew this legislative proposal on 29 September 2020.

empowerments, it is not possible to quantify precisely the costs which also strongly depend on the type of future crisis.

Respondents to the public consultation were supportive of targeted information requests to industry in order to manage crisis, on issues such as information regarding current primary disruptions (17 out of 20 respondents said yes and 2 said maybe), production capacities (9 said yes, 9 maybe) and existing stocks of goods (9 said yes, 10 said maybe) However, as already mentioned under Policy Option 1, business stakeholders called for the information to be disclosed on voluntary basis and insisted that industry should not be burdened by excessive requirements.

For what concerns the empowerment for Member States to oblige economic operators to ramp up production capacity of crisis-relevant products during the crisis, this would come with the possibility to offer targeted and necessary financial support, the decision on which will be up to the Member States concerned. This means that in practice, the net effect for companies may be beneficial, since the necessary production overhaul would be supported financially by the Member States as appropriate and it would allow the companies to increase their turnover due to more crisis-relevant products being produced meeting the spike in demand. The number of companies falling under the obligation to ramp up production is expected to be very limited and will strongly depend on the type of crisis – these are the companies operating in the value chains of a limited number of goods or products relevant for a certain type of crisis activated by strict criteria.

Respondents to the public consultation indicated a limited support for ramping up or repurposing production on mandatory basis with government support (5 out 17 respondents). Business stakeholders did not support mandatory ramping up of production (BusinessEurope, ERT).

Impact on SMEs

Under this Policy Option, SMEs could be additionally affected by some of obligatory measures in block 8. In particular certain SMEs in key sectors for the crisis response could be affected by the mandatory information requests and by the obligation to ramp up their production capacity. For SMEs it could be easier to constitute data on production capacity and supply disruption in the case of an SME due to its size but at the same time SMEs have less resources and more limited capabilities to deal with such information requests. The obligation to ramp up production capacity with appropriate financial support from Member States could be net beneficial for SMEs in question. In their position paper, SMEUnited supported the possibility of financial support to encourage the development of production capacities for goods needed in the event of a crisis.

Impact on competitiveness

Under Policy Option 2, obligatory measures in block 8 could have an effect on competitiveness. Specifically, mandatory information requests could create additional costs for the concerned companies, thus hurting their profitability. The obligation to ramp up production of crisis-relevant products could on the other hand increase the competitiveness of the concerned companies, as it would allow them to meet a spike in demand more rapidly and with appropriate financial support from Member States. Overall, since these measures are expected to only concern a limited number of companies in very specific emergency situations, the additional effect on international competitiveness is expected to be small compared to Policy Option 1.

Impact on competition

Under Policy Option 2, obligatory measures in block 8 could have an effect on competition. Mandatory information requests by Member States could lead to costs, thus somewhat hurting the competitive position of the companies concerned. On the other hand, there would be safeguards for confidentiality and intellectual property protection, therefore the competition would not be affected

by a risk of disclosure of sensitive information. The obligation to ramp up production of crisis-relevant products could distort the competitive position of companies depending on the level of state financial support, as it could lead to them addressing a larger share of demand and higher profitability, but also to forego other profitable markets. Nevertheless, without this measure, the demand would not have been met at all in time and therefore this measure rectifies an inefficiency in the market. In any case, if these measures are short-lived and accelerate the return to the normal functioning of markets, their negative impact on competition should be limited. Overall, since these measures are expected to concern only a limited number of companies in very specific situations, the additional effect on competition is expected to be small compared to Policy Option 1.

Impact on international trade

Under Policy Option 2, reinforced contingency planning measures could lead to overall better crisis reaction in the Single Market, thus improving its performance and facilitating trade including international trade (block 2). Obligatory measures in block 8 could have an indirect effect on international trade, if there are costs for certain companies concerned which could make them somewhat less competitive and if some companies are obliged to ramp up production, as this would improve their competitive position and could allow EU companies to meet high demand for crisis-relevant products for which otherwise may be no other supplier than international suppliers at high cost. However improved production capacity could also lead to increase of exports in the medium term, as it has for example happened with vaccine production. Therefore the overall impact on international trade will depend on the specific circumstances of the crisis.

Impact on Member States (public authorities)

In terms of measures with immediate effect, for regular Union-level risk assessment and related contingency measures, the benefits are harvested during times of crisis, by having lower negative effects of the particular type of crisis thanks to these preparatory measures. In particular, due to regular trainings and drills as well as the existence of crisis protocols, Member States' administrations would be significantly better prepared to face any future crisis.

In terms of costs with immediate effect, the risk assessment would be conducted by the Commission and would not imply additional costs for the Member States. The functioning of the Early Warning System would be part of the functioning of the Advisory Group and would also not imply additional costs compared to the normal coordination activities within the Member States. The development of crisis protocols would be led by the Commission and would also be part of the functioning of the Advisory Group. Participation in the trainings and drills organised by the Commission would imply costs for Member States in terms of time of experts that would be participating in these trainings and drills. Member States would also have to organise trainings for their own experts which would result in additional costs, depending on the extent of such trainings (block 2).

In the emergency mode, obligatory measures in block 8 (activated only during emergency) could lead to certain administrative costs to the extent that the coordination of such measures would require increased efforts. In the impact assessment on the Single Market Information Tool (SMIT) proposal (option 4), it was estimated that the overall one-off costs for Member States could be up to 0.72 million EUR to operate such information requests. However the measures considered under SMEI would be very limited in duration and in the number of companies concerned and would strongly depend on the type of emergency. Member States might have also additional costs related to financial support of companies ramping up production. This will be decided by individual Member States depending on the emergency and the type and complexity of production, following a case by case assessment.

Impact on the Commission (budgetary implications)

In terms of measures with immediate effect, costs related to regular risk assessment could be regarded as business as usual as similar assessments are done by the relevant services of the Commission. The functioning of the Early Warning System would be part of the functioning of the Advisory Group and would also not imply additional costs compared to the normal coordination activities of the Commission. The development of crisis protocols would be led by the Commission and would also be part of the functioning of the Advisory Group, however this would also enter into normal activities of the Commission. Organisation of trainings and drills by the Commission would imply costs for the organisation of meetings and reimbursement of travel expenses, if such meetings were taking place physically, as well as potentially costs for subcontractors who would organise such trainings and drills. The precise costs would depend on the duration and regularity of training and drills (block 2).

In case of emergency, measures in block 8 would require the Commission to develop a number of recommendations to Member States as well as harmonised rules for mandatory information requests to be done by Member States. The development of such recommendations and legal provisions can be considered as part of normal activities of the Commission.

Social Impacts

Compared to Policy Option 1, particularly the binding measures in block 8 would provide additional social benefits. The capability for Member States to request information from economic operators and to oblige the economic operators to ramp up production for crisis-relevant products could plug a serious gap in meeting the demand for such products in a dire situation of a crisis and thus result in a significantly better overall EU crisis response, leading to a direct social impact in terms of improving living conditions and quality of life.

Environmental impacts

Policy Option 2 is expected to have similar environmental impacts as Policy Option 1.

1. POLICY OPTION 3

The differences of Policy Option 3 compared to Policy Option 2 are in blocks 3 and 8.

In block 3, Single Market vigilance, Member States are obliged to gather information concerning identified strategic supply chains and share that information with the Commission.

In Single Market vigilance mode, the Commission can draw up and regularly update by means of implementing acts a list with targets for strategic reserves to be constituted by Member States for the selected supply chains of goods and services of strategic importance. The Commission will issue recommendations requesting Member States to build up, maintain or reduce their strategic reserves in order to meet the targets and coordinate such efforts. Subject to an additional trigger (when there is evidence that industry's stockpiling is insufficient or inexistent, alternative supply sources do not work or are insufficient and an impact assessment by the Commission and the governance body indicates a need to build up strategic reserves), the Commission can oblige Member States to build up strategic reserves for selected goods of strategic importance if the Member States' strategic reserves fall significantly short of the targets.

In block 8, during emergency mode, the following measures would all be subject to an individual activation by means of implementing acts. The Commission could oblige the Member States to

distribute the products previously stockpiled by Member States following the issuance of targets in order to address dire shortages of such products. The Commission could directly oblige the economic operators to ramp up their production capacity of crisis-relevant goods by means of repurposing their production lines or creating new production lines. The Commission could oblige the Member States to speed up permitting procedures during the crisis. The Commission could oblige economic operators to accept and prioritise orders of crisis-relevant products. Finally, the Commission could issue binding requests of information to economic operators as to their production capacities, current supply chain disruptions and related data. This is different from Policy Option 2 where the only binding measures were requests for information and obligation to ramp up production capacity and these were done by Member States.

The assessment below focuses on these new elements in comparison with Policy Option 2.

Economic Impacts

Impact on companies

The toolbox of measures under Policy Option 3 is expected to bring even larger further **economic benefits** for companies, in particular during an emergency, due to the availability of strong measures that would allow to further improve EU-level crisis response leading to significantly better availability of crisis-relevant products and less obstacles to free movement.

In terms of measures with immediate effect, there are no differences compared to Policy Option 2.

During the vigilance mode, companies could be indirectly concerned by the Member States information gathering on identified supply chains of goods and services of strategic importance. It is likely that Member States may contact companies in order to obtain certain information about supply chains that only companies might have. However such exchanges would be of voluntary nature and would pertain to the normal activity of companies, therefore it can be considered that there are no costs for companies in addition to business as usual.

For what concerns the constitution of strategic reserves, while it would be the obligation of Member States, it could nevertheless affect companies. The reserves would concern goods from the selected supply chains of strategic importance and in those supply chains, the constitution of reserves may contribute to the increase of the overall demand for such goods and may consequently affect the price of such goods. This would impact companies that produce such goods, increasing their turnover and profitability, and companies that need such goods for their operations, increasing their costs. In the public consultation, 8 out of 20 respondents considered that a strategic storage or stockpiling system coordinated at EU level would be an efficient solution to crises. Some stakeholders were in favour of strategic stockpiling (SMEUnited, VDMA) whereas others were not or called for it to be done at the national level (Eurocommerce, Eurochambres, Dansk Industri).

During the emergency mode, the possibility to implement measures in block 8 would be subject to the activation of the emergency mode. Furthermore, there would be additional activation by a Commission implementing act for individual measures of obligatory nature.

For the obligation for Member States to distribute the previously stockpiled goods in the case of dire shortages, companies that need such goods for their operations and would receive them, as applicable, would be extremely positively affected as this would allow them to continue their operations. This would have a beneficial effect throughout the supply chain, as also their suppliers and customers would be able to continue operations. The distribution of the previously stockpiled

goods would be done following the discussions in the Advisory Group involving industry as needed. In the public consultation, targeted and coordinated distribution of products relevant for a certain type of crisis was considered efficient by 6 out of 17 respondents.

For the obligation for the economic operators to ramp up their production capacity of crisis-relevant goods by means of repurposing their production lines or creating new production lines, which under Policy Option 3 would be done by the Commission, this would be done on the basis of financial support by the Commission (which in such a case would be provided under a separate financial instrument). Consequently, the impacts of this measure on companies would be similar to the impact of a similar measure done by Member States, as discussed under Policy Option 2. In the public consultation, obligation on undertakings to accept and prioritise orders of goods and services relevant to a crisis in order to enhance their availability during a crisis was considered efficient by 3 out of 16 respondents.

The Commission could oblige the Member States to speed up permitting procedures during the crisis. This could have very positive impacts on the companies that are in the process of obtaining such permits as it would allow them to start their economic activity much faster, leading to higher turnover and profitability.

The Commission could oblige economic operators to accept and prioritise orders of crisis-relevant products. Subject to all the relevant activations, the Commission will then take a decision to place such priority rated order which will take into account the principles of necessity and proportionality, the legitimate interests of the economic operator concerned and the cost and effort required for any change in production sequence. The priority rated order will be placed at fair and reasonable price. Such priority rated orders will have a strong impact on the companies concerned, as they will need to set aside their normal production orders and fulfil the orders placed by the Commission. Considering such orders would be placed at fair and reasonable price, it is expected that such orders may increase the turnover of these companies and may thereby contribute to higher profits, however the specific effect will depend on the circumstances of a particular company. Placing of such orders will negatively affect the normal customers of such companies as their orders would be delayed or even cancelled, depending on the situation. However by legislation they would be freed from liability for the resulting delay or non-fulfilment of their contractual obligation vis-à-vis third parties. Such orders could also affect the competitors of these companies, as the spillover demand may lead to higher turnover and profits for them. As explained under Policy Option 2, respondents to the public consultation and business stakeholders were not in favour of mandatory ramping up or repurposing of production.

Binding requests of information by the Commission to economic operators as to their production capacities, current supply chain disruptions and related data could lead to costs for companies. However costs would be similar to the costs of binding requests if they were done by the Member States, as under Policy Option 2.

Impact on SMEs

For measures different under this Policy Option, SMEs would experience similar impacts as all companies. However the effects (positive and negative) could be even more important for SMEs. In particular, priority-rated orders could impact the whole production capacity of SMEs, whereas for larger companies they may represent only a fraction of their production as they may have diversified production portfolio. Speeding up permitting could be decisive for economic success of an SME in a crisis situation. Distribution of strategic reserves could also be of a very high benefit to the SMEs that would be concerned and their customers and suppliers. Like under Policy Option 2, for mandatory information requests, it could be easier to collect the data on production capacity for

an SME due to its smaller size, however SMEs may have less resources and more limited capabilities to deal with such requests. The obligation to ramp up production capacity with appropriate financial support from Member States could be net beneficial for SMEs in question.

In its position paper, SMEUnited expressed support for measures such as preventative measures such as a monitoring system to anticipate future shortages and a possibility to oblige companies to prioritise orders in times of crisis, as well as strategic reserves to improve the availability of crisis-relevant goods.

Impact on competitiveness

Under Policy Option 3, the measures different under this Option as compared to Policy Option 2 could have an effect on competitiveness. The obligations to ramp up production of crisis-relevant products and to accept priority-rated orders could increase the competitiveness of the concerned companies, as it would allow them to potentially increase their turnover and profitability. While the strategic reserves would be constituted and distributed by the Member States, this measure could impact competitiveness by providing the much-needed inputs to companies that need them during an emergency, which would allow them to continue their operations and may ultimately prevent their bankruptcy, with a similar cascading effect along the supply chain. Speeding up permitting could also be beneficial for competitiveness, allowing the concerned companies to start their activities faster. Mandatory information requests could create additional costs for the concerned companies, thus hurting their profitability. Overall, while these measures are expected to only concern a limited number of companies in very specific emergency situations, this could nevertheless result in a significant positive effect on competitiveness compared to Policy Option 2 due to the likely effectiveness of such measures in ensuring the availability of crisis-relevant products.

Impact on competition

Under Policy Option 3, the measures different under this Option as compared to Policy Option 2 could have an effect on competition.

While the strategic reserves would be constituted and distributed by the Member States, this measure could impact competition due to the fact that there would be an intervention in the market both during the vigilance mode (constitution) and during the emergency mode (distribution). Depending on the product, the effect on the market could be substantial. The constitution of strategic reserves will happen under the appropriate public procurement rules, thus ensuring fair competition. The distribution of strategic reserves, when applicable, will be done taking into account the situation of the market and the legitimate interests of market participants, thus also ensuring fair competition.

The obligation to ramp up production of crisis-relevant products could distort the competitive position of the concerned companies, as depending on the level of state financial support it could lead to them addressing a larger share of demand and to higher profitability but also to forego other profitable markets. However this does not mean taking market share at the expense of other companies as the rationale of this measure is to create production capacity to meet the spike in demand which would not otherwise have been met. On the other hand, the obligation to repurpose production lines could be beneficial for companies in the short term, but could be costly for companies in the longer term if such repurposed production lines would not be useful after the crisis and would have to be repurposed again.

The obligation to accept priority-rated orders may also impact competition as the concerned companies would not be able to fulfil their other contracts on time or at all, thus potentially driving

their customers to other companies. Nevertheless it could also result in higher turnover and higher profitability.

Mandatory information requests could create additional costs for the concerned companies, thus somewhat hurting the competitive situation of the companies concerned. On the other hand, there would be safeguards for confidentiality and intellectual property protection, therefore the competition would not be affected by a risk of disclosure of sensitive information.

Overall, while these measures are expected to concern a limited number of companies in very specific emergency situations, under this Policy Option there could be an important effect on competition, depending on the measure chosen, in particular due to the effect on the competitive position of the specific companies concerned by mandatory measures.

Impact on international trade

Under Policy Option 3, the new measures as compared to Policy Option 2 would affect international trade.

The constitution (block 3) and distribution (block 8) of strategic reserves by Member States could affect international trade. Depending on the volume of the new reserves, their constitution could affect both international trade flows and prices in the world market. However it is expected that the measure would have an overall balancing effect, as the reserves would be constituted in anticipation of potential shortages, i.e. when the prices are relatively lower, and would be released during shortages, i.e. when the prices are higher due to the spike in demand. This would have the effect of advancing potential inflows of the crisis-relevant products to an earlier stage, when there are no shortages.

The obligation to ramp up production of crisis-relevant products and/or repurpose production lines could increase the output of the crisis-relevant products in the EU, thus decreasing the potential strain on international demand for such products. This could have the effect of rebalancing international trade flows. The obligation to accept priority-rated orders may have a similar effect, as would speeding up permitting. Improved production capacity could also lead to increase of exports in the medium term, again taking the example of the vaccine production.

Mandatory information requests could create additional costs for the concerned companies, thus somewhat hurting their competitive situation and their performance internationally.

The overall impact on international trade under Policy Option 3 will depend on the specific circumstances of the crisis, but it is expected that there would be rebalancing of the trade flows depending on the extent that EU's production capacity for crisis-relevant products would be improved.

Impact on Member States (public authorities)

In the vigilance mode, Member States would be obliged to gather information concerning identified strategic supply chains, to monitor such supply chains for a list of indicators as set out in the Union risk assessment and share that information with the Commission. Depending on the specifics of the identified value chains and the information that is already available to the Member States, this could impose quite significant administrative costs for them. While it is expected that most of the information would still come from the companies on the voluntary basis, Member States would need to spend significant efforts to collect this information and to analyse it. They would also be obliged to compile lists of contacts of the economic operators functioning along the identified supply chains. The benefits of this process would be harvested during a crisis, as it would

significantly improve the EU's ability to react to supply shortages due to the full overview that would be available based on the monitoring and would allow to take targeted measures foreseen in the rest of the toolbox.

Furthermore, in the vigilance mode, the Commission can draw up and regularly update by means of implementing acts a list with targets for strategic reserves to be constituted by Member States for the selected supply chains of goods and services of strategic importance, and can enforce the compliance with these targets through additional steps. Depending on the specific products selected for the application of this measure and the required target volumes included in the lists with targets, this measure could have very significant implications for Member States, both financially (as Member States would need to procure the products that would form part of the strategic reserves, organise storage facilities and provide for possible disposal if such products become unusable in the course of time) and administratively (as the management of these processes would require significant human resources). Member States would be obliged to inform the Commission about their individual public procurement actions to constitute such strategic reserves. The checks and balances are built into the system as the Member States would have to agree to both the targets and the binding measures to build up the reserves as both would require adoption by implementing acts.

In block 8, **during emergency mode**, the Commission could oblige the Member States to distribute the products previously stockpiled by Member States following the issuance of targets in order to address dire shortages of such products. The additional costs to Member States would only be linked to the costs of distribution.

The Commission could oblige the Member States to speed up permitting procedures during the crisis. This could have important administrative implications for the Member States, as it would imply compliance and administrative costs in order to implement such a change in their procedures.

The Commission's rights to oblige the economic operators to ramp up their production capacity of crisis-relevant goods, to oblige economic operators to accept and prioritise orders of crisis-relevant products and to issue binding requests of information to economic operators as to their production capacities, current supply chain disruptions and related data is not expected to have significant cost implications for Member States' authorities.

Member States questioned the inclusion of mandatory information requests and drew attention to the need to respect the principles of necessity and proportionality (letter of nine Member States) and due consideration of possible administrative burdens on businesses, also stressing that information requests should not be mandatory (DE, PL, BG). However due to the fact that Member States are involved in activating both vigilance and emergency mode (via Council and Commission implementing acts, respectively) as well as in additionally activating each of the obligatory measures in block 8 (via Commission implementing acts), these measures would comply with principles of subsidiarity and proportionality, as the necessary checks and balances would be built into the procedure.

Impact on the Commission (budgetary implications)

In the vigilance mode, the new obligation for Member States to gather information and monitor the supply chains would also mean that the Commission would be getting this information which would feed into its own analysis and monitoring activities. However this does not lead to new obligations for the Commission. The Commission would also step up the monitoring of free movement obstacles, however this can be considered part of its normal activities.

Furthermore, in the vigilance mode, the Commission can draw up lists of targets for the constitution of strategic reserves. This does not imply additional costs for the Commission as this action can be considered part of its normal activities.

During emergency mode, the Commission could oblige the Member States to distribute the products previously stockpiled, it could oblige economic operators to ramp up production, it could oblige the Member States to speed up permitting procedures during the crisis, it could issue priority rated orders, it could send binding information requests to economic operators. All of these actions would require detailed analysis and monitoring for the Commission departments concerned and a significant amount of administrative resources would be needed to develop the relevant legislation and to agree it with the Member States. However these activities, while extraordinary due to a crisis, can be considered part of normal functioning of the Commission.

Social Impacts

Compared to Policy Option 2, the measures introduced by Policy Option 3 would provide very significant additional social benefits. The mechanism to constitute and then distribute strategic reserves, the right for the Commission to oblige economic operators to ramp up production of crisis-relevant products, to issue priority-rated orders, to speed up permitting, and to issue mandatory information requests would all serve as exceptional measures that could however be decisive in ensuring the availability of crisis-relevant products in case of a dire need in a crisis. This could result in a significantly better overall EU crisis response, leading to an even stronger direct social impact in terms of improving living conditions and quality of life and even saving lives of citizens, depending on the crisis.

Environmental impacts

Policy Option 3 is expected in general to have similar environmental impacts as Policy Option 2. However the obligation for Member States to speed up permitting procedures may lead to expedition of some such procedures, which potentially could have environmental impacts due to less scrutiny.

7. HOW DO THE OPTIONS COMPARE?

For what concerns the **effectiveness** in meeting the objective on minimising obstacles to free movement (SO1), the objective is likely to be effectively met by all three Policy Options due to the presence of the same building blocks on the free movement and on transparency in all three POs with similar effects. For addressing shortages and safeguarding availability of crisis-relevant goods and services (SO2), PO1 is least likely to meet this objective, as the toolbox available to the policymaker would be limited to guidance for the measures applicable to supply chains and the effects would strongly depend on the voluntary uptake by authorities and/or economic operators. PO2 would be somewhat more effective in this regard, as there would be some empowerments for Member States to take strong measures in relation to information requests or ramping up production. The EU level risk assessment done by the Commission would play an important role too. PO3 would be most likely to meet this objective due to the strongest possible toolbox available to ensure availability of crisis-relevant goods and services, as in this PO the Commission would have the possibility to oblige Member States to take measures on constitution and distribution of strategic reserves, to speed up permitting, and to oblige economic operators to ramp up production, to accept priority-rated orders and to respond to binding information requests, all subject to appropriate checks and balances, thus giving the Commission the full spectrum of tools to address shortages and safeguard the availability of crisis-relevant goods and services.

For what concerns the **efficiency** in terms of meeting the objectives, PO1 is the most efficient options as it foresees the least costs compared with the other two POs, and in particular no costs for companies except for voluntary measures they may undertake, and very limited costs to Member States and the Commission, consisting in the immediate term of the costs of the Advisory Group, and in the emergency mode of costs of a limited number of tools that would only be used if applicable to the crisis. Yet PO1 provides a substantial improvement on the baseline in terms of addressing especially SO1 and to an extent SO2. PO2 is less efficient as it contains in particular measures that could be costly for Member States (financial support for companies in case of ramping up of production) and for companies (mandatory information requests), although such an expansion of the toolbox would lead to a more effective coverage of SO2. Finally, PO3 is less efficient due to the fact that it may lead to substantial costs, in particular the costs of constitution and distribution of strategic reserves by Member States, as well as costs linked to obligatory measures such as speeding up permitting, ramping up production, priority-rated orders and mandatory information requests to companies. However such a full toolbox is likely to provide the strongest tools to tackle in particular SO2.

For what concerns **subsidiarity/proportionality** of policy options, PO1 is assessed as PO reflecting these principles to the fullest due to the fact that there are no obligatory measures for companies and the Member States retain substantive freedom to introduce crisis measures according to their preferences, only needing to comply with proportionate provisions such as key principles of free movement and transparency and administrative assistance measures. PO2 is assessed to also comply with these principles, with some measures such as Member States’ empowerment to issue information requests and oblige companies to ramp up production considered stronger in terms of degree of intervention. PO3 contains far-reaching measures at the level of the Commission in blocks 3 and 8. Stakeholders and Member States have expressed doubts about whether these measures comply with the principles of proportionality and subsidiarity. However due to the fact that Member States are involved in activating both vigilance and emergency mode as well as in additionally activating each of the obligatory measures in these blocks, it is assessed that PO3 is still compliant with principles of subsidiarity and proportionality.

Comparison of options’ effectiveness in meeting objectives, efficiency, subsidiarity/proportionality

	Effectiveness in meeting objectives		Efficiency	Subsidiarity/ proportionality
	SO1 / Minimise obstacles to free movement of goods, services and persons in times of crisis	SO2 / Address shortages and safeguard availability of crisis-relevant goods and services		
<i>Option 1</i>	+++	+	+++	+++
<i>Option 2</i>	+++	++	++	++
<i>Option 3</i>	+++	+++	+	+

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact; - minor negative impact; -- negative impact; --- significant negative impact

For **companies**, all three POs would result in positive impacts, as they would contribute to uphold free movement and availability of crisis-relevant products. For companies, the largest support was expressed for measures included in PO1, including measures to minimise obstacles to free movement and to ensure transparency, as well as for measures of voluntary nature, whereas far-reaching measures were generally less supported by business stakeholders. Under PO1, no mandatory costs are foreseen for companies. Companies could face more costs under PO2 as they

could be obliged by Member States to respond to information request and to ramp up production. **Member States** have been very supportive of measures under PO1, in particular measures to ensure free movement as well as measures on conformity assessment and public procurement. Member States are also more supportive of measures based on guidance and recommendations which leave to them the decisions on whether to follow these recommendations. Member States would face larger costs under PO2 as they would be empowered to issue information requests to companies and oblige them to ramp up production, while providing financial support. For PO3, Member States have expressed ambiguous positions, with some support for far-reaching measures to address shortages and with some opposition. Under PO3, Member States would face substantially higher costs, in particular due to the measures linked to strategic reserves. In terms of the impact on the **civil society**, it is assessed that PO3 would have the largest positive impact, as it would allow to ensure the best possible availability of crisis-relevant products, leading to the strongest impact on citizens, whereas PO2 would have somewhat lesser positive impact and PO1 would have still less positive impact.

Comparison of options - impacts on key stakeholders groups and their support

	Companies	Member States	Civil society
<i>Option 1</i>	+++	++	+
<i>Option 2</i>	++	+	++
<i>Option 3</i>	+	+/-	+++

Legend: +- no / neutral impact; + minor positive impact; ++ positive impact; +++ significant positive impact; - minor negative impact; -- negative impact; --- significant negative impact

8. PREFERRED OPTION

This Impact Assessment does not present a preferred option. Instead, the preferred option is left for political decision based on the comparison of policy options included in section 7 of this report. On the basis of this comparison, all three POs appear to be effective in meeting specific objective 1 to minimise obstacles to free movement of goods, services and persons in times of crisis, however PO3 scores as the most effective in meeting specific objective 2 to address shortages and safeguard availability of crisis-relevant goods and services, with PO2 scoring in between. PO1 is also assessed as the most efficient and scoring highest on subsidiarity/proportionality, with PO2 scoring less and PO3 scoring lowest, though still with positive impact. Stakeholders and Member States have expressed doubts about whether measures in PO3 comply with the principles of proportionality and subsidiarity. In terms of stakeholder impacts and support, PO1 would have the strongest support among companies and Member States, with PO2 somewhat less positive support and PO3 supported only to some extent. In terms of feasibility, PO3 is about solidarity and the binding measures only kick in when it is clear that industry needs support. While some Member States have expressed reservations on these measures, the aim of the PO3 is to help Member States in crisis management by ensuring harmonised rules instead of uncoordinated national measures leading to fragmentation. PO3 would have the strongest positive impact on the society as it would provide the strongest toolbox, with PO2 and PO1 having lesser positive impact.

8.1. REFIT (simplification and improved efficiency)

The Strawberry Regulation will be repealed together with the adoption of the Single Market Emergency Instrument. This will lead to the simplification of the legal framework due to the fact

that this mechanism is rarely used and its information exchange system is insufficient as it's too slow and outdated (see more information in section 8.2).

8.2 Application of the 'one in, one out' approach

The Single Market Emergency Instrument provides a toolbox of measures to address Single Market emergency, consisting a set of measures applicable at all times as well as certain measures only applicable in vigilance or emergency modes, to be separately activated. There are **no administrative costs for businesses and citizens** that would apply with immediate effect and during the normal functioning of the Single Market.

The measures foreseen in the emergency and vigilance modes would be used in very exceptional circumstances. Their initiation would be subject to conditions and a triggering procedure upon the advice of the governance body (see details in section 5). As assessed in section 6, there could be some administrative costs for companies mostly related to information requests (voluntary under Policy Option 1 and mandatory under Policy Options 2 and 3). As these measures could be triggered only in case of future unknown type of crisis, it is impossible to quantify the number of companies impacted. Therefore the Impact Assessment specifies the type of potential impacts and magnitude of potential administrative costs per information request for companies based on previous impact assessment concerning similar provisions (see section 6 for details). Companies could also be directly affected by measures such as obligatory ramping up of production and priority-rated orders, however the effect could be net benefit.

The Regulation (EC) No. 2679/98 setting up an response mechanism to address obstacles to the free movement of goods attributable to a Member State leading to serious disruptions and requiring immediate action ('The Strawberry Regulation') will be repealed. According to its evaluation finalised in October 2019 and supported by an external study, this mechanism is rarely used and its information exchange system is insufficient as it's too slow and outdated. There are no costs borne by **businesses** or **citizens** due to the implementation of this Regulation because of the fact that the Regulation is about the exchange of information and reporting among national authorities and between them and the Commission. For what concerns the **national authorities**, the costs are low given that there are few cases of obstacles reported per year and the exchange of information takes place by email, however it could still lead to some limited administrative costs savings for public administrations⁹³.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The Commission will carry out an evaluation of the effectiveness, efficiency, coherence, proportionality and subsidiarity of this legislative initiative and present a report on the main findings to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions five years after the date of application of the legislative acts. The Commission may propose in that evaluation report how to improve the Single Market Emergency Instrument. This review mechanism is similar to the review mechanisms included with the Commission proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level⁹⁴ as well as with the Commission proposal for a Regulation of the European Parliament and of

⁹³ As assessed in the evaluation supporting study and the evaluation Commission Staff Working Document SWD(2019)371 final of 8 October 2019.

⁹⁴ COM(2021)577 final.

the Council establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)⁹⁵.

Member States and representative organisations of economic operators will be obliged to provide the Commission with the information necessary for the preparation of that report.

The Commission and Member States will regularly monitor the application of the legal acts, in particular the effectiveness of the measures facilitating the free movement of goods, persons and services during the crisis on the persons and businesses concerned as well as the functioning of the Single Market, and the impacts of the information requests and monitoring, building and distribution of the strategic reserves and other measures increasing the availability of products and services on the Single Market to economic operators and their representatives.

⁹⁵ COM(2022)46 final.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The Single Market Emergency Instrument initiative is part of the 2022 CWP under the Commission’s priority ‘A Europe fit for the digital age’.

The lead DG for this initiative is the DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW). The Directorate in charge is Directorate A – Strategy and Economic Analysis. The initiative is encoded in Decide Planning with the reference PLAN/2021/11161.

2. ORGANISATION AND TIMING

The Secretariat-General set up the Inter-service Steering Group to assist in preparing the initiative in Q2 2021. There have been three ISSG meetings. The last ISSG consultation took place on 10 June 2022.

The Call for Evidence for this initiative was published on 13 April 2022 and was open to feedback from all stakeholders for a period of four weeks, until 11 May 2022.

The timing for adoption of the new act by the Commission is Q3 2022.

3. CONSULTATION OF THE RSB

This Impact Assessment was sent to the RSB on 15 June 2022. A meeting with the RSB took place on 6 July 2022. The RSB issued a negative opinion on 8 July 2022, following which this Impact Assessment was revised as follows:

RSB Recommendations	Revisions introduced
(B) Summary of findings	
(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.	<p>The definition of a Single Market emergency was added in section 5.2</p> <p>The proposed definition of the Single Market emergency is: <i>‘Single Market emergency’ means a wide-ranging impact of a natural or man-made crisis on the Single Market in at least two Member States that severely disrupts or threatens to severely disrupt the functioning of the Single Market or puts its supply chains that are indispensable for the normal functioning of society and have a limited substitution and diversification potential at risk.</i></p> <p>Section 5.2 “setup of the initiative” specifies the criteria, and decision mechanisms for establishing and terminating an emergency.</p> <p>Section 5.2 further explains the “traffic light” approach of the initiative with three modes: 1. normal times “green mode” 2. Vigilance mode “yellow light” 3. Emergency mode “green light”. Table 2 in section 5.3 specifies which building block of the SMEI could be activated under</p>

	<p>which mode.</p> <p>In section 5.2 “setup of the initiative”, decisional and analytical requirements and steps for activating different modes and additional triggers for some of the building blocks or measures have been clarified.</p>
<p>(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.</p>	<p>Assessment in section 6 specifies which impacts will occur with the immediate effect (normal times) and which impacts could be expected under the vigilance and emergency modes.</p> <p>The assessment provides estimates of immediate impacts.</p> <p>The assessment was elaborated to cover more type of impacts i.e. economic impacts for key stakeholders (businesses, MS and Commission), impacts on SMEs, impacts on competitiveness, competition, international trade. The assessment covers all three types of impacts economic, social and environmental. The stakeholder feedback is transparently reflected in the assessment in section 6.</p> <p>Detailed assessment of alternative approaches to eight building blocks was added in Annex 6.</p>
<p>(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.</p>	<p>The IA defined three alternative policy options which reflect different levels of political ambition and different levels of support of stakeholders. These alternative policy options are also feasible policy choices open to policy makers.</p> <p>They are based on combination of different approaches to some of the building blocks. For some of the building blocks, the choice of the preferred policy approach is straightforward taking into account the feedback from stakeholders, proportionality and subsidiarity of measures. For others, in particular far-reaching measures, the views of stakeholders including Member States and businesses differ, hence the different approaches for these blocks have been included in the different policy options based on detailed assessment of annex 6. The description of alternative policy options is provided in section 5.</p> <p>The comparison of options in section 7 was extended to cover proportionality and subsidiarity.</p>
<p>(C) What to improve</p>	
<p>(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.</p>	<p>Section 2 clarifies that the objective of SMEI is not to provide solutions to overcome a future crisis as a whole, but rather to enable a swift and flexible response to Single Market impacts of a crisis. The purpose is to provide immediate solutions to ensure that the Single Market works as it should during crises. While the root causes of shortages of crisis-relevant products and services may be unrelated to the Single Market, shortages of such products and services can be severely amplified during a crisis by a non-functional Single Market, in particular due to: 1) Member States competing against each other in securing the availability of such products in separate and uncoordinated public procurement procedures; 2) Member States imposing uncoordinated and contradictory national measures such as export restrictions; 3) the lack of crisis provisions in the relevant Single Market</p>

<p>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.</p> <p>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).</p> <p>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</p>	<p>legislation that would allow to place products on the market with the appropriate urgency.</p> <p>Section 2 further explains that while the root causes of shortages of crisis-relevant products and services may be unrelated to the Single Market, shortages of such products and services can be severely amplified during a crisis by a non-functional Single Market. The aim of the instrument is not to resolve structural issues that require more long-term solutions reinforcing the EU open strategic autonomy in fields such as raw materials, semiconductors and energy. Yet the impacts of such shortages during an emergency might have severe disruptive effects on the availability of crisis-relevant products and might require quick corrective actions to support the functioning of the Single Market. There is a lack of EU-level measures to identify, anticipate and monitor such supply chain disruptions that can have an impact on the availability of crisis-relevant products during an emergency. There are also no effective measures to tackle such shortages during an emergency. This can lead to or amplify further the shortages of crisis-relevant products during an emergency, thus hampering the EU-level crisis response.</p> <p>Section 5 also lays out the triggering conditions of each mode, demonstrating that a severe crisis is always a precondition for using the stronger measures in the SMEI toolbox, with a number of checks and balances built in to ensure that they are not used outside of such crises.</p> <p>Section 3.1 includes the clarification on the use of Article 114. The enhancing of production capacities, the speeding up of permitting, priority rated orders as well as the accumulation and distribution of strategic reserves also aim to ensure a coherent response to future crises and to avoid the fragmentation of the Single Market and hence justifies the use of Article 114 as the legal basis.</p> <p>Section 3.1 includes an explanation that MS will continue to invoke Article 4(2) and how the SMEI will articulate with this.</p>
<p>(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.</p> <p>Moreover, the report should explain how Single</p>	<p>A new section "The setup of the initiative" was added in the IA (section 5.2). This section explains the overall approach to the instrument and specifies criteria for activating "vigilance" and "emergency" modes. It also clarifies the process for activating the different modes. The SMEI governance body will propose the activation and the scope of the Single Market vigilance and emergency modes and analyse the relevant information gathered by voluntary or mandatory means including from the economic operators by the Member States or the Commission depending on the chosen policy option. The triggering of the Single Market emergency will be done by means of Council implementing act and would be justified by the magnitude of the crisis / importance of the decision (2 days following the Commission proposal to activate). The emergency stage will be activated for six months with the possibility to be renewed for another six</p>

<p>Market ‘emergency’ status would interact with the emergency status decided at the Member State level.</p>	<p>months or terminated before.</p> <p>Section 3.3 and in particular paragraph 5 thereof includes an explanation on the interaction between the Single Market emergency status and the emergency status at the level of the Member States.</p>
<p>(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.</p>	<p>As explained under point in the summary of findings, the IA defined three alternative policy options in section 5 which reflect different levels of political ambition and different levels of support of stakeholder to meet the expectations and constraints of stakeholders, Member States and Parliament. The policy options are formed of all building blocks in combinations of different policy approaches e.g. varying from guidance to mandatory obligations. Furthermore, the IA clarifies that the instrument is a toolbox so the inclusion of all building blocks which are necessary to address all problem drivers does not mean that all of the building blocks will be activated in every crisis situation. The choice of the triggers is explained e.g. are based on already adopted Commission proposals and legislation, as well as the timing they apply (green, yellow, red modes) together with the specific measures envisaged for each mode. Decision process of the mechanism is also explained, indicating the role of the Commission, the Advisory Group or the Member States.</p>
<p>(4) The report should better justify the selection of the nine building blocks. It should:</p> <ul style="list-style-type: none"> • 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 	<p>The building blocks are reflecting problem drivers. The structure of section 2.2 and numbering of drivers was changed to show this link more clearly. The problem tree in section 2 and Table 1 showing links between problems/drivers/ gaps/ building blocks in section 5 were adjusted accordingly. The stakeholder’s views were considered in defining three policy approaches for each building block. Finally, the stakeholders views underpinned the assessment of policy approaches in Annex 6 in order to define which approaches should be retained.</p> <p>Table 1 in section 5 was extended to show the links between gaps in the Single Market legislation, drivers, problems and building blocks. The gaps analysis was integrated in the description of relevant problem drivers in section 2. The legal context section (1.2) was redrafted to explain better the context and not legal gaps.</p> <p>The tables in section 5 on the links between gaps in the Single Market legislation, drivers, problems and building blocks (Table 1) and the table explaining policy approaches for different building blocks (Table 2) were extended to include modes when different building blocks are activated (all times, vigilance mode and emergency mode).</p> <p>The description of the relevant driver on supply chain disruptions (see section 2.2) includes further evidence. The measures concerning strategic reserves and supply chains are included in the building blocks 3 and 8. For these blocks, different policy approaches were retained and included in the alternative policy options (see Annex</p>

<p>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,</p> <ul style="list-style-type: none"> • 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. 	<p>6). In particular for block 8, three policy alternatives ranging from guidance (approach 1) to obligations to businesses to accept and prioritise orders; ramp up production capacity and provide crisis-relevant information (approach 3) are retained and assessed in alternative policy options.</p> <p>As mentioned above, three alternative policy options include different approach to building blocks related to stockpiling and supply chains. The assessment of these options (section 6) is underpinned with stakeholder's views. Furthermore the comparison of alternative policy options in section 7 includes a comparison against subsidiarity/ proportionality criterion and also include a comparison table with key impacts and supports of different stakeholder's views. The concerns of stakeholders are transparently in rating of different policy options in these comparison tables.</p>
<p>(5) The analysis of impacts should be strengthened. It should:</p> <ul style="list-style-type: none"> • 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', 	<p>The introduction to section 6 clarifies the limitations of evidence supporting the impact analysis. For impacts with immediate effect, the impacts analysis aim to provide quantification of costs.</p> <p>Given that for certain measures the necessary evidence will become available only in a crisis situation (unknown today), the assessment provides a qualitative assessment of the type of impacts to be expected for different stakeholders groups. It acknowledges that evidence will become only in the (pre) crisis situation, the need for the assessment of impacts before activating certain measures is reflected in the decision mechanisms (as explained in section 5, set-up of the instrument).</p> <p>The assessment of options in section 6 assess the most relevant economic impacts: impacts for key stakeholders (in particular impact on businesses), impacts on international trade, competition and SMEs. The analysis in the SME Test (Annex 7) was extended.</p> <p>The IA provides a qualitative assessment of relevant environmental and social impacts of policy options in section 6.</p> <p>Annex 3 was improved to summarise a comprehensive overview if costs and benefits for different stakeholders. The immediate costs were quantified. The assessment shows that there are no immediate administrative or adjustment costs for businesses and citizens for the purpose of "One-In, One-Out". The assessment in section 6, section 8.2 and annex 3 further specifies that there could administrative costs in the vigilance and emergency mode for companies mostly related to information requests (voluntary under policy option 1 and mandatory under policy options 2 and 3) As these measures could be</p>

<ul style="list-style-type: none"> • 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). 	<p>triggered only in case of future unknown type of crisis, it is impossible to quantify the number of companies impacted. Therefore the IA specifies type of potential impacts and magnitude of potential administrative costs per information request for companies</p> <p>The assessment of impacts in section 6 includes the budgetary implications for the Commission for measures with the immediate effect. The same applies to costs for Member States with the immediate effect. The description of policy measures under building block 8 in section 5 specifies that in case of ramping up/repurposing of production or priority-rated orders, companies would be entitled to financial support for the former or compensation at fair price for the latter. Given that the activation of these measures would depend on the type of crisis and would be subject to additional triggering mechanisms including the assessment of potential impacts (see section 5.2), the budgetary implications of such measures need to be assessed on case by case basis.</p> <p>The assessment of options in section 6 specifies clearly immediate impacts and impacts which will materialise in the vigilance and emergency mode.</p> <p>It was clearly specified that the constitution of strategic reserves would happen in the vigilance mode, i.e. before the potential arrival of the emergency.</p>
<p>(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.</p>	<p>Section 7 comparing have been changed and it fully reflects the impact analysis done in section 6.</p> <p>The justification of scores flows on one hand from the assessment in section 6 and is also provided in the text accompanying the comparison tables.</p> <p>As explained above, three alternative policy options were identified based on the assessment of policy approaches for building blocks in Annex 6. These policy options are alternative combinations which are then assessed in details in section 6 and compared in terms of effectiveness, efficiency, proportionality/ subsidiarity and impacts/ support of key stakeholders to allow policy makers for evidence based policy decisions.</p>

The revised Impact Assessment was sent to the RSB on 29 July 2022. On 17 August 2022, the RSB issued a positive opinion with comments, following which the Impact Assessment was updated as follows:

RSB Recommendations	Revisions introduced
(B) Summary of findings	
(1) The report does not sufficiently identify, explore or distinguish between different types of	Indications on effects of potential future crises added to Section 2, separately for problem 1 (Obstacles to free

<p>crises that may impact the functioning of the Single Market.</p>	<p>movement) and for problem 2 (Shortages of crisis-relevant products and services). Specifically, the effects of potential crises such as natural disasters, technological disasters, geopolitical threats, migration crises, terrorist attacks, financial crises, another pandemic, or of a crisis of a completely unpredictable nature, have been analysed with regards to possible impact in terms of obstacles to free movement and shortages of crisis-relevant products.</p>
<p>(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.</p>	<p>Section 3 modified to account for the interplay with potential measures under Article 4(2) TFEU. Specifically, it has been explained that there is a possibility of overlap between measures taken to maintain law and order and safeguard national security taken in the context of this Article and measures impacting the Single Market in a crisis. It has been explained that a specific provision would be included to clarify that SMEI would be without prejudice to measures taken by Member States in the context of Article 4(2) TFEU which would therefore take precedence. It has also been explained that the presence of an effective coordination mechanism such as SMEI would likely increase mutual trust and lessen the need for measures of last resort in the context of Article 4(2) TFEU.</p>
<p>(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.</p>	<p>Detailed explanation of the content and the functioning of a set of measures envisaged under Policy Option 3 ('Solidarity') has been provided in the Section 5.2. In particular, detailed information on the procedure and steps to be used for the constitution of strategic reserves have been described under vigilance mode. Detailed information on coordinated distribution of strategic reserves and on priority rated orders has been added under emergency mode. Justification on subsidiarity and proportionality provided in Section 6.3.</p>
<p>(C) What to improve</p>	
<p>(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 COVID-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</p>	<p>Indications on effects of potential future crises added to Section 2, separately for problem 1 (Obstacles to free movement) and for problem 2 (Shortages of crisis-relevant products and services). Specifically, the effects of potential crises such as natural disasters, technological disasters, geopolitical threats, migration crises, terrorist attacks, financial crises, another pandemic, or of a crisis of a completely unpredictable nature, have been analysed with regards to possible impact in terms of obstacles to free movement and shortages of crisis-relevant products.</p> <p>A clearer distinction added in the text of Section 2 to highlight that the instrument will focus on emergency and crisis triggered situations that could require a coordinated action at the EU level.</p>

<p>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.</p>	<p>Problem driver 1 modified to account for the lack of Single Market focus in the existing mechanisms.</p>
<p>(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.</p>	<p>Section 3 modified to account for the interplay with potential measures under Article 4(2) TFEU. Specifically, it has been explained that there is a possibility of overlap between measures taken to maintain law and order and safeguard national security taken in the context of this Article and measures impacting the Single Market in a crisis. It has been explained that a specific provision would be included to clarify that SMEI would be without prejudice to measures taken by Member States in the context of Article 4(2) TFEU which would therefore take precedence. It has also been explained that the presence of an effective coordination mechanism such as SMEI would likely increase mutual trust and lessen the need for measures of last resort in the context of Article 4(2) TFEU.</p>
<p>(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</p>	<p>Detailed explanation of the content and the functioning of a set of measures envisaged under Policy Option 3 (‘Solidarity’) has been provided in the Section 5.2. In particular, detailed information on the procedure and steps to be used for the constitution of strategic reserves have been described under vigilance mode. Detailed information on coordinated distribution of strategic reserves and on priority rated orders has been added under emergency mode. Justification on subsidiarity and proportionality provided in Section 6.3.</p> <p>An explanation of the selection of policy approach 3 for building block 5 added in Annex 6.</p> <p>Detailed information on the functioning of strategic reserves added in Section 5.2, for both vigilance and</p>

<p>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).</p>	<p>emergency modes.</p> <p>Reference added in Annex 5 indicating the possible need for a separate financial statement for the Commission’s powers to oblige companies to repurpose or ramp up production under Policy Option 3, likely modelled after Emergency Support Instrument used during the COVID-19 pandemic.</p>
<p>(4) The report should explain how the digital by default principle will be applied in the measures envisaged under the SMEI instrument.</p>	<p>A detailed explanation of the application of digital by default principle has been added in Section 5.3.</p>
<p>(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.</p>	<p>Specification by main stakeholder type added for the respondents to the public consultation in the text of the report.</p>

4. EVIDENCE, SOURCES AND QUALITY

Evidence and data that were used in this Impact Assessment included:

- “The impact of COVID-19 on the Internal Market”, study at the request of the EP IMCO Committee;
- Evaluation of the “Strawberry Regulation” (EC) No 2679/98 and its supporting external study;
- Evaluation of the New Legislative Framework;
- Relevant information and/or evidence collected in the context of preparation of existing or proposed EU crisis response initiatives and mechanisms, including through consultation activities or impact assessment studies (e.g. the Data Act, Single Market Information Tool (SMIT), HERA, Schengen Borders Code, Contingency plan for ensuring food supply and food security, the integrated political crisis response mechanism (IPCR), Contingency plan for transport, EU Digital COVID Certificate Regulation, Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic and its adaptations);
- Academic studies and literature on the effect of previous crises on the functioning of the Single Market, as well as existing position papers and other documents drawn up by relevant stakeholders;
- Newspaper articles and press materials.

The references are cited in the main text of the report as appropriate.

The Impact Assessment further relies on the information received from consultation activities as detailed in the synopsis report contained in Annex 2 of this Impact Assessment.

ANNEX 2: STAKEHOLDER CONSULTATION (SYNOPSIS REPORT)

In the context of the Impact Assessment on the Single Market Emergency Instrument, various consultation activities were conducted between October 2021 and May 2022. The purpose of the consultation was to collect evidence and views from a broad range of stakeholders, giving them an opportunity to provide relevant data and information on the problems and potential solutions concerning crisis-related disruptions of the Single Market. While attempting to reach the widest possible range of stakeholders, the results of the consultation activities are not designed to be representative. This Annex presents the results of the consultation activities carried out.

The consultation activities included:

- a call for evidence published on the “Have your say” portal and open from 13 April to 11 May 2022,
- a public consultation conducted via a questionnaire published on the same portal for the same dates,
- a stakeholder workshop on 6 May 2022,
- a Member State survey in May 2022 and
- Targeted consultations conducted by means of meetings with Member States and specific stakeholders.

Concerning the call for evidence, the public consultation and the stakeholder workshop, all three were open to the public.

1. Overview of the participants

For all stakeholder activities, the main stakeholder groups addressed were:

- National authorities responsible for the Single Market;
- Governmental organisations involved in cross-border interaction (such as regional authorities of cross-border regions, public employment authorities involved in cross-border job placement, etc.)
- Non-Governmental Organisations representing the civil society;
- EU and national consumer associations;
- Associations representing industry, businesses, professionals and crafts;
- Businesses, including online platforms and Small and Medium-sized Enterprises (SMEs);
- Social partners;
- Academic experts on free movement in the Single Market and on international supply chains;
- Individual EU citizens, including mobile citizens and cross-border workers.

For **the call for evidence**, 55 answers were received coming mainly from EU citizens (28 respondents), business associations (14) and company/business organisations (5). Respondents to the call for evidence were mainly located in Belgium (16), Slovakia (11) and Germany (10).

For **the public consultation**, 25 answers were received coming mainly from business associations (14 respondents), public authorities (4), EU citizens (3) and companies/business organisations (3). Respondents were mainly located in Belgium (10) and Germany (4).

For **the stakeholder workshop**, there were 168 registered participants. These participants came from public authorities (106 participants), business associations (49) and academic/research institutions (5). The participants were located in Belgium (40), Portugal (15) and in 27 other countries, including Iceland, Norway and Switzerland.

For **the Member States survey**, the survey was sent to all Member States. As of 1 June 2022, 13 Member States (BE, CZ, DK, EE, ES, IT, LV, LT, NL, AT, PL, PT, SI) submitted responses to the survey and two other Member States (IE, SE) sent additional materials in this context.

The consultation activities were completed by **targeted consultations** of different types of stakeholders and interviews. In particular, the objectives and scope of the initiative have been discussed with the Member State authorities in several of the Council Working Parties and High Level Group meetings in the course of 2021 and 2022, as well as in a number of bilateral meetings. Meetings with a number of consumer and industry associations have taken place in 2021 and 2022.

Stakeholder type	Public consultation and Call for Evidence	Targeted consultation	Final workshop
National authorities	✓	✓	✓
Civil Society	✓		✓
Consumer associations	✓	✓	✓
Industry associations	✓	✓	✓
Economic operators	✓		✓
Social partners	✓		✓
Academic experts	✓		✓
Individual citizens	✓		

2. Summary of results

2.1 Call for evidence

Business associations provided detailed feedback and evidence on the initiative. They mainly agree with the need to ensure free movement as well as greater transparency and coordination in times of crisis. Most experiences described by stakeholders came from the COVID-19 crisis due to its serious impacts on citizens, cross-border workers and on the global economy through lockdown measures including border controls and entry/exit bans which also contributed to supply chains disruptions. In this context, stakeholders also raised issues regarding standardisation and the lack of procedures to ensure that products and services remain conform and safe, even in a crisis situation. Feedback from business associations mainly came from the healthcare and pharmaceuticals sectors

as medicines were subject to heavy export bans and stockpiling requirements in some Member States.

Stakeholders called for the scope of the initiative to be focused and for a legally sound definition of a crisis as well as limited timing of exceptional measures and for simplification of procedures undertaken during a crisis. Stakeholders also agreed on the need for any SMEI-related measures to be streamlined and consistent with other crisis management tools existing at the EU level such as the Chips Act and Health Emergency Preparedness and Response Authority (HERA).

On the specific measures to be included in the initiative, some business organisations underlined the fact that predicting the effects of a crisis on supply chains and value chains is very complex. Therefore, businesses should not face obligations or heavy burdens. Business associations also called for a strengthened dialogue with businesses and industries to include them in decision-making. On stockpiling, several respondents pointed out that uncoordinated and unilateral measures from some Member States proved to be a major obstacle during the first months of the pandemic. For example, several Member States encouraged industries to stop exporting and instead stockpile while other Member States forced wholesalers and/or manufacturers to stockpile medicines. Such measures had similar effects to export restrictions and caused disruption in the functioning of supply chains even if stockpiling was not used as much as the export restrictions. Some business associations call therefore for strategic stockpiling that focuses on very specific goods. Business associations stressed the lack of harmonisation of data-gathering at the EU level and called for the use of the principle of proportionality when imposing market monitoring obligations on companies. While the idea of facilitating the procedures for placing the products concerned on the market is mostly approved, stakeholders stress the need to be careful not to develop parallel regulatory frameworks with lower standards or to distort the level playing field.

Among the EU citizens that responded to the call for evidence, 19 respondents did not agree with the initiative. They pointed out a risk of loss of sovereignty of Member States in the management of a crisis and interference with national affairs. They also highlighted the structural economic differences between Member States which can make solidarity initiatives more difficult.

2.2 Public consultation

The public consultation questionnaire included questions on the problems experienced during the recent crises as well as on the possible optional modules to be included in the future instrument.

For the problems experience, on the effect of restrictions on free movement of persons, cross-border service provision or export of goods, 23 of 24 respondents stated that they were negatively affected, with 12 to a great extent. 13 respondents pointed to the effect in private activity as a consumer or service recipient, 6 in professional activity as a worker, 13 in professional activity as a service provider, 12 in professional activity as an entrepreneur, 14 as a company employing cross-border workers, 17 as a company relying on cross-border service providers, 6 as a citizen wishing to travel.

On the difficulties experienced when wishing to purchase goods, 13 respondents out of 17 pointed at the product not being available for purchase (3 often), 14 out of 17 at the product available with a very high price increase of over 30% (6 often), 15 out of 17 at the product available with a high price increase of over 10% (9 often), 13 out of 17 at the product available with a very high delay in delivery (4 often), and 15 out of 17 at the product available with a high delay in delivery (5 often).

Due to difficulties in purchasing goods or services, from the point of view of businesses, the following consequences occurred: lower production volumes for 13 out of 16 respondents (10

often), delays in production for 14 out of 16 (11 often), lost business opportunities for 11 out of 16 (10 often), lost investment opportunities for 9 out of 15 (8 often), liquidity problems for 4 out of 15 (3 often), staff redundancies for 10 out of 16 (7 often).

For measures to anticipate disruptions and prepare for crises before they arise, the following responses were received in terms of adequacy of measures:

- targeted monitoring mechanism of identified supply chains through data gathered from economic operators to anticipate shortages affecting the smooth functioning of the Single Market – 14 out of 24 respondents supported it, 9 to a great extent
- regular risk assessment by industry – 22 out of 24 respondents supported it, 13 to a great extent
- regular risk assessment by Member States – 22 out of 24 respondents supported it, 13 to a great extent
- regular risk assessment by the Commission – 23 out of 24 respondents supported it, 12 to a great extent
- emergency training drills for national and EU experts – 22 out of 24 respondents supported it, 8 to a great extent
- promoting the reinforcement of the resilience of the EU economy through voluntary industry-driven initiatives – 22 out of 24 respondents supported it, 5 to a great extent
- promoting the reinforcement of the resilience of the EU economy through or mandatory industry-driven initiatives – 13 out of 24 respondents supported it, 1 to a great extent; 11 did not support at all.

For what concerns the targeted information needed from industry in order to anticipate and prepare for the crisis adequately, the following choices were supported:

- information regarding their production capacities (5 respondents said yes, 7 said maybe out of 14 respondents)
- information regarding their current primary disruptions (11 respondents said yes, 1 said maybe out of 14 respondents)
- information regarding existing stocks of goods of potential relevance to that particular crisis (7 respondents said yes, 5 said maybe out of 15 respondents)
- information regarding their prices (2 said yes, 2 said maybe out of 15 respondents)
- information regarding their supply chains (5 said yes, 6 said maybe out of 15 respondents)
- any existing data necessary to assess the nature of a potential future the crisis or to identify and assess potential mitigation or emergency measures at national or Union level (5 said yes, 7 said maybe out of 14 respondents).

For what concerns the targeted information needed from industry in order to manage a crisis adequately, the following choices were supported:

- information regarding their production capacities (9 respondents said yes, 9 said maybe out of 20 respondents)
- information regarding their current primary disruptions (17 respondents said yes, 2 said maybe out of 20 respondents)
- information regarding existing stocks of goods of potential relevance to that particular crisis (9 respondents said yes, 10 said maybe out of 20 respondents)
- information regarding their prices (4 said yes, 5 said maybe out of 21 respondents)
- information regarding their supply chains (7 said yes, 6 said maybe out of 20 respondents)

- any existing data necessary to assess the nature of a potential future the crisis or to identify and assess potential mitigation or emergency measures at national or Union level (7 said yes, 7 said maybe out of 20 respondents).

On the question of a strategic storage or stockpiling system for goods of strategic importance, 19 respondents out of 21 were supportive of such a measure (4 to a great extent). There were a number of divergent suggestions on how to determine such goods of strategic importance, both in terms of methodology and in terms of specific goods. On the question whether the respondent's organisation has such a stockpiling system in place, only 2 out of 20 respondents replied positively. 8 out of 20 respondents considered that a strategic storage or stockpiling system coordinated at EU level would be an efficient solution to crises.

In terms of addressing obstacles to free movement in times of crisis, 21 out of 21 respondents (17 to a great extent) supported providing key principles concerning crisis measures restricting the free movement of certain categories of goods as well as persons, workers and professionals. 18 out of 22 respondents (11 to a great extent) supported conditions/mechanisms for drawing up key principles to determine products and/or services that are indispensable in the context of a given crisis and for facilitating their free movement. 19 out of 21 respondents (12 to a great extent) supported setting out key principles to identify a blacklist of national measures restricting the free movement of goods, services and persons incompatible with the particular crisis situation.

On the actions regarding information sharing and/or notifications of national crisis measures as a solution to the crisis situations, the following responses were received:

- Specific mandatory notification mechanisms for any national crisis measures restricting the intra-EU exportation of goods and restricting services provisions followed by flash peer review by the Member States and the Commission, during which adoption is suspended – 20 out of 22 respondents supportive, 15 to a great extent
- Voluntary information sharing on national crisis measures by Member States – 14 out of 21 respondents supportive, 2 to a great extent
- Require Member States to notify the national crisis measures and specific exemptions or special treatment that exist for recognised groups such as transport workers and service providers, health care workers, cross-border commuters etc. affecting the Single Market – 21 out of 22 respondents supportive, 16 to a great extent
- Publish the summary of the national crisis measures on a dedicated EU website where citizens and businesses could acquire information about the national crisis measures – 21 out of 22 respondents supportive, 16 to a great extent
- Set up information contact points at EU level where citizens and businesses could acquire further information about the EU and national crisis measures – 21 out of 22 respondents supportive, 9 to a great extent
- Require Member States to set up information contact points at national level where citizens and businesses could acquire further information about the national crisis measures affecting the Single Market – 21 out of 22 respondents supportive, 14 to a great extent.

As regards the timely availability of critical products relevant to a crisis, the following responses were received in terms of the efficiency of each measure:

- Streamlining EU product rules (such as mandatory conformity assessment and standards) and prioritising products' controls for a limited time, to enable a swift deployment of products of potential relevance to a crisis on the market – 14 out of 17 respondents considered efficient, 10 highly efficient

- Ramping up production capacity, e.g. by repurposing or extending existing production lines on a voluntary basis – 13 out of 17 respondents considered efficient, 3 highly efficient
- Ramping up production capacity, e.g. by repurposing or extending existing production lines on mandatory basis with governmental support including the possibility of speeding up permitting procedures at national level, as a measure of last resort when the supply of crisis-related goods does not meet the need to adequately manage a crisis – 5 out of 17 respondents considered efficient, 2 highly efficient
- Targeted and coordinated distribution of products relevant for a certain type of crisis when there are dire shortages of crisis-relevant resources in times of crisis – 6 out of 17 respondents considered efficient, 3 highly efficient
- Obligation on undertakings to accept and prioritise orders of goods and services relevant to a crisis in order to enhance their availability during a crisis – 3 out of 16 respondents considered efficient, 2 highly efficient.

2.3 Stakeholder workshop

The objective of the online stakeholder workshop which took place on 6 May 2022 was to collect feedback from participants in an interactive way and to encourage active participation in the other consultation activities. The discussion was structured along two pillars: possible crisis response measures and options and possible preparedness measures and options. The workshop included an audience interaction using Slido where the participants could express their support for different variants of measures.

Stakeholders broadly supported an instrument that ensures free movement of goods, services and workers (for example Eurocommerce) and were in favour of a clear and focused scope of SMEI focused on the Single Market freedoms (for example BusinessEurope).

The clear definition of emergency and the mechanism for activation and de-activation were very important (BusinessEurope, German Confederation of Crafts and Small Businesses, the Danish Business Authority).

On specific measures in the crisis response pillar, Eurocommerce expressed support for specific measures such as proportionality guidance or even a blacklist of measures and a fast-track notification procedure. The Danish Business Authority called for prevention of intra-EU restrictions but invited SMEI to make use of existing instruments for notifications and standards. BusinessEurope noted that during the COVID-19 crisis, the various attempts to define essential services and products led to confusion with some products that were treated differently depending on the shops where they were sold.

Strong doubts were raised on crisis preparedness pillar, in particular over the potential obligation for economic operators to prioritise some production lines or disclose sensitive information (BusinessEurope). Stakeholders warned to take care not to aggregate supply chain disruptions by imposing additional obligation on the industry, for example through stockpiling (Eurocommerce). The German Confederation of Crafts and Small Businesses said there should be a possibility or obligation for a stockpiling Member State to supply a Member State that is experiencing a shortage or cannot deliver the products concerned. The Confederation of Swedish Enterprise mentioned that during the pandemic that some Member States stopped the stockpiles that companies had already made in their country and hindered the efforts made by companies and noted that if Member States that have made extensive efforts in terms of stockpiling cannot be expected to share their stockpiles with those who have made no such efforts.

In terms of audience interaction, 54 responses were received on the crisis response pillar and 40 responses were received on the crisis preparedness pillar. Participants were broadly in favour of measures on ensuring free movement of crisis-relevant goods, persons and services (each option gathering from 48 to 56% support), of obligatory notifications of national crisis measures (76% supported), of disseminating information about MS and EU crisis measures via electronic platform for notified information (72%) and via a single point of contact in the EU (58%), with less support for voluntary options. In terms of obtaining information from businesses, participants were in favour to encourage voluntary sharing (75%). 69% were in favour of mandatory exchange of gathered information by Member States in a dedicated forum. On ensuring the availability of products relevant for a certain type of crisis, guidance on increasing availability of products and prioritising market surveillance and technical specifications for crisis-relevant products was supported by 57% and prioritisation of market surveillance of crisis-relevant products by 49% of participants. Joint procurement by the Commission on behalf of the Member States was supported by 53% and guidance on emergency procurement in Member States by 49% of participants. Among the measures of last resort, recommendations gathered more support than obligatory solutions, with recommendation to businesses to ramp up production capacity of crisis-relevant products was supported by 73% and recommendation to businesses to prioritise orders of crisis-relevant products by 63% gathering particular support.

On the crisis preparedness pillar, risk assessment and preparedness measures were broadly supported (with recommendation to MS being supported by 55%, guidance by 50% and an obligation to MS/EU by 38%). 59% supported a recommendation to train and organise drills for national experts in preparedness and crisis communication. Guidance to Member States on voluntary targeted monitoring of identified strategic supply chains for shortages was supported by 61%. For stockpiling, recommendations to Member States on mitigating measures, stockpiling and strategic storage and distribution were supported by 67% and guidance to businesses on stockpiling and its use was supported by 61%.

2.4 Member States survey

14 Member States (BE, CZ, DK, EE, ES, IT, LV, LT, NL, AT, PL, PT, FI, SI) replied to the survey on national tools and measures for addressing emergencies that may have an impact on the functioning of the Single Market during a crisis. Two Member States (IE and SI) sent additional material in this context. They were asked to provide answers to 10 questions divided into three main blocks: questions about national crisis response measures (1 to 4), questions about national crisis preparedness measures (5 to 9), and questions about national measures in light of future crises (10).

Member States based their answers mainly on the COVID-19 crisis as well as Russia's invasion of Ukraine. During both crises, Member States took measures firstly to mitigate the resulting economic impact. Most measures were aimed at propping up financial solvency to ensure sufficient liquidity for production and facilitate economic recovery through grants, bridge-financing loans and tax reductions. Measures have also been introduced to provide the necessary supply of critical goods by helping companies to find new suppliers and facilitating public procurement for critical goods. To ensure the continued functioning of the Single Market by addressing obstacles to the movement of goods and services, Green Lanes for road transport vehicles were introduced following the Commission's guidelines. Despite complaints about the lack of transparency and coordination between the Member States on the measures taken, cooperation initiatives among the Member States on an ad hoc basis to share information on measures that could affect the Single Market were also highlighted (i.e. "Cross-Border Task Force Corona" between NL, DE and BE ensured that the border between the Netherlands and Germany remained open during the pandemic). Most measures were introduced horizontally but some measures also targeted specific

industrial ecosystems depending on the type of crisis. The COVID-19 crisis enhanced measures targeting transport and health sectors while Russia's invasion of Ukraine led to measures in the field of energy and agri-food. Regarding legislative gaps in EU law in relation to the measures that the Member States wanted to take to resolve the crisis, a number of Member States referred to the need for more rapid or flexible public procurement framework as well as state aid rules. Individual Member States also mentioned issues such as air services regulation (though quickly resolved), GDPR and Connecting Europe Facility. It was also considered that it would be necessary to improve the mechanisms for reporting national crisis measures adopted by a Member State to the Commission and in particular to the other Member States, and to establish a mechanism for assessing the effects of such measures on the Single Market.

The survey looked at the crisis preparedness measures already in place in the Member States and in particular, the presence of a national monitoring system and strategic storage or stockpiling system of goods of key importance. Regarding monitoring, some Member States implemented risk assessment mechanisms in designated critical sectors (BE, CZ, DK, EE, ES, IT, LV, LT, FI, PL) and strengthened the exchange of information between stakeholders in vital sectors and competent authorities at the national level. Regarding stockpiling, most Member States have not yet implemented such a system. Some Member States have, however, strategic storage/stockpiling systems for raw materials, such as Estonia with the Stockpiling Agency operating since July 2021, Spain with the creation by the National Security Council of the Strategic Reserve based on Industrial Production Capacities on October 2020, and Poland with the Government Programme of Strategic Reserves created in December 2020. In Finland, the preparedness action of the authorities is based on the relevant legislation and the National Emergency Supply Agency (NESA) coordinates and supports the action for preparedness and resilience of supply chains at the business sector. Finland employs a stockpiling system with three different types of stocks: national emergency stocks, compulsory stocks and security stocks. Areas of stockpiling include, for example, imported fuels, crude oil and oil products, chemicals, grains and seeds, medicines, hospital supplies as well as critical products and materials. Provision on emergency stockpiling are provided on several pieces of legislation. Other Member States have set up strategic stocks for specific products (such as gas, oil, basic food, drinking water, metals, protective equipment, medical equipment, and medicines). Russia's invasion of Ukraine, meanwhile, has prompted more Member States to initiate plans and task forces to manage supply chain disruptions through similar measures.

In light of future crises, Member States acknowledge the need to strengthen preparation and appropriate response to such events. Specifically, most Member States acknowledge the need to carry out risk assessment concerning the availability of non-medical goods and critical raw materials; strategic storage or stockpiling of such goods; and design tools that allow increasing the availability of such goods, including speeding up permitting procedures, targeted mandatory information requests to businesses on their stocks and production capacities and priority rate orders. The replies to the survey indicate that such measures should be mainly coordinated at the national level by including relevant and key stakeholders and experts in the process. At the EU level, Member States mainly call for an improvement of information-sharing platforms and well-designed coordination mechanisms.

2.5 Targeted consultations

SMEI was discussed with Member States in a number of High Level Group meetings and Working Parties of the Council. In particular discussions took place on the following dates:

- HLG 4 February 2021

- COMPCRO 14 June 2021
- HLG 9 September 2021
- COMPCRO 20 September 2021
- COMPCRO 1 December 2021
- HLG 3 February 2022
- COMPCRO 23 May 2022

We received specific position papers from the following Member States:

- Joint considerations by Denmark, Estonia, Finland, Ireland, Netherlands, Slovenia and Sweden (11 March 2022)
- Netherlands (non-official paper of 19 April 2022)
- Sweden (10 May 2022)
- Estonia (11 May 2022)
- Denmark (11 May 2022)
- Ireland (11 May 2022)
- Finland (27 May 2022)
- Letter by Belgium, Denmark, Finland, Ireland, Malta, Netherlands, Portugal, Slovenia, Sweden (3 June 2022)
- Luxembourg (14 June 2022)

Additionally, we received 11 position papers from stakeholders as attachments to the public consultation questionnaire and 18 position papers as attachments to the call for evidence (with some overlaps), as well as one additional position paper by email. In addition to the stakeholder workshop, there were also a number of meetings with individual stakeholders to present and discuss the proposal.

SMEI proposal was also discussed with the representatives of the European Parliament, in particular in an exchange of views with the IMCO Committee on 17 May 2022, and with EFTA/EEA representatives.

For what concerns the positions of the Member States, overall the majority of Member States have expressed support for an instrument that would ensure better coordination of measures, uphold the freedoms of the Single Market and leverage the Single Market to address crises. However, there differences of views with regards to individual building blocks of the initiative and options to be chosen.

Most Member States have voiced their support for mechanisms to ensure greater transparency and coordination during a crisis (for example BG, DK, DE, EE, IE, FI, LV, MT, NL, PL, SE, SI, letter of nine Member States of 3 June 2022). They have called for a clear definition of a crisis and of activation mechanism of the instrument (for example joint letter of 11 March 2022 and individually BE, CZ, IE, DE, EE, MT, LT, and NL, AT, PT, RO, and SI).

Further, Member States have widely supported measures to ensure free movement of persons, goods and services (for example BE, BG, DK, IE, EE, FI, LU, NL, PL, PT, RO, SE, letter of nine Member States of 3 June 2022). Some Member States have warned about the difficulties of introducing a new notification obligation and/or the need to build on the existing mechanisms (for example joint letter of 11 March 2022 and individually DK, IE, FI, SE), while stressing the importance of ensuring transparency for citizens and businesses with regards to measures taken

across Member States (joint letter of 11 March 2022) and calling for an online platform providing standardised information on measures (BE, LV, PL).

When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance (joint letter of 11 March 2022, also AT, FR, DE).

A number of Member States have voiced concern about including in the scope of the initiative of measures to ensure crisis preparedness and to address difficulties in supply chains. For example, a letter of 3 June 2022 from nine Member States questioned the inclusion of measures such as stockpiling, monitoring and enhancing the resilience of strategic supply chains, mandatory information requests to economic operators and priority orders. Similar concerns were expressed in individual letters from DK, IE, NL, FI, and SE, also drawing attention to the need to follow strictly the principles of necessity and proportionality of measures and to avoid the related administrative burden. A number of other MS, including DE, BG, LT, have also raised questions in this direction. DE, PL, BG have also stressed that information requests should not be mandatory. On the other hand, MS such as PL, RO, EL, AT, LU have spoken in favour of addressing crisis preparedness and supply chains disruptions.

A number of stakeholders representing the business community have expressed support for a clear definition of a crisis, greater coordination and transparency, measures to ensure free movement of workers, fast-track notifications of national measures, fast track procedures for development and publishing of harmonised standards, EU and national single points of information, emergency drills for experts. Additional suggestions included from business stakeholders included measures such as a common dedicated online information interface modelled on Re-open EU, harmonised electronic laissez-passer systems for specific groups of workers, and speedier framework for emergency state aid. Business stakeholders have warned against specific measures such supply chain mechanisms, ex ante market monitoring, obligatory orders to ramp up production, mandatory information requests to businesses under preparedness stage, modification of public procurement rules, stockpiling, and called for all measures to be analysed against the criteria of necessity and proportionality.

In its contribution, ETUC (European Trade Union Confederation) stressed the need to address challenges faced by cross-border workers, in particular frontier, posted, seasonal and transport workers as well as lack of coordination and cooperation between MS and difficulties to access information. Furthermore, it stated that SMEI should support EU strategic autonomy agenda and sustainable supply chains which required initiatives such as identification of strategic supply chains and monitoring to anticipate shortages.

ANNEX 3: WHO IS AFFECTED AND HOW?

Businesses will be positively affected, in particularly during an emergency, due to better EU-level crisis response leading to less obstacles to free movement and better availability of crisis-relevant products. Measures in the toolbox that would have a direct positive effect on businesses include key principles to ensure free movement and supporting measures, transparency and administrative assistance during emergency, public procurement during emergency and measures to place products faster on the market during emergency, and speeding up permitting during emergency. Businesses however could also face costs and their operations could be impacted, notably due to measures to support supply chains during emergency, in particular information requests to companies, obligations to ramp up production and to accept priority-rated orders.

Citizens would benefit from the overall better EU-level crisis response thanks to the presence of the coordination mechanisms as well as the toolbox to ensure less obstacles to free movement and better availability of crisis-relevant products. They would further directly benefit from key principles to ensure free movement, in particular as it concerns free movement of persons, in their capacity as workers and consumers. They could also directly benefit from distribution of previously stockpiled crisis-relevant products of strategic importance. There are no direct costs to citizens.

Member States would benefit from overall better EU-level crisis response and directly benefit from the existence of a dedicated governance body ensuring coordination during a crisis with impact on the Single Market. There would be administrative and compliance costs for Member States for a range of measures foreseen under the toolbox, including for contingency planning, gathering information on supply chains, participation in match-making and constitution of strategic reserves under vigilance mode, as well as in emergency mode for compliance with key principles for free movement, measures on transparency and administrative assistance, compliance with measures on placing crisis-relevant products on the market, participation in public procurement during emergency and measures impacting crisis-relevant supply chains during emergency.

For **the Commission**, we consider that the activity of developing new guidance, recommendations and coordinating obligatory measures forms part of the normal activities. The Commission would nevertheless incur additional specific costs, in particular for the organisation of the SMEI Advisory Group meetings, organising trainings and drills for national experts, conducting Union-level risk assessment, organising match-making between companies, analysis of notifications under transparency and administrative assistance.

This Impact Assessment does not indicate the preferred option. The choice is left for political decision based on the assessment of impacts of the three identified policy options presented in this Impact Assessment. However, an indication of costs and benefits of the different measures could be presented below:

1. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions)		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct benefits</i>		
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	Total amount not quantifiable but benefits	Benefit for citizens and businesses

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	generated better crisis response, thanks to better availability of crisis-relevant products and services.	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	Direct adjustment costs	-	-	-	-	-	Costs of gathering information on identified supply

applicable in vigilance mode (see triggering mechanisms in section 5) ⁹⁶							chains and monitoring them for a list of indicators (PO3); costs of participation in match-making; costs of constituting 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) ⁹⁷	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	-	-	-	-	-	-
	Direct enforcement costs	-	-	-	-	-	-
	Indirect costs	-	-	Opportunity costs linked to ramping up production	-	-	-

⁹⁶ 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.

⁹⁷ 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.

				(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.

2. RELEVANT SUSTAINABLE DEVELOPMENT GOALS

III. Overview of relevant Sustainable Development Goals		
Relevant SDG	Expected progress towards the Goal	Comments
SDG 1: No poverty	The Single Market Emergency Instrument will help to prevent bankruptcies, to sustain employment opportunities and to prevent redundancies, thereby indirectly contributing to reduction of poverty in the European Union.	
SDG 8: Decent work and economic growth	The Single Market Emergency Instrument will contribute to the sustainable development goal of decent work and economic growth by ensuring a well-functioning Single Market in times of crisis and therefore mitigate severe economic repercussions through loss of business opportunities and crisis-related redundancies.	
SDG 9: Industry, innovation and infrastructure	The Single Market Emergency Instrument will help prevent obstacles to free movement of goods, services and persons, thereby ensuring that all groups can continue to benefit from access to infrastructure, including from roads and cross-border infrastructure installations.	
SDG 10: Reduced inequalities	The Single Market Emergency Instrument will help to remove the obstacles to free movement of goods, services and persons and provide more access to all groups to crisis-relevant goods, especially addressing difficulties experienced by vulnerable groups particularly at risk in a crisis,	

	such as those in outermost regions and in cross-border communities.	
SDG 16: Peace, justice and strong institutions	The Single Market Emergency Instrument will put in place a governance system for managing Single Market impacts of large-scale exceptional crises and stimulates at the same time the strengthening of national-level governance and institutions that are resilient enough and can withstand shock and crisis.	

ANNEX 4: ANALYTICAL METHODS

The analysis contained in this Impact Assessment builds on data collected from desk research (academic studies, economic reports, media items, existing impact assessment reports such as Data Act or SMIT proposals, etc.), input from stakeholder outreach activities and Commission officials' expert knowledge. Information has been analysed against the main problems identified for the purpose of this initiative, the problem drivers as well as stakeholder positions.

Whenever possible, the Impact Assessment provides a quantitative analysis of benefits and costs relating to the main economic and social impacts. The cost/benefit analysis, however, is not fully comprehensive due to significant data gaps.

The evidence base of the report is strongly limited due to the relatively low number of responses to the call for evidence and the public consultation, and the lack of a supporting study. We tried to remedy this situation by conducting a stakeholder workshop attended by a large number of stakeholders and by conducting a series of targeted consultations, especially with Member States and stakeholders. The views of stakeholders are transparently reflected in the Impact Assessment.

There is a general lack of granular information at company, Member States and EU level on the actions and activities undertaken to mitigate possible future shortages of supply chains.

It should be noted that the aim of this assessment is to provide ranges of the magnitude of potential impacts generated by each policy option, rather than exact monetisation. Given that for certain measures the necessary evidence will become available only in a crisis situation (unknown today), the assessment provides a qualitative assessment of the type of impacts to be expected for different stakeholders groups. Since for some of the measures, evidence will become available only in the (pre)-crisis situation, the need for the additional analysis and assessment before activating certain measures is reflected in the decision mechanisms (as explained in section 5, set-up of the instrument).

ANNEX 5: DETAILED OVERVIEW OF POLICY approaches per building block

DETAILED OVERVIEW OF POLICY APPROACHES PER BUILDING BLOCK				
<i>Building blocks</i>	<i>Policy approach 1: Soft law</i>	<i>Policy approach 2: Targeted legal solutions combined with soft law</i>	<i>Policy approach 3: Comprehensive legal framework combined with some soft law</i>	<i>Mode when the building block applies.</i>
1. Governance, coordination, and cooperation	<p>Informal network of experts set up by DG GROW will serve as the technical-level forum for:</p> <ul style="list-style-type: none"> ✓ discussion and voluntary exchange of crisis-related information and ✓ voluntary coordination of national crisis management measures. ✓ It will cooperate closely with IPCR and other relevant crisis related EG <p>The informal network of experts will assist the Commission in:</p> <ul style="list-style-type: none"> ✓ Providing information that is useful for proposing the activation and scope of emergency and the activation of Single Market vigilance mode for measures outside 	<p>Advisory Group set up by the SMEI regulation will serve as the technical-level forum for:</p> <ul style="list-style-type: none"> ✓ discussion and mandatory exchange of crisis-related information and ✓ mandatory coordination of national crisis management measures ✓ ‘vigilance’ and crisis response cooperation ✓ It will cooperate closely with IPCR and other relevant crisis related EG <p>The Advisory Group will advise and assist the Commission in:</p> <ul style="list-style-type: none"> ✓ Proposing the activation and scope of emergency and the activation of Single Market vigilance mode for measures outside the Single Market emergency ✓ Analyse crisis-relevant information gathered by Member States by means of surveys or mandatory 	<p>High Level Board with high-level MS representatives, chaired by COM supported by dedicated technical sub-groups.</p> <p>It will serve as a high-level forum for:</p> <ul style="list-style-type: none"> ✓ discussion and mandatory exchange of crisis-related information and ✓ obligatory coordination of national crisis management measures and ✓ Single Market vigilance and crisis response cooperation. ✓ It will cooperate closely with IPCR and other relevant crisis related EG and crisis response and preparedness bodies <p>The HLB will assist the Commission in:</p> <ul style="list-style-type: none"> ✓ Proposing the activation and scope of emergency and the activation of Single Market vigilance mode for measures outside the Single Market Analyse information gathered by COM from economic operators by means of mandatory information requests that can serve as a basis for recommending crisis response 	Applies at all times

	<p>the Single Market</p> <p>✓ Free exchange on crisis-relevant information received by COM and the MS from economic operators on a voluntary basis that can serve as a basis for recommending crisis response measures for the MS and Commission</p> <p>Any high-level political coordination of the crisis response will occur in the IPCR and the relevant Council working party.</p> <p>Recommendation to the Member States to exchange crisis-relevant information, including information that the economic operators have shared with them on a voluntary basis, with other Member States and the EU institutions during crises and in anticipation of the crises.</p>	<p>information requests from economic operators that can serve as a basis for recommending crisis response and vigilance measures. Any high-level political coordination of crisis response will occur in the IPCR and the relevant Council working party</p> <p>Obligation of the Member States to share between themselves and with the Commission within the expert group and the Council in anticipation of the crises the following important information:</p> <ul style="list-style-type: none"> ✓ information on national level mitigation measures, including strategic storage and stockpiling of goods of strategic importance; ✓ information on identified shortages affecting the smooth functioning of the Single Market as a result of national level targeted monitoring of identified strategic supply chains; ✓ Information on the results of periodic/regular assessment of risks by expert bodies and groups on national level Information on any relevant industry-led initiatives aiming at enhancing the resilience of strategic supply chains 	<p>measures for the MS and the Commission</p> <p>✓ Supporting the Commission in relevant international partnerships/fora/organisations (allowing for coordination of the position of the Member States in international organisations where the Commission is not a member)</p> <p>Obligation of the Member States to share any crisis-relevant information in the HLB with other Member States and the Commission. HLB shares information with IPCR and other crisis-relevant EU-level bodies.</p> <p>Obligation of the Commission to share information that it has obtained from the economic operators via mandatory information requests with the High Level Board.</p>	
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		<p>Obligation of the Member States to share between themselves and with the Commission and the Council within the expert group during crises the following information:</p> <ul style="list-style-type: none"> ✓ information obtained from the economic operators via mandatory information requests ✓ information on national procurement needs in preparation of joint procurement by the Commission ✓ Information on any acceptance and prioritisation of orders of crisis-relevant products that are indispensable during the crisis by economic operators ✓ Information on ramping up of the production capacity of crisis-relevant goods by any economic operator that is active in their territory ✓ Information on speeding up permitting procedures during the crisis in order to increase the production capacity of crisis-relevant products ✓ Information on distribution of (possibly previously stockpiled) products relevant for the specific crisis when there are dire shortages of crisis-relevant resources on the Single Market in times of crisis ✓ Information necessary for adequate coordination of national crisis response 		
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		<p>measures and crisis communication</p> <p>Recommendation to the Member States to exchange any other crisis-relevant and vigilance information with other Member States and the EU institutions during crises and in anticipation of the crises.</p>		
<p>2. Crisis contingency planning</p> <ul style="list-style-type: none"> - <i>Regular assessment of risks</i> - <i>Emergency trainings and drills of relevant national experts</i> - <i>Crisis protocols</i> - <i>Compendium of crisis response measures</i> 	<p>New guidance where necessary for the functioning of the Single Market in times of crises on:</p> <ul style="list-style-type: none"> ✓ voluntary assessment of risks to supply chains of goods and services of strategic importance on a regular basis by the economic operators, if/where such assessment not already undertaken by the industry ✓ crisis-relevant training and drills for national experts <p>Compendium of crisis response measures, prepared and maintained by the informal network of experts, including guidance/recommendations that have been used in the past.</p>	<p>Recommendation to the Member States:</p> <ul style="list-style-type: none"> ✓ to assess risks to supply chains of goods and services of strategic importance on a regular basis including in national expert bodies or groups and in consultation with the industry, if/where assessment not already undertaken by the industry ✓ to train and organise drills in crisis vigilance and crisis communication to relevant national experts <p>Compendium of crisis response measures, prepared and maintained by the Member States and the Commission in the Advisory Group, including guidance/recommendations that have been used in the past.</p>	<p>Recommendation to the Member States:</p> <ul style="list-style-type: none"> ✓ to assess risks of supply chains of goods and services of strategic importance on a regular basis and in consultation with the industry, if/where assessment not already undertaken by the industry <p>Obligation of the Commission to:</p> <ul style="list-style-type: none"> ✓ carry out regularly a risk assessment at Union level for supply chains of strategic goods and services, in consultation with the industry and in cooperation with all relevant Commission expert groups and on the basis of all available information provided by Member States and the industry ✓ operate in cooperation with the Member States an early warning system for alerts of incidents that have the potential to significantly affect or significantly affect the functioning of the Single Market and 	Applies at all times

			<p>its supply chains</p> <ul style="list-style-type: none"> ✓ devise in cooperation with the Member States a framework for crisis protocols and crisis communication that assigns the roles and responsibilities of the relevant Member States authorities and EU bodies for the vigilance and Single Market emergency modes ✓ provide adequate training on crisis coordination and cooperation and information exchange for national experts. ✓ conduct stress tests, simulations and in-action and after-action reviews of the national crisis protocols and communication plans with Member States Obligation to Member States ✓ to train their relevant crisis management staff regularly on the communication, coordination and collaboration tools as well as vigilance and crisis response measures <p>Compendium of crisis response measures, prepared and maintained by the Commission for the High Level Board, including guidance/recommendations that have been used in the past.</p>	
3. Single Market vigilance	Guidance on voluntary stepped-up information gathering concerning identified strategic supply	Recommendation to the Member States on information gathering concerning identified strategic supply chains and obstacles to free	Subject to the activation of the Single Market vigilance mode by means of Commission implementing act:	Vigilance mode

	<p>chains for the companies that are part of such value chains to identify/monitor shortages affecting the functioning of the Single Market, to facilitate the role of the industry in building up resilience.</p> <p>New guidance to economic operators on mitigating measures, including strategic storage or stockpiling of goods of strategic importance and their use where necessary for the functioning of the Single Market in times of crises, to facilitate the role of the industry in ensuring resilience.</p> <p>Guidance on the use of the negotiated procedure under the Public Procurement Directive for compiling any relevant Member States level strategic reserves.</p>	<p>movement, to identify /monitor shortages affecting the functioning of the Single Market as regards the companies that operate in their territory in those supply chains. Industry stakeholders in the relevant supply chain(s) to be invited by Member States to provide targeted information factors impacting the availability of such goods and services (e.g. production capacity, stocks, supplier's limitations, possibilities for diversification and substitution, demand conditions, bottlenecks).</p> <p>The Commission (together with Member States as appropriate) would actively promote matchmaking among companies in the identified supply chains.</p> <p>Recommendations to the Member States where necessary for the functioning of the Single Market in times of crises on mitigating measures, including building up strategic storage and stockpiling of goods of strategic importance to be distributed across the Single Market at the time of crisis to alleviate the relevant shortages. Recommendations would focus on Member States facilitating the role of the industry in ensuring resilience, and on possible further measures where the industry is unable or unwilling to provide effective</p>	<p>The obligation of the MS to monitor identified supply chains of goods and services of strategic importance with the Commission coordinating such monitoring. Industry stakeholders in the relevant supply chain(s) to be invited by Member States to provide targeted information factors impacting the availability of such goods and services.</p> <p>The information gathering would concern those supply chains of goods and services of strategic importance that the Commission has identified in the Union level risk assessment as having higher risks for the onset of Single Market emergencies. The supply chains of goods and services of strategic importance could be defined based on elements of strategic importance identified in Regulation of screening of Foreign Direct Investments and the Commission Staff Working Document on strategic dependencies. Strategically important areas of the economy could be understood as areas with critical importance to the EU and its Member States' strategic interests such as security, safety, public order, health and the green and digital transformation, including critical infrastructure, critical technologies and inputs which are essential for safeguarding such interests, the disruption, failure, loss or destruction of which would have a significant impact in a Member State or the Union). Consequently, the goods and services of strategic importance could be defined as those that are necessary for maintaining economic activities in the Single Market</p>	
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		<p>solutions.</p> <p>Guidance on the use of the negotiated procedure under the Public Procurement Directive for compiling any relevant Member States level strategic reserves.</p>	<p>in strategically important areas of the economy.</p> <p>The Member States would be obliged to compile lists of contacts of the economic operators functioning along the identified supply chains of strategic goods and services. Whereas the competent authorities of Member States Such would rely on such lists in monitoring supply chain concerned, it would also be relied on by the Commission for the mandatory information requests.</p> <p>The Commission would actively promote matchmaking among companies in the identified supply chains.</p> <p>The Commission would step up the monitoring of relevant free movement obstacles.</p> <p>Subject to evidence that 1) industry's stockpiling is insufficient or inexistent, 2) alternative supply sources do not exist or are insufficient and on the basis of 3) impact assessment by the Commission in cooperation with the Advisory Group indicating the need for strategic reserves, the Commission may activate, by means of implementing act, strategic reserve measure:</p> <p>Obligation of the Commission to draw up and regularly update, by means of implementing acts, a list with targets for strategic reserves to be constituted by Member States for the selected supply chains of goods and services of strategic</p>	
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			<p>importance, taking into account:</p> <ul style="list-style-type: none"> a. the probability and impact of shocks and risks identified in the Union level risk assessment; b. the level of existing reserves in the EU; c. the costs for building and maintaining reserves. <p>The Commission will issue Recommendations requesting Member States to build up, maintain or reduce their strategic reserves in order to meet the targets.</p> <p>The Commission will coordinate and streamline efforts of Member States to build up and maintain strategic reserves by promoting the exchange of information and cooperation between Member States, facilitating public-private cooperation.</p> <p><i>Subject to additional trigger by means of Commission implementing acts (during the activation of the Single Market vigilance) upon the condition that i) there is evidence that industry's stockpiling is insufficient or inexistent, ii) alternative supply sources do not work or are insufficient and iii) impact assessment by the Commission and governance body indicates a need for building up strategic</i></p>	
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			<p><i>reserves.</i></p> <p>Where the strategic reserves of Member States fall significantly short of the targets, the Commission can oblige the Member States to build up strategic reserves for selected goods of strategic importance that would correspond to such targets.</p> <p>The Commission will coordinate and streamline efforts of MS to build up and maintain strategic reserves.</p> <p>MS would rely on the provisions of the Procurement Directive for carrying out any necessary individual or coordinated procurement for building up their strategic reserves.</p>	
<p>4. Key principles and supportive measures for facilitating free movement during emergency</p>	<p>New guidance or Recommendations where necessary for the functioning of the Single Market in times of crises on free movement of crisis-relevant workers, service providers, persons and goods.</p>	<p>Subject to the activation of the Single Market emergency mode:</p> <p>Reinforcing key principles of free movement of crisis-relevant workers, service providers, goods in binding rules where appropriate for effective crisis management:</p> <ul style="list-style-type: none"> ✓ to identify restrictions of free movement of goods, services and persons that are incompatible with the Single Market in the particular crisis situation and to create black lists of such measures ✓ to provide for some supportive measures for reinforcing free movement during the crisis (e.g. defining essential travel, 	<p>Subject to the activation of the Single Market emergency mode:</p> <p>Providing for a comprehensive set of rules supporting free movement of goods and persons (including workers, posted workers, service providers), especially crisis-relevant goods and persons in times of crisis in binding rules where appropriate for effective crisis management.</p>	<p>Emergency mode</p>

		essential worker, etc.)		
		Recommendation to Member States where necessary for the functioning of the Single Market in times of crises on free movement of persons (including workers and service providers) and goods.		
5. Transparency and administrative assistance during emergency <ul style="list-style-type: none"> - <i>Notification of national crisis measures</i> - <i>Information and assistance in relation to national crisis measures</i> 	<p>Member States share national crisis measures voluntarily with COM⁹⁸ and other MS. The shared information serves as a basis of discussion of appropriate policy response to crisis in the expert group, but also published in the electronic platform for businesses and citizens.</p> <p>Provide national and EU level crisis info, in particular on the introduced national restrictions that has been obtained voluntarily by means of an electronic platform <i>in English</i>.</p> <p>Recommendation to the</p>	<p>Subject to the activation of the Single Market emergency mode:</p> <p><i>Binding simplified</i> fast-track notification mechanism of any free movement restrictions (any restrictions of freedom to provide services, including on free movement of persons, workers, posted workers and their exit or entry bans, free movement of agricultural goods)⁹⁹ with the purpose of providing transparency to businesses, citizens and other MS and ensuring free movement of goods, services and persons + flash peer review of draft notified measures in the EG¹⁰⁰:</p> <ul style="list-style-type: none"> ✓ Provide crisis info obtained at national and EU level via the 	<p>Subject to the activation of the Single Market emergency mode:</p> <p><i>Binding full-fledged</i> fast-track notification mechanism¹⁰¹</p> <p>+ flash peer review of draft notified measures</p> <p>+ possibility to declare the notified national crisis measures incompatible with EU law by COM Decision¹⁰² and to request the Member State in question to refrain from adopting the draft measures or to abolish the adopted measures:</p> <ul style="list-style-type: none"> ✓ Provide by means of an electronic platform crisis info at national and EU level, obtained via mandatory fast-track notifications, available <i>in all EU languages</i> 	Emergency mode

⁹⁸ COM may in principle start normal infringement proceedings if any notified crisis measure is incompatible with EU law.

⁹⁹ Not applicable to the reintroduction of internal border controls under the Schengen Borders Code as there is a separate notification obligation.

¹⁰⁰ Besides the flash peer review comments, COM may in principle start normal infringement proceedings if any notified crisis measure is incompatible with EU law.

¹⁰¹ Not applicable to the reintroduction of internal border controls under the Schengen Borders Code as there is a separate notification obligation.

¹⁰² The possibility for the Commission is an option and not an obligation. It is always without prejudice to other tools such infringement procedures, administrative and political letters etc.

	Member States to provide administrative assistance to businesses, workers, services providers, consumers and citizens for fulfilment of any crisis-related formalities and procedures.	mandatory simplified notifications and other publicly available sources by means of an electronic platform <i>in English</i> Member States will set up national single contact points for crisis-relevant information and administrative assistance to citizens, consumers and businesses	Display national crisis measures <i>and their summaries on Your Europe websites</i> in all EU languages ✓ Establish national and EU contact points for businesses and citizens to obtain information about applicable national and EU level crisis measures and to get administrative assistance for fulfilling any related administrative requirements	
6. Speeding up the placing of crisis-relevant goods on the market during emergency	Guidance on: ✓ increasing availability of products and ✓ prioritizing market surveillance and controls	The use of the elements below is subject to the activation of the Single Market emergency mode: Targeted amendments of existing Single Market harmonisation legislation ✓ enabling national market surveillance authorities to authorise the placing on the market of critical products while conformity assessment is ongoing. ✓ Possibility for the Commission to adopt technical specifications for harmonised/non-harmonised products where no harmonised standard exists. ✓ Obligations to MS to prioritise market surveillance for crisis-relevant products The use of those new elements would be subject to the activation of the Single Market emergency mode.	The use of the new elements below is subject to the activation of the Single Market emergency mode Targeted amendments of existing Single Market harmonisation legislation for products ✓ derogating from existing conformity assessment procedures during a specific timeframe ✓ Possibility to use normal European standards for harmonised/non-harmonised products in the absence of harmonised standards. ✓ Obligation to prioritise market surveillance for crisis-relevant products The use of those new elements would be subject to the activation of the Single Market emergency mode.	Emergency mode

<p>7. Public procurement during emergency</p>	<p>New guidance where necessary for the functioning of the Single Market in times of crises on:</p> <ul style="list-style-type: none"> ✓ the use of emergency provisions of public procurement (negotiated procedure) by individual Member States and/or joint occasional procurement by several Member States under the Procurement Directives ✓ voluntary coordination of public procurement action by individual Member States during the crisis 	<p>The use of below measures is subject to the activation of the Single Market emergency mode:</p> <p>New provision on joint procurement/common purchasing by the Commission for some or all Member States, including innovation procurement if requested by the Member States¹⁰³, with MS budget whereby the Commission draws up the proposal for framework agreement organising in detail the joint procurement to be signed by the participating Member States. Such procurement would exclude any joint/coordinated procurement by the same Member States that does not involve the Commission at the same time.</p> <p>New provision obliging the Member States to coordinate with and consult other Member States and the Commission prior to engaging in individual procurement action of crisis-relevant products during the crisis.</p> <p>New guidance where necessary for the functioning of the Single Market in times of crises on:</p>	<p>The use of below measures is subject to the activation of the Single Market emergency mode:</p> <p>Targeted amendments of the Procurement Directives allowing Member States to derogate from existing public procurement procedures/suspend the application of the Procurement Directives for procurement of crisis-relevant products during a specific timeframe during the crisis¹⁰⁴.</p> <p>New provision on joint procurement/common purchasing by the Commission for some or all Member States, including innovation procurement which would exclude any procurement by any Member States jointly or individually at the same time.¹⁰⁵ It could allow the Commission to derogate from several steps of normal procurement procedures under the Financial Regulation. (possibility to provide proof or evidence on exclusion and selection criteria after signature of contract provided that a declaration on honour has been submitted in this regard before the award;</p> <p>the Commission may modify the contract, as necessary to adapt to the evolution of</p>	<p>Emergency mode</p>
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¹⁰³ If the emergency procurement provisions of the proposal for the Regulation revising the Financial Regulation will not be adopted by the time SMEI will be adopted

¹⁰⁵ If the emergency procurement provisions of the proposal for the Regulation revising the Financial Regulation will not be adopted by the time SMEI will be adopted.

		<ul style="list-style-type: none"> ✓ the use of emergency provisions of public procurement (negotiated procedure) by individual Member States ✓ the use of occasional joint procurement by the Member States under the Procurement Directives 	<p>the Single Market emergency;</p> <p>possibility to add contracting authorities, not identified in procurement documents, after the signature of the contract;</p> <p>The contracting authorities shall be entitled to request the delivery of goods or services as from the date of sending the draft contracts resulting from the procurement carried out for the purposes of this Regulation, no later than 24 hours as from the award.</p>	
<p>8. Measures impacting crisis-relevant supply chains during emergency</p> <ul style="list-style-type: none"> - <i>Distribution of crisis-relevant goods at the time of dire shortages</i> - <i>Ramping up the production lines of crisis-relevant products</i> - <i>Speeding up permitting procedures</i> - <i>Accepting and prioritising orders of crisis-relevant products by economic operators</i> - <i>Obtaining information from economic operators</i> 	<p>Guidance on distribution of possibly previously stockpiled products relevant for a certain type of crisis when there are dire shortages of crisis-relevant resources in times of crisis, to facilitate the role of industry in ensuring resilience.</p> <p>Guidance on ways how the Member States could encourage the economic operators to ramp up their production capacity of crisis-relevant products during the crisis, including by means of possible targeted and necessary financial support.</p> <p>Guidance on speeding up permitting procedures during the crisis in order to</p>	<p>The use of below measures is subject to the individual activation of the measures during the activation of the Single Market emergency mode:</p> <p>Measures (recommendations and empowerments to Member States as described below) would be envisaged only where the industry is unable or unwilling to provide effective solutions without reasonable justification, further to guidance by the Commission.</p> <p>Recommendation to the Member States on distribution of possibly previously stockpiled products relevant for a certain type of crisis based on the principle of solidarity when there are dire shortages of crisis-relevant resources in times of crisis.</p>	<p>The use of below measures is subject to individual activation of the measures during the activation of the Single Market emergency mode:</p> <p>Obligation of the Member States to distribute possibly previously stockpiled products relevant for a certain type of crisis when the reserves have been financed by the EU and there are dire shortages of crisis-relevant resources in times of crisis.</p> <p>As regards distribution of any other national strategic reserves, which have been financed by the Member States, the Commission could issue a Recommendation to the Member States on distribution of possibly previously stockpiled products relevant for a certain type of crisis based on the principle of solidarity when there are dire shortages of crisis-relevant resources in times of crisis.</p>	Emergency mode

	<p>ramp up the production capacity for products relevant for the specific type of crisis.</p> <p>Guidance on the ways how the Member States could encourage the economic operators to accept and prioritise orders of crisis-relevant products in order to enhance the availability of indispensable goods for provision of critical services or other important reasons during the crisis.</p> <p>Recommendation to the economic operators to share crisis-relevant info.</p>	<p>Empowering the Member States by means of legislation to oblige the economic operators to ramp up their production capacity of crisis-relevant products during the crisis, with the possibility to offer targeted and necessary financial support.</p> <p>Recommendation to the Member States on speeding up permitting procedures during the crisis in order to ramp up the production capacity for products relevant for the specific type of crisis.</p> <p>Recommendation to the Member States to encourage the economic operators to accept and prioritise orders of crisis-relevant products in order to enhance the availability of indispensable goods for provision of critical services or other important reasons during the crisis and to free them from liability for the resulting delay or non-fulfilment of their contractual obligations vis-à-vis third parties.</p> <p>Providing for harmonised rules for mandatory information requests of targeted crisis-relevant information by the Member States to economic operators in crisis-</p>	<p>Empowering the Commission by means of legislation to oblige the economic operators to ramp up their production capacity of crisis-relevant goods (e.g. repurposing their production lines or creating new production lines) to address severe shortages on the Single Market at the time of crisis (possibly accompanied by EU-level targeted and necessary financial support¹⁰⁶).</p> <p>Obliging the Member States to speed up permitting procedures during the crisis by means of legislation in order to ramp up the production capacity for products relevant for the specific type of crisis in case of severe shortages.</p> <p>Obligation of the economic operators to accept and prioritise orders of EU authorities of crisis-relevant products in order to enhance the availability of indispensable goods for provision of critical services or other important reasons during the crisis freeing them from liability for the resulting delay or non-fulfilment of their contractual obligations vis-à-vis third parties. In first stage, such priority rated orders could be issued as regards the input needed for production of the crisis-relevant goods. In the second stage, they could be issued as regards the final products that</p>	
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¹⁰⁶ In case this measure is retained, such an empowerment for the Commission would imply a need for a special financial instrument (based on the model of Emergency Support Instrument which was activated during the COVID-19 crisis to help the EU address the pandemic, in particular to secure the COVID-19 vaccines) to reimburse the economic operators for their costs in such a scenario.

		<p>relevant supply chains as to their production capacities, current supply chain disruptions + data necessary for assessment of the nature and magnitude of the supply chain disruptions. Mandatory information requests to be limited to cases of utmost necessity and where economic operators have refused to provide necessary targeted information in the context of Single Market vigilance measures, i.e. clear cases of non-cooperation in crisis situations. Safeguards for confidentiality and IP protection foreseen. Such information requests by the Member States can be contested before the relevant national courts.</p>	<p>qualify as crisis-relevant products.</p> <p>Commission empowered to issue mandatory requests of crisis-relevant information to economic operators in crisis-relevant supply chains, based on the lists of contacts or relevant ad hoc information provided by the Member States, as to their production capacities, current supply chain disruptions + data necessary for assessment of the nature and magnitude of the supply. Mandatory information requests to be limited to cases of utmost necessity and where economic operators have refused to provide necessary targeted information in the context of Single Market vigilance, i.e. clear cases of non-cooperation in crisis situations. Safeguards for confidentiality and protection of business secrets foreseen. Such direct information requests can be contested before the European Court of Justice.</p>	
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ANNEX 6: ANALYSIS OF POLICY APPROACHES PER BUILDING BLOCK

1. Building block 1 – Governance, coordination and cooperation

Policy approach 1 – Informal network of experts set up by DG GROW

Costs related to policy option 1 are insignificant as it implies a very high business as usual factor for the Commission and for the Member States. Commission costs relate to setting up an expert group and organising the meeting. This is estimated at 30.000 EUR annually, which is based on a standard budget for a meeting with 27 MS experts of 15.000 EUR. The organisation of the meetings would require for the Commission ½ AD FTE that could be added through reallocation of staff. This would increase to 1 AD during the vigilance mode and to 2 AD during the emergency mode, due to the higher recurrence of the meetings. This could be covered by reallocation of existing resources.

The costs for the Member States will be limited to the preparation, participation and follow up on the said meeting that may estimate also to ½ FTE per Member State.

Policy option 1 provides economic *benefits* for national authorities of having more complete information through the discussions and voluntary exchange of crisis-related information and voluntary coordination of national crisis. The benefits account also for being able to coordinate the measures with other Member States that in turn may result in effectiveness of decisions at EU level to manage a crisis and ensure the functioning of the Single Market.

Policy approach 2 – Formal Expert Group, called Advisory Group, set up by Commission Decision

The *costs* related to policy option 2 should be low and relevant for the reimbursement by COM of travel expenses similar to existing expert groups. These costs would be similar to costs under Approach 1, amounting to around 30.000 EUR annually for the Commission as well as the relevant FTEs and ½ FTE per Member State. The costs for the Member States will be limited to the preparation, participation and follow up on the said meeting that may estimate also to ½ FTE per Member State.

The *benefits* of policy option 2 are reflected by having more complete information gathered through the mandatory coordination of national crisis and by being able to coordinate the measures with other Member States. The indirect benefits may be projected on the effectiveness of decisions at EU level to manage a crisis and ensure the functioning of the Single Market due to more comprehensive information exchanged between the Member States in the formal group. Overall, there would be economic benefits due to better crisis response, thanks to better availability of crisis-relevant products and services. In terms of *social benefits*, since this options may contribute to less restrictive measures in relation to free movement, there may be benefits for cross-border and/or posted workers and their livelihoods which rely on accessing their workplace. Less restrictive measures in case of crises may also be beneficial for continued business operations and thereby reduce the risk of redundancies etc. in case of Single Market emergencies.

The *costs* of the exchange of information system under policy approach 2 fall largely on the Member States. Their magnitude depends on the extent to which they have information available already in a suitable format. In that case, additional costs for the transmission are likely to be low. Otherwise additional efforts are needed, but these depend on the nature of the information required in a concrete crisis and cannot be estimated in the abstract.

The *benefits* of policy approach 2 outweigh the costs given that the governance body will be equipped with granular information at national level that in turn will enable an accurate assessment of the situation for informed crisis relevant decisions/actions to be taken by the relevant decision making bodies (the Commission, the Council).

Policy approach 3 – High Level Board with high-level Member States representatives

The *costs* related to policy option 3 would be similar to costs for the Commission for running the any other High Level Group or Expert Group with reimbursement costs of approximately 30.000 EUR/year for two meetings, as well as the relevant FTEs. The costs for the Member States are largely similar to previous Approaches, with estimated ½ FTE needed per Member State.

The *benefits* are similar to those in Policy Option 2.

Stakeholder's feedback

Most Member States have voiced their support for mechanisms to ensure greater transparency and coordination during a crisis (for example BG, DK, DE, EE, IE, FI, LV, MT, NL, PL, SE, SI, letter of nine Member States of 3 June 2022). In their responses to call for evidence and public consultations, business stakeholders stressed that the initiative should ensure cooperation, coordination and exchange of information and should focus on crisis response. In their replies to the Member States questionnaire, Member States recommend to build on current EU coordination fora (IPCR). In targeted bilateral consultations some Member States like the NL expressed their preference for the creation of a network of competent authorities.

Conclusions

Policy approach 2 is retained for further analysis based on the following justification:

Although the informal network of experts of approach 1 would be able to serve as a forum for discussions between the Member States and the Commission, it would not have the benefit of a clear legal mandate to gather and exchange information. Voluntary information exchange within such a forum would depend on the willingness of the Member States to share information with each other. It would occur in a haphazard manner and at an unpredictable pace; it would not be able to ensure that all Member States and the Commission would be aware of all national crisis measures in their entirety in a timely manner. Moreover, voluntary coordination would not add much to achieve the coordination of national crisis measures and eliminate the harm done by uncoordinated crisis measures to the Single Market.

The designated expert group for Single Market emergencies, envisaged in approach 2, would be able to ensure technical level fact-finding, analysis, and coordination and information exchange during the Single Market vigilance and crisis stages. It would not duplicate any higher level fora, such as the IPCR. It would rather concentrate on providing the IPCR via the Commission with the necessary technical information for higher level political coordination and discussions.

The High Level Board, envisaged in approach 3 would consist of high level representatives of the Commission and the Member States and could, combined with its ad hoc working groups, carry out discussions, analysis and coordination at both technical and political levels. But its weakness is that its level of representation is similar to that of the IPCR and there could be confusion as to which forum would be competent to discuss

Single Market crisis-related matters (similarly with the recent clashes between the Health Security Committee of the HERA system and the IPCR, which led to the dismissal of the Chairperson of the Health Security Committee).

The costs for different approaches are comparable but their effectiveness differs significantly.

2. Building block 2 – Crisis contingency planning

Policy approach 1 – Guidance on risk assessment, crisis-relevant training and drills, compendium of crisis response measures

The *costs and benefits* are similar to business as usual for the Commission.

Policy approach 2 – Recommendation to the Member States for risk assessment, trainings and drills; Compendium of crisis response measures prepared collectively

The *costs* for the Member States depend largely if the Member States follow or not Commission's Recommendation. For some Member States such activities are business as usual except for the developments of emergency drills for certain preselected emergency cases that would require additional human resources and subcontracting studies. The costs depend on the type and complexity of the chosen emergency drills. The *benefits* are harvested during times of crisis, by diminishing the negative effects of the particular type of crisis thanks to these preparatory measures. Since the policy approach 2 is based on voluntary participation, the costs and benefits will strongly depend on the uptake by Member States. It could be assumed that Member States that currently conduct similar activities, will continue to do so while only a limited number of Member States will opt-in for measures foreseen in the recommendation.

Policy approach 3 – Recommendation to Member States on risk assessment; Obligation for the Commission to develop crisis-relevant training and drills + Union level risk assessment + Early Warning System + crisis protocols + Compendium of crisis response measures

For the Commission, *costs* related to regular risk assessment could be regarded as business as usual as similar assessments are done by the relevant services of the Commission. There would be also costs for the Commission to provide trainings and conduct stress-tests and drills, develop crisis protocols and a compendium of measures.

The *benefits* are harvested during times of crisis, by having lower negative effects of the particular type of crisis thanks to these preparatory measures.

Stakeholders' feedback

In the public consultation, regular risk assessment by the industry was supported by 22 out of 24 respondents, by Member States by 22 out of 24 and by the Commission by 23 out of 24. Emergency training and drills were supported by 22 out of 24 respondents. Business stakeholders expressed support for risk assessment by public authorities (BusinessEurope) and emergency simulation exercises (SMEUnited). In light of future crisis, most Member States having responded to the Member States questionnaire agree that preparedness measures such as risk assessments concerning the availability of non-medical goods and critical raw materials that are indispensable. They acknowledge that in most case, national authorities are best prepared to take above mentioned measures.

Conclusions

Policy approach 2 and policy approach 3 are retained for further analysis based on the following justification.

Policy approach 1 concerning preparatory actions would entail soft measures. The voluntary guidance and training may serve to encourage and support risk assessment efforts and build capacity of economic operators and national administrations when it comes to possible future crises affecting the functioning of the Single Market. It would rely on the readiness of industry players and national authorities to invest in preparatory actions and may not effectively change practices (or the absence thereof) when it comes to such actions. This option would reflect maximum subsidiarity and may empower economic operators to reinforce their role in ensuring resilience, however it may not achieve tangible improvements, nor would it benefit from greater coherence and coordination of preparatory actions that may be necessary for crises affecting the Single Market, i.e. entailing challenges intrinsically more wide-reaching than national and/or company level issues.

Policy approach 2 would provide recommendations to the Member States for the assessment of risks on a regular basis including by expert bodies and in collaboration with the industry. Recommendations would also cover training and drills for crisis vigilance and communication involving relevant national and regional experts. While this option is likely to entail a better coordinated approach to risk assessment at national level, it may not ensure coherence, nor mandate any coordination of preparatory actions between Member States at the EU level, which might be necessary for anticipating or mitigating crisis situations affecting the functioning of the Single Market, where industry action may not be sufficient. However it would require substantially less administrative effort from the Commission.

Policy approach 3 would entail the strongest policy approach combining recommendations to Member States to assess risks in relation to strategic supply chains on a regular basis and in coordination with all relevant national and regional bodies as well as industry stakeholders. Moreover, Member States would report on their assessment to the Commission and to other Member States on a regular basis. In addition, the Commission would carry out regular assessments of risks at Union level, building on the findings on national assessments which the Commission would monitor. Such union level assessment would be discussed with the Member States on a regular basis to maximise coherence. As part of this, the Commission would operate an early warning system based on early warning indicators agreed with the Member States. Such approach would appear more effective than systems building primarily on individual assessment at national level and/or by the industry.

The organisation of training and drills would become mandatory both by Member States and the Commission, the latter involving designated national contact points. The Commission would moreover develop a manual containing a strategy for crisis communication and crisis protocols addressing the Single Market impacts of crises to leverage a coordinated approach (mapping out who does what at the EU and national level, including industry, in case of a crisis), which would be used during a crisis.

3. Building block 3 – Single Market vigilance

Policy Approach 1 – Guidance to companies on voluntary targeted information gathering and guidance to economic operators on voluntary stockpiling

The *costs and benefits* related to this policy option are similar to business as usual since the measures are limited to issuing guidance on voluntary stepped-up information gathering and stockpiling.

It could be reasonably assumed that the guidance will encourage Member States or economic operators to start collecting information or build stockpiling of goods of strategic importance.

Policy Approach 2 – Recommendation to the Member States on information gathering concerning strategic supply chains and recommendation to Member States on strategic reserves + promotion of match-making

The *costs* depend on actions ultimately taken by the Member States when the Single Market vigilance mode is activated. Such costs are expected to be similar to business as usual as most of the Member States that have replied to the targeted questionnaire indicated that they have national level activities to monitor the market with early warning systems in place.

In terms of strategic reserves, the Commission will prepare the recommendation. Any costs will depend on the uptake of this Recommendation by Member States.

Matchmaking between companies in identified strategic supply chains would be primarily coordinated by the Commission, requiring up to 2 AD FTE totalling an estimated 314.000 EUR/year. Possible involvement of Member States in matchmaking activities may entail more limited resources, involving up to 1 FTE at approximately 157.000 EUR/year.

These measures may bring economic *benefits* thanks to better information and predictability of Single Market issues (obstacles and possible shortages), less costs and better planning as well as better crisis response as well as better availability of crisis-relevant products and services. This policy approach may likely lead to informed decisions and actions that in turn may generate, for example better availability of goods and services in terms of choice, volume and speed or less disruptions of working conditions, in particular for cross-border workers. However, there are limitations on the extent of the benefits of this option given that the monitoring activity is left at the discretion of the Member States.

Policy Approach 3 – Obligation for Member States to gather targeted information + promotion of matchmaking by the Commission + Obligation for the Commission to coordinate strategic reserves to be constituted by Member States, including lists of targets, recommendations and obligation to build up strategic reserves + Obligation to inform about individual public procurement actions

Similar to policy approach 2 and only further to activation of the Single Market vigilance mode, the *costs* related to this policy option are largely falling on the Member States but activities are assumed to be carried out mostly by existing human resources in national ministries. The cost related to matchmaking are the same as under policy approach 2.

The costs for coordinating strategic reserves for the Commission would be limited to coordination costs. However, Member States would bear the costs of creating concrete targets for reserves in areas where risks of security of supply in strategic supply chains are observed. They would also have to inform the Commission and other Member States about their individual public procurement actions to build up strategic reserves.

This option may bring about economic *benefits* thanks to better information and predictability of Single Market issues (obstacles and possible shortages), less costs and better planning as well as better crisis response as well as better availability of crisis-relevant products and services. This policy option may likely lead to informed decisions and actions that in turn may generate, for example better availability of goods and services in terms of choice, volume, in times of crisis.

Stakeholders' feedback

In the public consultation, 14 out of 24 respondents supported targeted monitoring mechanism (above referred to as targeted information gathering) of identified supply chains to anticipate shortages. Some business stakeholders were in favour of voluntary or mandatory mechanisms to anticipate future shortages (for example SMEUnited, European, VDMA, ETUC), whereas others considered that it was not in line with the principles of proportionality and necessity (BusinessEurope, ERT, and Dansk Industri). In the stakeholder workshop, guidance to Member States on voluntary targeted monitoring of identified strategic supply chains for shortages was supported by 61%.

However, some Member States, such as DK, emphasise that gathering information would potentially require a great deal of work and coordination. This would imply in their view significant burdens for public authorities and businesses subjected to reporting requirements, and also entail risks around forced disclosure of sensitive business information. Member States have pointed out in their replies to the Member States questionnaire that the private sector could be further involved in management of stockpiles.

On strategic stockpiling, some stakeholders were in favour (SMEUnited, VDMA) whereas others were not or called for it to be done at the national level (Eurocommerce, Eurochambres, Dansk Industri). A number of Member States have voiced concern about including in the scope of the initiative measures such as stockpiling. Similar concerns were expressed in individual letters from DK, IE, NL, FI, and SE, also drawing attention to the need to follow strictly the principles of necessity and proportionality of measures and to avoid the related administrative burden.

Conclusions

Policy approach 2 and policy approach 3 are retained for further analysis based on the following justification:

Under Policy approach 1, which is subject to the activation of the Single Market vigilance mode, the Commission would provide guidance on targeted information gathering of identified strategic supply chains and obstacles to free movement to companies which are part of such supply chains. This option although voluntary, may have the benefit of increased and more coherent monitoring by industry, who would be well placed to carry out such information gathering within specific fields. Companies

may subsequently, again on a voluntary basis, flag emerging issues to public authorities. The voluntary nature of this option may however limit its effectiveness when it comes to identifying shortages and addressing them jointly by public and private players, as it would in part rely on the readiness of companies to pass on information, etc. While it may support targeted and effective industry initiatives to remedy possible shortages, it could have limited usefulness for informing policy discussions between Member States/at EU level, in the event that public intervention may prove necessary to complement industry action in building up resilience.

Policy Approach 2, also subject to the activation of the Single Market vigilance mode, provides for recommendations to Member States on the information gathering concerning identified strategic supply chains and obstacles to free movement based on their national competences, concerning the companies that operate in their territory and form part of such value chains. Member States would invite industry stakeholders in the selected supply chains to voluntarily provide targeted information on factors impacting the availability of goods and services therein. In addition, the Commission together with Member States would actively promote matchmaking among companies in the strategic supply chains concerned. The Commission will also issue recommendation on stockpiling of goods of strategic importance. This approach may lead to a more comprehensive and coherent approach to prioritising and organising information gathering by Member States in full collaboration with industry present on their territory. It would also be favourable in terms of subsidiarity, since Member States would maintain autonomy in relation the organisation of information gathering. However, this option may fall short of being effective, since information gathering would remain voluntary. There would also be no obligation to share the findings thereof, or to foresee any follow-up actions such as early warning systems. This option may therefore not serve to inform EU level policy discussions between Member States in a structured manner, which would be needed in the event that public intervention proves necessary to complement industry action in building up resilience.

Policy approach 3, again subject to the activation of the Single Market vigilance mode, foresees that Member States carry out regular and targeted information gathering concerning supply chains of strategic importance, in view of ensuring the functioning of the Single Market. It would be accompanied by guidance including on indicators, as appropriate, for a targeted yet comprehensive and coherent approach. This option would oblige Member States to identify supply chains of strategic importance according to certain criteria and in full collaboration with industry stakeholders. In addition, the Commission together with Member States would actively promote matchmaking among companies in the strategic supply chains concerned. Altogether, this option would entail a structured and consistent approach to information gathering across Member States, who would however maintain autonomy when it comes to its precise organisation. The involvement of industry would be facilitated, including through dedicated administrative means for collecting information from companies. By formally involving all levels in the targeted information gathering based on common criteria/indicators, this option would ensure a coherent approach. Moreover, it foresees that national level findings be shared with the Commission and other Member States in an EU level forum, to enable targeted discussions, further analysis and to inform coordinated policy action if necessary.

As regards strategic reserves, policy approach 3 foresees empowering the Commission to request information from Member States on their levels of strategic reserves. Together with Member States, the Commission would create concrete targets for reserves in areas

where risks of security of supply in strategic supply chains are observed. The Commission would then issue recommendations to Member States in relation to their strategic reserves to meet such targets. Subject to additional activation, the Commission could oblige Member States to build up strategic reserves for selected goods of strategic importance that would correspond to such targets.

4. *Building block 4 – Key principles and supportive measures for facilitating free movement during emergency*

Policy approach 1 – Guidance or Recommendations on free movement

The *costs* for the Commission are insignificant and they are equivalent with business as usual. The costs for the Member States would be less than business as usual, as it implies that Member States will issue less national measures in times of crisis. The key principles' objective is to keep the national measures to bare minimum aligned to necessity and proportionality principles. The benefits could be significant in terms of less national restrictions affecting the free movement with overall economic and societal benefits if the Member States would decide to follow such guidance and Recommendations¹⁰⁷. If not, this option would bring about significant social costs for frontier workers and cross-border workers and service providers who rely on their free movement rights for their income. Such workers and service providers will therefore be at a greater risk of loss of income and poverty and will require income support measures from the Member States concerned. Given that the initiative aims also to ensure free movement of medical professionals during public health emergencies, non-compliance of the Member States with the guidance can also bring about significant costs for the Member States that rely on cross-border health care and care professionals.

Policy approach 2 – Reinforcing key principles of free movement of crisis-relevant workers, service providers, goods in binding rules

There are no additional costs for the Commission for developing key principles as the key principles will already be embedded in the legal text of the initiative.

The benefits are to be seen in less national measures restricting the free movement, given that it is expected that the Member States will use the key principles in assessing the necessity and proportionality of their national crisis measures that in turn will limit restrictive actions. To this end, it is estimated that the *benefits* outweigh the costs. The Single Market impact of the crises includes social costs for crisis-relevant workers such as longer working hours, less resting time, higher exposure to health and safety risks and environmental hazards, limitations of the right to strike and assembly. The facilitation of the free movement of such workers during the crisis will bring about a decrease increase in those costs. All the workers will further benefit from the possibility to continue their professional activities and to preserve their income during the crisis.

Policy approach 3 - Binding rules on free movement in times of crisis

The *costs* for the Commission to develop binding rules are expected to be low and covered by existing resources. The costs to Member States are expected to be lower than

¹⁰⁷ The European Court of Auditors has pointed out in its “Special Report on Free movement in the EU at the time of COVID-19 pandemic” that even one year after the beginning of COVID-19 pandemic, Member States' practices show that responses were still mostly uncoordinated and were not always consistent with Commission guidance and Council Recommendations on free movement, see p. 5 of the Special Report.

under business as usual and under option 1 as they may not have to develop any new national rules.

Under this policy approach, it is expected that workers would fully benefit of their free movement rights, therefore increasing their well-being due to employment opportunities and no loss of income.

There could be significant economic and societal *benefits* like the availability of the goods and services needed for the proper functioning of the Single Market and timely support to the functioning of health care and care systems of the Member States, given that intra-EU exports and imports of goods and services as well as free movement of persons remains fully functional in times of crises that may affect the Single Market.

Stakeholders' feedback

Member States have widely supported measures to ensure free movement of persons, goods and services (for example BE, BG, DK, IE, EE, FI, LU, NL, PL, PT, RO, SE, letter of nine Member States of 3 June 2022). 21 out of 21 respondents to the public consultation supported providing key principles concerning crisis measures restricting the free movement of certain categories of goods as well as persons, workers and professionals. 19 out of 21 respondents supported setting out key principles to identify a blacklist of national measures restricting the free movement of goods, services and persons incompatible with the particular crisis situation. Business stakeholders widely supported measures to ensure free movement, singling out the needs of cross-border workers, critical occupations and supporting solutions such as key principles and blacklists.

Conclusions

Policy approach 2 is retained for further analysis based on the following justification.

Policy approach 1 is very light in terms of any administrative burden for the Member States and also for the Commission, containing some principles that the Member States are suggested to follow when applying the free movement. However, it is also clear that Member States who will not follow the Recommendations or guidance will only receive a suggestion to align themselves to the Recommendation. This being said, Member States continue to be bound by the relevant provisions of EU law, under which restrictions to the free movement of persons may only be adopted on the basis of public interest grounds and if they comply with the general principles of EU law, such as proportionality and non-discrimination.

The aim to ensure free movement of crisis-relevant workers, service providers, persons and goods at the time of the Single Market emergency can remain largely unattained for the businesses, workers and citizens concerned if the Member States would not voluntarily adhere to the recommendations and guidance as it happened during COVID/19 pandemic (see section 2 of the Impact Assessment). It appears also that Member States did not know how to interpret the terms used in the recommendations and guidance documents, as they were not defined in sufficient detail. Some Member States have contacted the Commission for additional guidance on the contents of such terms (e.g. Lithuania asked whether essential travel would concern business representatives of retail businesses when they travel for business). This raises questions of efficiency.

Policy approach 2 aims to lay down the key principles (a set of framework rules) that the Member States need to observe at the time of crisis when applying the free movement

rights in the Regulation for a Single Market Emergency Instrument, complementing it with a Recommendation for all other aspects. These concretised rules, and blacklists of free movement restrictions that would be in any case prohibited during the Single Market emergencies, would allow the Member States to understand clearly what is expected of them during the crisis, when designing their crisis response measures. According to the building block 5, Transparency and administrative assistance, other Member States and Commission would provide feedback on notified Member States crisis response measures. Finally, if any crisis measures of the Member States would still contain free movement restrictions that do not comply with the Treaty obligations, the persons, workers, services providers and truck drivers could rely on such concretised rules (key principles and blacklists) against any uncooperative Member State authorities.

This approach would allow for defining the terms and types of persons that need to be granted their free movement rights even at the time of very restricted movement, thus providing for more clarity and a somewhat more efficient legal framework. It would also foresee some supportive measures that would facilitate the free movement of persons during the crisis, defining essential travel and essential worker in a legally binding document. Where necessary for the specific types of crises, it would be complemented by means of crisis-specific recommendations on free movement of crisis-related persons, goods, services and workers at the time of that particular crisis.

Policy approach 3 would provide for a comprehensive legal framework facilitating free movement of all persons, services, goods and workers during the crisis, adding at the same time another layer of protection to the free movement of crisis-relevant goods and persons in times of crisis in binding rules where appropriate for effective crisis management. The comprehensive legal framework of Option 3 would extend the key principles and blacklists to free movement of all persons, services, goods and workers during the crisis. Such rules supporting and facilitating free movement during the crisis would also concern the free movement of civil protection workers. However this approach would be extremely far-reaching and therefore it would not be in line with the principle of subsidiarity, as EU-level rules under this approach would fully replace the possibility of Member States to introduce their own rules. Therefore this approach is not retained.

5. *Building block 5 – Transparency and administrative assistance during emergency*

Policy approach 1 – Member States share national crisis measures voluntarily

Costs for the Member States related to policy Option 1 are largely similar to business as usual whereby Member States may choose to notify or not measures such as entry and exit bans affecting the free movement of persons or adopted measures restricting the free movement of agri-food products across the Single Market.

The *costs* for the Commission are also largely business as usual. The Commission will follow up on the measures voluntarily notified by the Member States as it is currently foreseen. The cost for setting up the electronic platform are similar to the costs for Re-open EU platform. These costs are estimated to include, in addition to normal coordination of activities: 1 FTE dedicated Contract Agent (CA IV): 100.000 EUR, updates (current and further support performed by subcontracted service providers): 433.000 EUR, IT maintenance 67.000 EUR, for a total of 600.000 EUR per annum.

Citizens, businesses and other Member States have *benefits* out of the policy approach 1 given that they will have access to information about national and EU level crisis info, in particular on the introduced national restrictions, obtained voluntarily.

Policy approach 2 – Binding simplified fast-track notification mechanism + flash peer review

The *costs* for notification mechanism are slightly higher than current costs for Single Market Transparency Directive and the costs of notification mechanism under the Service Directive due to obligations imposed to the member's states to notify any free movement restrictions. Based on the impact assessment on Services Directive notification proposal¹⁰⁸ from Member States, the average time spent to comply with the notification procedure is 12 hours per notification. This leads to administrative costs of €385.20 per notification assuming the EU average of hourly earnings for civil servants holding a university degree of €32.10. For restrictions affecting the free movement of persons, we calculate additional resources of 2 AD officials.

The *costs* for the Commission for setting up an electronic platform for disseminating crisis-related information is similar to the costs for the Re-open EU platform, which are 600.000 EUR per annum, see above under policy approach 1.

As regards the *costs* for the Commission for the policy approach 2, based on the impact assessment report on Services Directive notification proposal, on average, the assessment of a notification by a Commission staff member will take 2-3 hours. In case comments or questions addressed to the Member State concerned are to be prepared, it is estimated that this will lead to an additional 5 hours of work. This option will impact the Commission in that it will lead to additional work stemming from the comments received from stakeholders who will be granted access to the notifications to be considered. Another element could be the possible increase of notifications from those Member States currently not completely fulfilling the obligation under the Services Directive. Further to this increase in workload, there is likely to be an impact on the translation costs. Currently a notification from a Member State is translated into English. The current translation cost is on average €26 per page. Notifications are on average between 2 and 3 pages long. This leads to an average translation cost per notification of €65¹⁰⁹.

Policy approach 3 – Binding full-fledged fast-track notification mechanism + flash peer review + possibility to declare the adopted measures null and void

The *costs* for notification mechanism are similar as under policy approach 2 but could be slightly higher as the notification will be not simplified but fully fledged i.e. probably requiring more hours of work both the Commission staff and by the Member States also provide quicker feedback, as compared to the current urgency procedure under the SMTD. As the notifications are binding, the same increase in the number of notifications is to be expected as under policy approach 2. The same costs related to setting up an electronic platform are expected as under policy approach 2.

Stakeholders' feedback

Stakeholders have largely supported actions regarding information sharing and/or notifications of national crisis measures as a solution to the crisis situations. 20 out of 22 public consultation respondents were in favour of specific mandatory notification

¹⁰⁸ The cost estimate based on the impact assessment on Services Directive notification proposal from 2016, [SWD\(2016\)434 \(europa.eu\)](#).

¹⁰⁹ See previous.

mechanisms followed by flash peer review. Voluntary information sharing was also supported (14 out of 21 respondents). 21 out of 22 respondents expressed support both for EU-level and national level contact points, as well as for publishing the summary of the national crisis measures on a dedicated EU website. In the stakeholder workshop, majorities of participants supported obligatory notifications and disseminating information via electronic platform and a single point of contact in the EU, with less support for voluntary options.

Business stakeholders stressed the need to address difficulties to access information and the need for Member States to share information about national measures, supported notification mechanism and called for dedicated information interface and hotline.

Some Member States have warned about the difficulties of introducing a new notification obligation and/or the need to build on the existing mechanisms (for example joint letter of 11 March 2022 and individually DK, IE, FI, SE), while stressing the importance of ensuring transparency for citizens and businesses with regards to measures taken across Member States (joint letter of 11 March 2022) and calling for an online platform providing standardised information on measures (BE, LV, PL). In its replies to the Member States questionnaire, LV recommends setting up a dedicated platform where all the necessary information would be available in times of crisis: webpage for up-to-date information, like the existing Re-open EU platform that provides information on travel and health measures.

Conclusions

Policy approach 3 is retained for further analysis based on the following justification.

Policy approach 1 which invites the Member States to share their crisis response measures that restrict free movement of goods, services and persons with other Member States and the Commission on a voluntary basis, does not allow the Commission, other Member States as well as businesses and citizens to get during a crisis a full and timely picture of the national crisis measures in all Member States. Therefore the economic operators and citizens may not adjust their behaviour and business activities to the crisis realities in an optimal manner. Even if some information would be published voluntarily, economic operators and citizens would be facing the need to frequently verify the voluntarily published information with each of the host Member States where they operate. They would also need to request for administrative assistance from many different national-level authorities in local languages to be able to comply with any crisis-related formalities and procedures.

Policy approach 2 builds upon the existing Single Market Transparency Directive, broadening its scope of application to measures affecting free movement of persons and all types of services as regards notification of draft crisis measures, but does not require notification of adopted crisis response measures that restrict free movement rights and does not provide for any procedures for following up on voluntary notifications of such adopted crisis measures. Similarly to the SMTD system, it provides for the peer review by the Member States, and for a possibility for the Commission to provide comments on the notified draft that the notifying Member States are obliged to take into account. This option allows Member States to avoid the notification of adopted urgent crisis measures or swift follow-up to any notified adopted crisis measures.

It obliges the Member States to put in place single points of contact for the crisis measures that would provide the citizens, businesses, workers, service providers, posted workers with crisis-related information which is tailored for their specific needs and would provide assistance for completion of any crisis-related administrative formalities and procedures in the given Member State.

Policy approach 3 would require Member States to notify their draft crisis response measures that restrict free movement of goods, services and persons (including workers) at the time of crisis and would require the Commission and Member States to provide quicker feedback, as compared to the current urgency procedure under the SMTD. Where the Member States need to take the crisis measures immediately, they would be obliged to notify such measures immediately, and the Commission would be able to follow-up any non-compliant measures by means of a Commission Decision that would declare the non-compliant measures null and void. Therefore this approach would be most effective in terms of ensuring an effective follow-up by the Commission of the measures taken by Member States.

It would be completed by means of national and EU-level single points of contacts that would provide information on national and EU level crisis response measures and would provide administrative assistance for fulfilment of national and EU level additional crisis-related formalities and procedures.

Stakeholders have also strongly supported the introduction of an effective obligatory notification mechanism. Policy approach 2 would only contain a soft means of follow-up (a peer review in the Expert Group) without any binding powers and would therefore lack effectiveness. In contrast, under policy approach 3 there would be an effective means of follow-up by the Commission of the measures taken by Member States. Therefore policy approach 3 is retained for further analysis.

6. *Building block 6 – Speeding up the placing of crisis-relevant products on the market during emergency*

Policy approach 1 – Guidance on increasing availability of products

The *costs and benefits* are similar to business as usual – the Commission will develop the guidance under the usual activities for managing the application of single market product framework. Some economic and societal benefits may be brought forward by this option if the Member States choose to follow the Commission guidance.

Policy approach 2 – Targeted amendments to Single Market harmonisation legislation on placing on the market + technical specifications for harmonised/non-harmonised products + MS to prioritise market surveillance for crisis-relevant products

Under this option, there are limited *costs* for the Commission, expected to be covered by existing resources. Regarding the costs for the Member States, no additional costs are expected – familiarising with the new technical specification developed by the Commission and prioritising market surveillance would fall under business as usual. There will be less costs for the economic operators, including SMEs, given that they can place products on the market while conformity assessment is not finalised. There will be economic and societal *benefits* thanks to a swift deployment of crisis-relevant products on the market in times of crises. The risk of placing non-compliant products will be mitigated due to increased market surveillance.

Policy Option 3 - Targeted amendments to Single Market harmonisation legislation on placing on the market + technical specifications for harmonised/non-harmonised products + MS to prioritise market surveillance for crisis-relevant products + European standards

There are limited *costs* for Commission, expected to be covered by existing resources and there are no major costs on the Member States similar with the policy option 2. There will be economic and societal benefits thanks to a swift deployment of crisis-relevant products on the market in times of crises, e.g. personal protective equipment masks. However, in terms of societal *benefits*, this option may raise safety concerns given the use of European standards not assessed for presumption of conformity against the health and safety requirements of the product legislation.

Stakeholders' feedback

Streamlining EU product rules (such as mandatory conformity assessment and standards) and prioritising products' controls for a limited time, to enable a swift deployment of products of potential relevance to a crisis on the market was considered as an efficient solution by 14 out of 17 respondents in the public consultation. Business stakeholders expressed support for facilitating procedures for placing relevant products on the market (for example BusinessEurope, SMEUnited, VDMA, Dansk Industri).

When it comes to ensuring availability of crisis-relevant goods, Member States have expressed support for measures such as coordination of public procurement, fast-track conformity assessment and improved market surveillance (joint letter of 11 March 2022, also AT, FR, DE).

Conclusion:

Policy approach 2 is retained for further analysis based on the following justification.

Policy approach 1 would build on the experience of the pandemic and build on the soft law tools taken during this time. It would turn the ad hoc specific actions into a more permanent body of guidance. Thus specific guidance and recommendations could be envisaged along the lines of the Recommendation on PPE. Such an approach would however provide less predictability to all actors involved and could therefore decrease legal certainty. Also, it would not be possible to adopt technical specifications providing a presumption of conformity which would therefore not resolve the problem of missing harmonised standards.

Policy approach 2 entails targeted amendments of existing Single Market legislation enabling national market surveillance authorities to authorise the placing on the market of critical products while conformity assessment is ongoing during the time the crisis is activated. As such, crisis-relevant products for which no conformity assessment procedure has been initiated may be authorised by the Member States to be placed on the market provided that the products concerned ensure an adequate level of health and safety in accordance with the essential requirements laid down in the specific Union product harmonisation. This option also gives the Commission the possibility to adopt technical specifications where no harmonised standard exists. To this end, Commission is empowered to adopt technical specifications, via implementing acts, for the essential health and safety requirements set out in the sectorial legislation. The process for adopting the technical specification will be quicker than the standard process provided by the Standardisation Regulation 1025/2012 whereby the European Standardisation

Organisations will develop harmonised standards only following a specific request by the Commission.

This option proposes obligations to the Member States to prioritise market surveillance for crisis-relevant products that are placed on the market without CE marking, pending the completion of their conformity assessment.

Policy approach 3 proposes targeted amendments of existing Single Market legislation for products derogating from existing conformity assessment procedures during the time the emergency situation is activated. This could entail specific amendments of the standard conformity assessment procedure of a given product such as reducing certain requirements to be carried out during the procedure. This could be a reduction of timeframes or requiring a document check instead of product testing. To this end, manufacturers are allowed to place products on the market derogating from the standard procedure of conformity assessment required by the product legislation. These amendments would have to be chosen very carefully in each individual case to ensure that the overall level of safety of such products is not endangered by the derogations.

Also normal European standards that have not been harmonised could be identified where no harmonised standards exist. This does, however raise questions on legal certainty about the presumption of conformity with the essential requirements of the legislation in question. This would also ultimately raise questions concerning the safety of the products concerned.

7. Building block 7 – Public procurement during emergency

Policy approach 1 – Guidance

This option provides for *costs and benefits* that are considered business as usual.

Policy approach 2 – New provision on coordinated procurement/common purchasing

The *costs* under this policy option are similar to the costs for setting up Commission-led procurement of COVID-19 vaccines, which could be considered business as usual for the Commission. The *benefits* will outweigh the costs given that crisis relevant goods of dire are made available when they are most needed.

Policy approach 3 – Targeted amendments of the Procurement Directives + New provision on coordinated procurement/common purchasing

The *costs* for the Member States are lower than business as usual under this option due to possible derogation from procurement rules. Minor one-off costs may be incurred for the transposition of the targeted amendments. The costs for the Commission are similar to approach 2.

Stakeholders' feedback

Business stakeholders were in favour of guidance on public procurement (Eurochambres) and did not see the need to modify the rules (BusinessEurope, Dansk Industri). In the stakeholder workshop, joint procurement by the Commission on behalf of the Member States was supported by 53% and guidance on emergency procurement in Member States by 49% of participants.

Conclusion

Policy approach 2 is retained for further analysis based on the following justification.

Policy approach 1 would suggest to adopt new guidance and would rely on voluntary coordination of public procurement action by individual Member States during the crisis. This option would not be efficient, as the Member States may choose not to follow the guidance or Recommendation. In case there would be a need to leverage the purchasing power of the Commission, the Commission would need to procure jointly with the Member States based on the Financial Regulation. This would be more time consuming and less effective and efficient than the possibility of common purchasing by the Commission.

Policy approach 2: Allowing Member States to engage in joint public procurement under the Public Procurement Directives before the Commission would take any procurement action, would take into account the primary role and competence of the Member States in the area of public procurement.

Moreover the guidance could facilitate the use of the existing procurement provisions by the Member States at the time of the crisis, addressing any uncertainties as to how to apply such provisions. Such guidance seems therefore effective, efficient and coherent.

Policy approach 3 would propose targeted amendments of the Procurement Directives allowing Member States to derogate from existing public procurement procedures/suspend the application of the Procurement Directives for procurement of crisis-relevant products during a specific timeframe during the crisis. While this would increase the efficiency and effectiveness of the national crisis response in case of shortages of crisis-relevant goods resulting from severe disruptions of the free movement of goods, persons or services or from disruption of supply chains, it would go further than necessary for the attainment of those objectives. It would also be problematic since there would be no control over the public procurement and no respect for fundamental principles of procurement, such as prevention of corruption and avoidance of conflict of interest would be ensured. It would therefore not be coherent with the EU level public procurement framework.

8. *Building block 8 – Measures impacting crisis-relevant supply chains during emergency*

These are measures that will be applied only after the Single Market emergency mode has been activated and are applicable to the Commission, Member States and those businesses operating in the value chain of goods and products relevant for that particular type of crisis, depending on the design of the options.

Policy approach 1 – Guidance on distribution of strategic reserves + guidance on speeding up permitting procedures + guidance on prioritisation of orders + recommendation to economic operators to share information

This policy approach provides for *costs and benefits* that are considered business as usual for the Commission and Member States. All the measures are of voluntary nature and limited to recommendations and guidance. Companies may acquire indirect economic benefits which will depend on the uptake of the guidance by the Member States and companies. Such indirect benefits are harvested by redressing the functioning of the Single Market during emergencies thanks to adequate availability and allocation of crisis-

relevant goods to tackle the crisis at stake. However, there is likely to be only a very limited take-up of such measures and the benefits for the Single Market and for companies are expected to be very limited.

For information requests to businesses, policy approach 1 which encourages the businesses and the representative organisations to share the necessary crisis-relevant information by means of a recommendation is not capable of addressing the problem of lack of crisis-relevant information on supply chain disruptions and production capacities in a satisfactory manner. It appears that companies cite business secrets, the need to preserve the rating of listed companies, etc. as reasons why they would not wish to share the relevant information with the relevant national authorities and the Commission.

Policy approach 2 – Empowerment for Member States for mandatory information requests and mandatory ramping up of production following industry non-action + recommendations

Member States *costs* to follow the Commission recommendation on distributing previously stockpiled products would be business as usual. The costs related to speeding up permitting procedure might slightly increase by additional resources to deal with the administrative procedures in a quicker and more effective manner. However, such costs depend on each Member State's arrangements and are estimated to be insignificant and will depend on the uptake of Recommendation.

The policy approach 2 gives the empowerment to MS to oblige to ramp-up production, with financial support as appropriate. The number of companies falling under the obligation will depend on the type of crisis and the decision of a MS – these are however the companies operating in the value chains of a limited number of goods or products relevant for a certain type of crisis activated by strict criteria. The economic operators affected by these measures are expected to recover additional investment and operating costs through increased sales and due to financial support from Member States as appropriate.

In terms of costs related to mandatory information requests to companies, the costs are similar with those indicated by the impact assessment on the Single Market Information Tool (SMIT) proposal (option 4)¹¹⁰. For companies affected by mandatory info request the IA estimated costs to be approximately 0.29 million EUR. Costs for Member States were estimated to be up to 0.72 million EUR and costs for the Commission about 0.15 million EUR per year. However, it has to be noted that the measures proposed in SMEI related to information requests to companies are targeted and focused to a limited number of companies in the EU economy, that activate in supply chains that have a crisis – relevance for the Single Market, and for a limited period of time, as long as the emergency is activated. Those information requests will take full account of and will respect the rights to privacy and data protection and freedom to conduct a business activity of the economic operators under Articles 7, 8 and 16 of the EU Charter on Fundamental Rights respectively.

Policy approach 3 – The Commission's right to oblige Member States for mandatory distribution of strategic reserves + Oblige companies to ramp up production + Oblige Member States to speed up permitting procedures + Oblige

¹¹⁰ [Impact Assessment of the SMIT proposal, SWD\(2017\)217](#). The European Commission withdrew this legislative proposal on 29 September 2020.

companies to accept priority-rated orders + Issue mandatory information requests to economic operators

All the obligatory measures under this approach would be subject to individual activation via Commission implementing acts, thus giving the Member States the full control and providing the subsidiarity check.

The *benefits* for this approach are significantly higher than those of approach 2 as it would provide a very strong and effective toolbox to ensure availability of crisis-relevant goods.

The *costs* associated with approach 3 are higher given that Member States and economic operators are subject to mandatory requirements instead of being subject to recommendations that may or may not be followed. These costs will depend strongly on the nature of the crisis.

Stakeholders' views

A number of Member States have voiced concern about including in the scope of the initiative of measures to address difficulties in supply chains, also drawing attention to the need to follow strictly the principles of necessity and proportionality of measures and to avoid the related administrative burden. On the other hand, MS such as PL, RO, EL, AT, LU have spoken in favour of addressing crisis preparedness and supply chains disruptions.

Respondents to the public consultation considered that ramping up production capacity, e.g. by repurposing or extending existing production lines on a voluntary basis was efficient (13 out of 17 respondents), whereas doing so on mandatory basis with government support less so (5 out of 17 respondents). Targeted and coordinated distribution of products relevant for a certain type of crisis was considered efficient by 6 out of 17 respondents. Obligation on undertakings to accept and prioritise orders of goods and services relevant to a crisis in order to enhance their availability during a crisis was considered efficient by 3 out of 16 respondents. Business stakeholders did not support mandatory ramping up of production (BusinessEurope, ERT) and considered that recommendations would be sufficient (Eurochambres), stressing that businesses are best placed to manage their own supply chains (ERT, VDMA). In the stakeholder workshop, recommendations gathered more support than obligatory solutions, with recommendation to businesses to ramp up production capacity of crisis-relevant products was supported by 73% and recommendation to businesses to prioritise orders of crisis-relevant products by 63% gathering particular support.

Most Member States agree in their replies to the Member States questionnaire that in light of future crisis, tools that allow to increase the availability of non-medical goods and critical raw materials (speeding up permitting procedure, targeted mandatory information requests to businesses on their stocks and production capacities, priority rated orders) should be taken. They acknowledge that in most cases, national authorities are best prepared to take such measures.

They also point out in their replies to the Member States questionnaire that the private sector could be further involved in management of stockpiles and the continuity of supply chain. Supply chain-wise, the private sector should have the capacity to switch production from their day-to-day items to key items in times of crisis. Meanwhile, the public sector would continue the coordination efforts, knowing they can rely on the private sector. The public sector may need to finance the additional capacities of the private sector.

In the public consultation, respondents were supportive of targeted information requests from industry in order to manage crisis, on issues such as information regarding current primary disruptions (17 out of 20 respondents said yes and 2 said maybe), production capacities (9 said yes, 9 maybe) and existing stocks of goods (9 said yes, 10 said maybe). Business stakeholders however called for the information to be disclosed on voluntary basis and insisted that industry should not be burdened by excessive requirements, with BusinessEurope, ERT, European and others objecting to disclosure of business confidential information, and even stronger in the context of monitoring. In the stakeholder workshop, in terms of obtaining information from businesses, participants were in favour to encourage voluntary sharing (75%). Member States questioned the inclusion of mandatory information requests and drew attention to the need to respect the principles of necessity and proportionality (letter of nine Member States) and due consideration of possible administrative burdens on businesses, also stressing that information requests should not be mandatory (DE, PL, BG).

Conclusion

All three policy approaches are retained for further analysis.

The policy approach 1 is based on guidance and recommendations. While this could result in some improved availability of crisis-relevant products, it would not lead to direct action and would not guarantee the necessary coordination.

Under policy approach 2, the Member States would be empowered by means of legislation to oblige the economic operators to ramp up their production capacity of crisis-relevant products during the crisis. There would also be a number of recommendations to the Member States. This option would provide an incentive for Member States to act and would give them some means to ensure availability of crisis-relevant products, but would not significantly enhance their possibility of action and would not assure coordinated crisis response at the EU level. In terms of data requests, the required coordination between the national level authorities and the Commission would also take time and might therefore not make the information available to all the Member States in a speedy manner.

Policy approach 3 offers the strongest toolbox for direct action and provides for such a toolbox at the EU level. This approach is expected to provide the strongest means of direct action in the last resort situation and would be most effective in terms of ensuring the availability of crisis-relevant products in the times of crisis that requires quick and efficient response. In terms of information requests, this approach would provide for a quick and timely solution, but requires the cooperation of the Member States in identifying the relevant companies that are affected by crisis-relevant supply chain disruptions. Policy approach 3 however may raise potential concerns as to the subsidiarity of the proposed measures.

ANNEX 7: SME TEST

The initiative is considered as relevant for SMEs.

Step 1/4: Identification of affected businesses

With regards to the **main affected businesses**, to the extent that the instrument will improve the overall EU crisis response, all businesses and SMEs will benefit.

In particular for what concerns the measures on key principles for free movement and supporting measures, as well as transparency and administrative assistance, the benefits of these measures will apply widely to all companies operating across borders on the Single Market, as well as their customers and suppliers, as these measures will improve the flow of goods, services and persons and legal clarity and predictability associated with the possible restrictions of free movement. Many of such businesses are SMEs.

For measures in building blocks 6-8, i.e. placing the products on the market during emergency, public procurement during emergency, and measures on supply chains during emergency, the measures in these building blocks will affect more specifically the businesses involved in the relevant sectors and supply chains, i.e. producing and trading of crisis-relevant products and services. The specific sectors concerned will depend on the nature of the crisis.

Key question:

To what extent is the initiative relevant for SMEs? (not relevant, relevant, highly relevant)

This initiative is considered relevant for SMEs as they represent 99% of all EU companies. The initiative was considered as relevant for SMEs by the SME Filter.

Step 2/4: Consultation of SME Stakeholders

Individual SMEs did not submit specific observations in the context of the public consultation questionnaire. Business organisations representing SMEs, and in particular SMEUnited, participated in the stakeholder workshop on 6 May 2022. SMEUnited also submitted a position paper, in which it expressed support for the initiative and in particular for measures such as EU and national single points of information, facilitation of free movement of workers, acceleration of conformity assessment procedures during crises, as well as preventative measures such as a monitoring system to anticipate future shortages and a possibility to oblige companies to prioritise orders in times of crisis.

The planned initiative was presented and discussed during a meeting with SME associations (in the context of a Small Business Act follow-up meeting) on 11 May 2022. SMEs aspects were also discussed in the meeting with the SME Envoy Network on 20 May 2022 were also observers such as business organisations representing SMEs participated. The general comments expressed in that discussion included a call for the initiative to be focused on the functioning of the Single Market, notably free movement, rather than looking at preparedness elements. In particular for stockpiling, the costs on businesses have to be analysed. For notifications, there was a call to use the existing structures such as TRIS for disseminating information to businesses and citizens.

Step 3/4: Assessment of the impact on SMEs

As all companies, SMEs will benefit from the overall better EU-level crisis response due to less obstacles to free movement and better availability of crisis-relevant products.

Under Policy Option 1, SMEs are likely to be specifically affected by the measures under building blocks 3-8. SMEs will benefit from promotion of match-making (block 3). SMEs are particularly affected by the obstacles to the free movement and the lack of transparency of measures as their activities could be easily disrupted by restrictions especially in cross-border regions. Therefore the positive impacts of easing free movement (block 4) are expected to be especially pronounced for SMEs. They will particularly benefit from better transparency (block 5). SMEs will benefit from the possibility to place products faster on the market (block 6). Finally, SMEs may be somewhat affected by the joint procurement, however the precise effect is impossible to predict as it will depend on the nature of the crisis. Nevertheless it is possible that due to the larger overall size of tenders, SMEs may have less opportunities to win such a tender (block 7). Under Policy Option 1, it is not expected that SMEs would be impacted by voluntary measures such as information requests or stockpiling or prioritising orders (block 8) as companies will be able to decide on their own if they are willing to participate in these measures. Under this Policy Option 2, SMEs could be additionally affected by some of obligatory measures in block 8. In particular certain SMEs in key sectors for the crisis response could be affected by the mandatory information requests and by the obligation to ramp up their production capacity. For SMEs it could be easier to constitute data on production capacity and supply disruption in the case of an SME due to its size but at the same time SMEs have less resources and more limited capabilities to deal with such information requests. The obligation to ramp up production capacity with appropriate financial support from Member States could be net beneficial for SMEs in question. Under Policy Option 3, the effects (positive and negative) could be even more important for SMEs than for all companies. In particular, priority-rated orders could impact the whole production capacity of SMEs, whereas for larger companies they may represent only a fraction of their production as they may have diversified production portfolio. Speeding up permitting could be decisive for economic success of an SME in a crisis situation. Distribution of strategic reserves could also be of a very high benefit to the SMEs that would be concerned and their customers and suppliers. Like under Policy Option 2, for mandatory information requests, it could be easier to collect the data on production capacity for an SME due to its smaller size, however SMEs may have less resources and more limited capabilities to deal with such requests. The obligation to ramp up production capacity with appropriate financial support from Member States could be net beneficial for SMEs in question.

Overall, no costs for SMEs are therefore expected under Policy Option 1. SMEs could be particularly negatively affected by the mandatory information requests under PO2 and PO3. SMEs could particularly benefit from the obligation to ramp up production with appropriate financial support under PO2 and PO3. SMEs could further benefit from measures to speed up permitting and from priority-rated orders under PO3.

Step 4/4: Minimising negative impacts on SMEs

Some measures have been considered to mitigate the impacts on SMEs. These are:

- For measures likely to lead to strong impacts and potential costs for SMEs, in particular measures under block 8 such as mandatory information requests, requests to ramp up production and to accept priority-rated orders, during the additional activation of such measures specific analysis and assessment will be done as to their impact and proportionality, in particular their impact on SMEs, by the Commission in consultation with the governance body. This assessment will be part of the process of additional activation of these specific measures by a Commission implementing act (additional to the overall triggering of the emergency mode).
- When designing the tools to be used for retrieving information requests from companies, particular attention will be paid to make them easy to operate, thereby reducing costs, in particular for SMEs.
- Depending on the nature of the crisis and the concerned strategic supply chains and crisis-relevant products, specific accommodations will be provided for SMEs. While it is not possible to exempt microenterprises completely from the scope of measures such as mandatory information requests, as these enterprises may have specific unique know-how or patents of critical importance in a crisis, specific accommodations will include simplified survey designs, less onerous reporting requirements, and longer deadlines for responses, to the extent possible in view of the need for urgency in the context of a specific crisis.

ANNEX 8: OVERVIEW OF RESILIENCE MEASURES OF KEY INTERNATIONAL PARTNERS

This annex provides an overview of resilience measures taken by our key international partners for comparison and reference. It does not prejudge our possible assessment of these measures in terms of their compliance with WTO rules.

Table of Resilience Measures

1. Early Warning System: Market and Supply Chain Monitoring, In-depth Analysis
2. Collection of Key Supply Chain Information from Member States and Industry
3. Funding/Subsidies, Tax Incentives, Support to Investments, R&D etc., in Specific Sectors/Values Chains
4. Public Procurement Measures Used in Support of Domestic Production Capacities, Resilience, and Security of Supply, etc.
5. Stockpiling of Critical Inputs
6. Prioritisation of Supplies of Goods and Services
7. Trade Policy measures such as Tariffs, Export Restriction, Anti-coercion Measures
8. Specific measures for Critical Raw Materials
9. Specific Measures for Semiconductors

Included Countries: US, UK, Japan, China, Singapore, Korea, India, Australia

Early warning system: market and supply chain monitoring, in-depth dependencies, industrial capacities, etc.)

- **US: Executive Order 14017 ‘America’s Supply Chains’:** 100-days in-depth reviews of in semiconductors, high-capacity batteries, including for electric vehicles; critical and strategic minerals, pharmaceuticals and their active ingredients. Results and recommendations to ensure resilient supply 2021 and February 2022.
- **US:** Supply Chain Disruption Task Force coordinating inter-agency process on supply chain issues.
- **Korea:** Korea has an **early warning system** in place to monitor 20 key raw materials to ensure stable s
- The **Quad** (US, Australia, India, and Japan) has set up a **Critical and Emerging Technology Wo** improve the security of supply chains for critical technologies.
- **Japan: Economic Security Promotion Act (ESPA)** will select “*designated critical commodities*” and ensuring their steady supply chains that will analyse potential bottlenecks, required measures and a sectors with deadlines, funding, etc.
- **Singapore:** Singapore has **established a Future Economy Planning Office (FEPO)** within its M (MTI). FEPO’s key roles include develop industry transformation maps (ITMs), to secure Singapore’s e
- **Singapore:** Within Singapore’s Prime Minister Office resides the Centre for Strategic Futures (CFS). whose mission is to position the Singapore government to navigate emerging strategic challenges and h Latest publication: the Driving Forces Card.
- **UK:** Department of International Trade established a Global Supply Chains Directorate in April 2020 critical global supply chains. The directorate will prioritise by criticality the UK’s supply chains, assess maturity of the UK’s response.
- **Australia:** In 2021, The Australian government created the Office of Supply Chain Resilience under th monitor Australian supply chains’ resilience.
- **Australia and the UK** set up a joint Australia-UK supply chain resilience capability building initiati shared understanding and insight about common dependencies and critical supply chain risks.

Collection of key supply chain information from industr

- **US: The Defense Production Act (DPA)** allows the US government to obtain information from bus needed for industry studies.
- **US: Subpoena power of the Federal Trade Commission** enables the consumer protection agen companies to turn over information for research purposes, a power it has used to study the privacy pra and start-up acquisitions by the five U.S. tech giants, among other areas.
- **Japan: Under ESPA** Business operators (including foreign) engaged in the production, import or *commodities*” may be required to report data on the production, import, sale, procurement or storage o raw materials, and may be subject to on-site inspections.
- **Australia:** The Security of Critical Infrastructure Act 2018 creates a register for Critical Infrastruc picture of critical assets ownership. The Act also empowers the Department of Home Affairs to obtain c

assets, notably in the case of cyberattacks.

Funding/subsidies, tax incentives, support to investments, R&D etc., in supply chains

- **US: Energy Storage and Tax Incentive and Deployment Act** creates investment tax credit for energy storage. **Competition Act: \$250 billion supply chain resiliency and crisis response program** (to be adapted and piloted).
- **US: Investment and Infrastructure Jobs Act** makes available \$1.2 trillion investment in transportation infrastructure with domestic preference requirements (Buy America) attached.
- **US: The Export-Import Bank** offers medium- and long-term loans and loan guarantees available for "export-oriented manufacturing projects," with a particular focus on sectors such as semiconductors, biotech and bio-pharmaceuticals, energy, and energy storage.
- **Japan: State-owned Japan Oil, Gas and Metals National Corporation (JOGMEC)** supports supply chain development by Japanese companies through equity capital and liability guarantees. Investment by JOGMEC in projects involving Japanese companies to diversify supply. Its purpose, scope, structure, and obligations are defined in the ACT.
- **Japan:** Under the planned revision of JOGMEC ACT to be submitted to the Diet JOGMEC is to support Japanese businesses' rare earths exploration and refining operations¹¹¹.
- **Japan: Under ESPA,** specific companies supplying designated critical commodities can receive a variety of support to meet their needs, including financial and fiscal support (e.g., subsidies) over medium to long term. Materials designated as *special goods* will receive additional public support.
- **Japan: Under ESPA,** the government will designate *critical technologies* that will be eligible for public support in space science, marine science, quantum science and AI.
- **Supply Chain Resilience Initiative by Australia, India, and Japan** to cooperate on supply chain resilience in the Asia-Pacific region. Cooperation consists of sharing of best practices on supply chain resilience; and holding an investment matching event.
- **Australia:** Australia's Supply Chain Resilience Initiative provides businesses up to \$2 million to establish manufacturing capability or a related activity to address supply chain vulnerabilities for a critical product or input. The **Manufacturing Capability Plan**. The main new policy tool established in September 2021 is the **Supply Chain Resilience Initiative**.

¹¹¹ The revised legislation is reported to: i) increase the ceiling of JOGMEC's loan and investment ratio by expanding government's support through JOGMEC from the current level of 50% to 75% of investment in projects; ii) allow JOGMEC to invest in or grant debt guarantees to domestic Japanese mineral-refining operations (at present JOGMEC can only support refining operations overseas, in practice in China); iii) allow JOGMEC to actively support overseas mining and projects involving Japanese companies (risk money support).

improve access to critical products in times of crisis.

- **Korea: ‘Korean New Deal’** on investment in digital infrastructure with tax rebates for R&D and for fa
- **China:** Significant amounts of state aid in strategic sectors – consumer subsidies and rebates, exemption on R&D and public procurement are some examples of advantages received by New Energy Vehicle decade (estimated at more than USD 100 billion).
- **Singapore:** Singapore’s research priorities and funding have been detailed in the Research Innovation (RIE2025). RIE2025 gives priority to health, sustainability, digital economy, advanced manufacturing respond to new technological and societal driving force.
- **Singapore:** In February 2021, Singapore has announced the establishment of the **Southeast Asia Mar** tripartite alliance (public-private) to secure supply chain resilience in the region. Grants up to S\$ 1, Economic Development Board of Singapore (The Ministry of Trade and Industry’s economic develop Singapore (government agency for business development) provides matching events and platform “Strategic Partners” offer preferential services (reduced costs on leasing and logistics) for businesses tha

Public Procurement Measures Used in Support of Domestic Production C and Security of Supply, etc.

- **US: Buy America** - The Infrastructure Investment and Jobs Act (IIJA), enacted in November 2021 requirements to all federally funded infrastructure projects. All iron, steel, manufactured products, and produced in the United States. A product is considered to be manufactured in the US if 55% of its comp
- **US: ‘Buy American’ rules** for procurement not covered under the WTO Agreement on Government I all U.S. federal government agency purchases or federally financed purchases of goods valued over the 10 000). To be considered as being produced in the U.S., goods must be manufactured in the U.S. and components must come from the U.S. Waivers can be granted for the public interest, non-availability o unreasonable compared to equivalent foreign products. IT and “Commercial off-the-shelf” products ar how this will affect the US’ international commitments under the Government Procurement Agreement
- **China:** China applies Buy National policy, with a few exceptions. Under its Government Procurement access barriers, including “buy national policy” and “indigenous innovation,” which give preferential developed locally. In theory, foreign-invested companies in China are to be treated like domestic comp companies are preferred. For example, the 2006 Medium and Long Term National Plan for Science directs government agencies to buy products listed in certain procurement catalogues, which incl innovation products (with few exceptions).
- **Japan: Under ESPA,** the government will designate critical, core and sensitive infrastructures in railways, gas, oil etc. The government will have the right to pre-screen any projects in those sec potentially order operators to change suppliers or abandon transactions.
- **India:** India’s 2017 “Preference to Make in India” Order gives preference to local production of goods products within public procurement markets. The Order introduces classes suppliers (Class I, II and no how much local content those suppliers use (above 50%, 50%> and 20%> respectively). Sensitive sect require the supplier to be Class I or II for a bid to be eligible. Greatest procurement priority is allocated highest percentage of local content and the government may mandate technology transfers.

Stockpiling of Critical Inputs

- **US:** The U.S. Department of Energy (DOE), Department of Defense (DoD), and Department of State (DoS) signed a Memorandum of Understanding (MOU) that sets the foundation for a critical minerals stockpile to support the U.S. transition to clean energy and national security needs. DoD, which manages the National Defense Stockpile (NDS), currently stockpiles critical minerals for national security purposes. The MOU creates a new, interagency process for stockpiling minerals that enable vital clean energy and national security purposes.
- **Japan:** JOGMEC operates a national stockpiling system of rare metals to secure long-term raw materials sufficient to meet 60 to 180 days' demand. In addition, under the planned **Mining Act** to be adopted in 2023, Japan will have access to rare-earth resources in Japan's exclusive economic zone (offshore deposits).
- **Korea:** State owned **Korea Resources Corporation** runs a stockpile storage system for rare metals.
- **China:** it is estimated that China stockpiles 1.5 million to 2 million tons of copper, 800,000-900,000 tons of zinc, and 400,000 tons of zinc. China is also believed to have around 7,000 tons of cobalt, a key metal used in batteries.
- **Singapore:** Particularly in the field of food, the government can use its discretionary power to ensure national food security stockpiles, which need to be maintained for a stipulated period of time (such as the Rice Stockpile). Singapore, Malaysia and Indonesia imports, Singapore has stockpiles of food to prevent crisis. The presence of the stockpiles can affect their negotiation with overseas suppliers.
 - **UK:** The UK is creating **strategic reserves** of water treatment chemicals: monitoring stockpile requirements
- **Australia:** Australia maintains a National Medicine Stockpile storing medications, vaccines, antidotes to prevent supply chain disruptions in the health sector.

Prioritisation of Supplies of Goods and Services

- **US: The Defense Production Act** gives the US President the authority to expedite and expand the production of goods and services from the U.S. industrial base needed to promote the national defence. DPA authorities may be used to:
 - Require acceptance and preferential performance of contracts and orders.
 - Provide financial incentives and assistance for U.S. industry to expand productive capacity and supply chain purposes.
 - Provide antitrust protection for businesses to cooperate in planning and operations for national defence and homeland security.
 - The DPA provides authority to obtain information from businesses, including information needed for national defence and homeland security.
 - US will establish a DPA Program to provide loans, grants, and other financing to build and expand the industrial base.
- **China: Dual Circulation Strategy** is a new paradigm being rolled out since summer 2020. It calls for strengthening the large domestic market and leveraging/building its strengths, including comprehensive and deep supply chain integration with the rest of the world are also encouraged, not discouraged, but 'domestic circulation' must be able to cope in case of problems with foreign supplies.
- **UK: Via UK Make,** the UK is encouraging development of domestic production capacities for PPE with

Trade & Investment Measures such as Tariffs, Export Restriction, Anti-

- **US: “Section 232 investigations”** can lead to the imposition of tariffs on third country imports and information from companies and stakeholders.
- **US:** The DPA sets up the Committee on Foreign Investment in the United States (CFIUS). CFIUS can review and impose conditions on the acquisitions or refer the case to the President for decision. Australia, is exempted from review by CFIUS but the EU is not.
- **Korea: Promotion of tech acquisition through overseas M&A** for areas where it is difficult to secure items in domestic value chain. Acquisition funds of EUR 2 billion + advisory, consulting, and follow-up
- **China: Export Control Law** is a comprehensive framework for restricting exports of military and dual-use for national security and public policy reasons. Exports and transfers of products, technology, and services may be prohibited based on the product features, end-users, destinations, or end-user requirements and may be prohibited based on the product features, end-users, destinations, or end-user requirements and may be prohibited based on the product features, end-users, destinations, or end-user requirements. Imposition of temporary export controls on non-listed goods, services, and technology up to two-years. Products subject to export control also includes all rare earth metals.
- **UK:** The UK passed in 2021 the National Security and Investment Act (NSIA). NSIA sets up a FDI screening regime requiring notifications to the government for acquisitions in 17 “most sensitive” economic sectors, including energy. The government can review and potentially block acquisitions if they risk undermining the UK’s national security.
- **Australia:** Reforms to the Foreign Investment Review Board (FIRB) in 2020 introduced a mandate for FIRB to review acquisitions connected to “national security business” or “national security land” or linked to critical infrastructure cover 15 sectors including electricity, gas, water, port, healthcare and cloud among others. FIRB can divestment or prohibit the acquisition if it finds that it could present risks to national security.
- **US:** Export Control Reform Act allows the US government to enact controls on exports, re-exports of foundational technologies if they could be used to threaten the national security of the US or if they could provide an intelligence advantage to the US. 14 emerging technologies are identified, including biotech, AI and semiconductors.

Specific Measures for Critical Raw Materials

- **Korea:** has an **early warning system** in place to monitor 20 key raw materials to ensure stable supplies
- **US: Executive Order ‘America’s Supply Chains’:** in-depth reviews of industrial bases. The reviews include detailed questionnaires, as well as recommendations for strengthening resilience.
- **US: ‘section 232 investigations’** serves to collect market information from companies and stakeholders. The US has launched two investigations, on aluminium and steel, which conclusions led to tariff hikes of 10 and 25%. Investigations on vanadium and titanium sponges have not led to actions yet.
- **US: Executive Orders 13817** (A Federal Strategy To Ensure Secure and Reliable Supplies of Critical Minerals (Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals From Foreign Sources) and the Domestic Mining and Processing Industries). EO13817 launched an in-depth review of critical minerals for the US economy and national defence and looked into expanding mining production in the US. EO13817 directed the Interior to produce every 180 days a report on critical minerals supplies and potential risks from foreign sources.
- **Japan: JOGMEC** supports exploration and technological development by Japanese companies through investment guarantees. Investment by JOGMEC in rare earth overseas projects involving Japanese companies to ensure stable supplies. Scope, structure, and obligations are defined in the JOGMEC ACT.

- **Japan:** Under the planned revision of JOGMEC ACT to be submitted to the Diet JOGMEC is to support Japanese businesses' rare earths exploration and refining operations¹¹².
- **Japan:** JOGMEC operates a national stockpiling system of rare metals to secure long-term raw materials sufficient to meet 60 to 180 days' demand. In addition, under the planned **Mining Act** to be adopted, access to rare-earth resources in Japan's exclusive economic zone (offshore deposits).
- **Korea:** State owned **Korea Resources Corporation** runs a stockpile storage system for rare metals.
- **China:** big state-owned enterprises are encouraged to take a leading role in their sectors, to ensure maximum government directives and maximum benefit for China. The government actively supports consolidation, which is often also state-owned.
- **The UK and Australia:** The two countries have set up Working Group on critical minerals in 2020, continuing to identify investment opportunities that would bolster Australia's critical minerals sector and support energy ambitions.
- **UK: Plans to adopt the Critical Minerals Strategy later this year** to set out steps to ensure the UK is self-sufficient for critical minerals. It will help create the conditions needed to grow this vital sector and set out how the UK and other countries to create international standards and ensure supply chains are robust.
- **UK:** The UK also plans to establish the **Critical Minerals Intelligence Centre**, which will provide ongoing analysis of supply of and demand for critical minerals.

Specific Measures for Semiconductors

- **US: Chips Act** to include a \$52 billion budget directed towards domestic semiconductor research, development and production, and Senate are currently trying to agree on a common bill, which is supposed to be adopted before the start of 2023.
- **US: The Facilitating American-Built Semiconductors (FABS) Act**, still under discussion is to provide tax credits. The bill has not been adopted yet.
- **Japan:** Specific subsidies have been proposed in ESPA, targeted at the semiconductors sector to support a package worth approx. JPY 800 billion (EUR 6.15 billion) to support the domestic semiconductor industry, including the construction of the Taiwan Semiconductor Manufacturing Co. (TSMC) chip plant in Kumamoto Prefecture.
- **Korea: Korean tax incentives and subsidies to chipmakers** to encourage them to spend a combined total of 1.5 trillion KRW to facilitate Korea becoming a global powerhouse in memory and non-memory chips.
- **China:** Tax breaks, cheaper utility rates, low-interest loans, free or discounted land for chipmakers to support production and to advance technology and to incentivize reshoring and development of local capacity (foreign investment for these breaks).

¹¹² The revised legislation is reported to: i) increase the ceiling of JOGMEC's loan and investment ratio by expanding government's support through JOGMEC from the current level of 50% to 75% of investment in projects; ii) allow JOGMEC to invest in or grant debt guarantees to domestic Japanese mineral-refining operations (at present JOGMEC can only support refining operations overseas, in practice in China); iii) allow JOGMEC to actively support overseas mining and projects involving Japanese companies (risk money support).

List of Acronyms

DPA: Defense Production Act, **US**
EBA: European Battery Alliance, **EU**
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ESPA: Economic Security Promotion Act, **Japan**
FABS: Facilitating American-Built Semiconductors Act, **US**
FEPO: Future Economy Planning Office, **Singapore**
FIRB: Foreign Investment Review Board, **Australia**
GPA: Government Procurement Agreement – **Multilateral Agreement**
IIJA: Infrastructure Investment and Jobs Act, **US**
IPCEI: Important Project of Common European Interest, **EU**
IPI: International Procurement Instrument, **EU**
JOGMEC: State owned Japan Oil, Gas and Metals National Corporation, **Japan**
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Trade & Investment Measures such as Tariffs, Export Restriction, Anti-

- **US: “Section 232 investigations”** can lead to the imposition of tariffs on third country imports and information from companies and stakeholders.
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Brussels, 19.9.2022
SWD(2022) 289 final

PART 2/2

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

for a Single Market Emergency Instrument

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

and DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

{COM(2022) 459 final} - {SEC(2022) 323 final} - {SWD(2022) 288 final} -
{SWD(2022) 290 final}

Annex 9
Detailed mapping of Existing Emergency Instruments and Responses

Emergency instrument/measure	Status	Responsible DGs/bodies	Main features of possible use for SMEI	Crisis Definition	Triggering and De-triggering	(Non-)Regulatory Instruments	
COORDINATION AND INFORMATION EXCHANGE							
1	Integrated Political Crisis Response (IPCR) Mechanism	Council Implementing Decision Existing mechanism	Council	<p>The integrated political crisis response (IPCR) arrangements support rapid and coordinated decision-making at EU political level for major and complex crises, including acts of terrorism. Through this mechanism, the presidency of the Council coordinates the political response to the crisis by bringing together EU institutions, affected member states and other key actors.</p> <p>Why IPCR is not sufficient for SM crisis impacts (governance, coordination and response)</p> <ul style="list-style-type: none"> - It does not allow for technical level discussion, analysis and fact-finding, needs to be requested to intervene by any Member State concerned 	<p>Crisis: Article 3(a)*: “‘Crisis’ means a situation of such a wide-ranging impact or political significance, that it requires timely policy coordination and response at Union political level”.</p> <p>2 Cumulative Elements: 1) Wide-ranging impact or political significance + 2) Requirement of timely policy coordination & response at Union level</p>	<p>Two Modes: (Article 2(1)(2),(b))*:</p> <ul style="list-style-type: none"> • Information sharing mode (pre-stage) to establish the situation & prepare for possible full activation • Full activation mode to prepare response measures <p>Activation: (Article 4)*:</p> <ul style="list-style-type: none"> • Article 4(1)*: Presidency takes IPCR activation decision (initiative by Member States possible) • Article 4(2)*: Triggering upon invocation of solidarity clause (Article 222 TFEU) – still formal adoption by Presidency • Article 4(5)*: “The decision to activate the IPCR in <u>information sharing mode</u> may also be taken by agreement of the GSC, the Commission services and the EEAS, in consultation with the Presidency” 	<p>*Council Implementing Decision (EU) 2018/1993 of 11 December 2018 on the EU Integrated Political Crisis Response Arrangements L 320/28] EUR-Lex - 32018D1993 - EN - EUR-Lex (europa.eu)</p>

						<p>Switching between modes:</p> <ul style="list-style-type: none"> • Article 4(6)*: the Presidency may decide at any point to escalate or de-escalate the operation from one mode of activation to the other (exception: solidarity clause invocation requires full mode) <p>Deactivation: (Article 5):*</p> <ul style="list-style-type: none"> • Decision taken by Presidency after consultation with Member States, Commission and the HR (no deactivation when solidarity clause is invoked) 	
2	European Alliance Against Coronavirus	Ad-hoc group	GROW	An open forum joining social and industrial clusters with many other private and public agents and institutions created by European Clusters Alliance – daily meetings at the height of the crisis. Participation of up to 1100 experts daily. Direct feedback from industry to the Commission.	--	--	--
3	EU Rapid Alert Function	Ad-hoc solution Regulations	GROW	Objective is to detect, analyse, and report disruptions in value and supply chains. During its functioning, 84 disruptions were identified and reported and remedial actions proposed.	No specific definition of a disruption. Specifications in “Procedure for Handling Rapid Alerts Arising from Quality Defects” as part of the “Compilation of Community Procedures on Inspections and Exchange of Information” – published by EMEA in agreement with the European	Form of “activation” of network: Member states send alert notifications to the Commission without undue delay , at the latest within 48 hours after the (product) risk has been reported to them. The Commission then transmits alert notifications	*Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed (RASFF) Commission Regulation (EU) No

					<p>Commission with regard to defective medicinal products:</p> <ul style="list-style-type: none"> • There it states that only alerts shall be transmitted “whose urgency and seriousness cannot permit any delay in transmission”. (p. 3, No. 3.1) – cf. also: “when urgent action is required to protect public health and animal health” (p. 3, No. 1) • Further clarification: professional assessment of the “seriousness of the defect, its potential for causing harm” to patients, animals, consumers, operators, environment and “the likely distribution of the affected batch(es)” required • Classification in different classes of defects (potentially life threatening, etc.) 	<p>to all members of the network within 24 hours (upon verification) – border rejection notifications are transmitted without undue delay (cf. Articles 3, 5)*</p>	<p>16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed Text (europa.eu)</p> <p>Cf. also Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety EUR-Lex - 32002R0178 - EN - EUR-Lex (europa.eu)</p>
4	EU Rapid Alert system Function	Existing mechanism: European Union Rapid Information System (Safety Gate/RAPEX)	DG JUST	Rapid exchange of information between Member States about dangerous products.	<p>No specific definition of a disruption, but explains the emergency situation posed by a dangerous consumer product: Art 12 (1) of the GPSD: “Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible</p>	<p>Form of “activation” of network: Member states send alert notifications about dangerous products to the Commission. The Commission verifies, validates and transmits alert notifications to all Members of the network. Deadlines are set up by the “RAPEX Guidelines”*.</p>	<p>Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (GPSD) and *Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid</p>

					marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX. “ Where, in addition, a product poses a life-threatening risk and/or there have been fatal accidents, and in other cases where a RAPEX notification requires emergency action by all Member States, the notifying Member State submits to the Commission a ‘ Notification requiring emergency action ’.	Information System ‘RAPEX’ established under Article 12 of Directive 2001/95/EC on general product safety and its notification system.
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HEALTH, VACCINATION AND RELATED PRODUCTION CAPACITY

1	EU Vaccines Strategy and Joint Vaccine Procurement	Communi- cation	SANTE	<p>15 October 2020 - Commission has presented key elements to be taken into consideration by Member States for their COVID-19 vaccination strategies, in particular to ensure:</p> <ul style="list-style-type: none"> • Capacity of vaccination services to deliver COVID-19 vaccines, including skilled workforce and medical and protective equipment • Easy and affordable access to vaccines for target populations and priority groups • Deployment of vaccines with different characteristics and storage and transport needs, in particular in terms of cold chain, cooled transport and storage capacity • Clear communication on the benefits, risks and importance of COVID-19 vaccines to build public trust 	<p>No definition. However, the instrument is a reaction to the specific current crisis (pandemic) – cf. reference to the scale of the current COVID-19 crisis (cf. pp. 1, 9) and to the exceptional state of a “public health emergency” (p. 8)*.</p> <ul style="list-style-type: none"> • Cf. “The Commission is therefore proposing a Regulation to derogate temporarily - only for the period during which COVID-19 is regarded as a public health emergency - from certain provisions of the GMO Directive for clinical trials with COVID-19 vaccines (and also COVID-19 treatments) that contain or consist of GMOs. This proposed derogation will apply to the operations necessary for the clinical trial phase and for compassionate or emergency use in the context of COVID-19” (p. 8*). 	<p>*Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank – EU Strategy for COVID-19 vaccines communication-eu-strategy-vaccines-covid19_en.pdf (europa.eu)</p>
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				Coherent with joint procurement of vaccines via (advanced) purchase agreements and fair distribution of available vaccines to the MS.			
2	European Health Union	Legislative proposal	SANTE	<p>11 November 2020 – Publication of a set of proposals to strengthen the EU's health security framework, coordination, and to reinforce the crisis preparedness and response role of key EU agencies. In particular:</p> <ul style="list-style-type: none"> • New Regulation on serious cross-border threats to health (National pandemic preparedness plans, recommendations, reporting and auditing; integrated surveillance system at EU level; data reporting by MS; declaration of emergency situation; improved joint procurement for medicinal counter-measures and stockpiling) • With this stronger and more comprehensive legal framework, the Union can react rapidly and trigger the implementation of preparedness and response measures to cross-border threats to health across the EU • Reinforce ECDC's mandate (epidemiological surveillance; preparedness and response planning, reporting and auditing; risk management; capacity to mobilise and deploy EU Health Task Force to assist local response in Member States; network of EU reference laboratories) • Reinforce EMA's mandate (monitoring and mitigating the risk of shortages of critical medicines and medical devices; 	<p>Public health emergency: Article 2(1)(e)*: in order for the Regulation to apply, the threats need to fall under the categories of serious cross-border threats to health set out in (a) – (d): threats of biological/ chemical/ environmental/ climate/ unknown origin.</p>	<p>Recognition of emergency situations: Article 23(1):* “The Commission may, based on the expert opinion of the Advisory Committee referred to in Article 24, formally recognise a public health emergency at Union level; including pandemic situations where the serious cross-border threat to health in question endangers public health at the Union level.”</p> <p>2 Cumulative Elements for recognition: 1) Serious cross-border threat to health + 2) Endangerment of public health at Union level</p> <ul style="list-style-type: none"> • Prior liaising with the WHO (Article 23(3)*) • Adoption by means of implementing acts • Examination procedure in Article 27(2)* • Exception (Article 23(4), subpara. 3*): for cases where this is duly justified on imperative grounds of urgency related to the severity of a serious cross-border threat to health or due to the rapidity of 	<p>*Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU EUR-Lex - 52020PC0727 - EN - EUR-Lex (europa.eu)</p>

				scientific advice on medicines; coordinating studies and clinical trials to monitor the effectiveness and safety of vaccines)		<p>its spread among Member States – more expeditious procedure: immediately applicable implementing acts to recognise a public health emergency</p> <ul style="list-style-type: none"> • “The new rules will enable the activation of EU emergency response mechanisms, in close coordination with the World Health Organization (WHO), without making it contingent upon the WHO’s own declaration of a Public Health Emergency of International Concern (PHEIC).” (cf. No. 3, p. 7**) • Enabling effect of measures following the recognition (Article 25*) (recitals 18, 19*) <p>Termination: Article 23(2)*: termination as soon as one of the applicable conditions is no longer met.</p>	**Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats communication-european-health-union-resilience_en.pdf (europa.eu)
3	HERA Incubator and HERA	Preparedness plan and a plan for a possible future authority	SANTE/ GROW	17 February 2021 - The EU is setting up a European bio-defence preparedness plan “HERA Incubator” against COVID-19 variants to bring together researchers, biotech companies, manufacturers, regulators and public authorities to monitor	HERA: Public health emergency: Article 2(2)*: “‘Public health emergency’ means a public health emergency at Union level recognised by the Commission in accordance with	HERA: Activation: <ul style="list-style-type: none"> • Recognition of a public health emergency required (cf. Article 2(2)*) 	*Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the

variants, exchange data and cooperate on adapting vaccines. The plan will focus on:

- Detecting, analysing and adapting to virus variants;
- Speeding up regulatory approval of vaccines, providing guidance on data requirements and facilitating the certification of new or repurposed manufacturing infrastructures;
- Supporting the speedy mass production of adapted or novel COVID-19 vaccines
- Support for EU countries to carry out more testing and genome sequencing by developing specialised tests for new variants, with at least €75 million in EU funding and prepare for adapting vaccine and vaccine production capacity
- “EU FAB” project: a network of single or multi-user, single or multi-technology emergency response production capacity for vaccine and medicine manufacturing at European level;
- VACCELERATE, a clinical trials network making cooperation and data exchange during clinical trials on COVID-19 vaccines much smoother

Article 23 of Regulation (EU) No.../...[the SCBTH Regulation”, i.e. Regulation (EU) No .../... of the European Parliament and of the Council of ... on serious cross-border threats to health and repealing Decision No 1082/2013/EU].

“Europe needs to be better prepared to anticipate and address jointly the ongoing and increasing risks, **not only of pandemics but also of man-made threats such as bioterrorism.**”**

- **Article 3(1):** upon proposal of the Commission, the Council “**may adopt a regulation activating the emergency framework** where appropriate to the economic situation.”
- **Article 3(3)*:** Duration of the activation is limited to 6 months, but renewable (Article 4* procedure)
- **Funding:** Activation of emergency funding, Article 13*: “Where this measure is activated, emergency support under Regulation (EU) 2016/369 is activated to finance expenditure necessary to address the public health emergency [...]”
“In the event of a public health emergency at Union level, in order to ensure the necessary flexibility and rapidity in implementation, the Council could also trigger financing through the Emergency Support Instrument (ESI), demonstrated in the past to be both flexible and fast. During the COVID-19 crisis, the ESI27 proved efficient and effective in ensuring rapid and flexible funding,

event of a public health emergency at Union level
[hera_2021_propcouncereg_medical-countermeasures_en.pdf \(europa.eu\)](#)

**Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union
[hera_2021_comm_en.pdf \(europa.eu\)](#)

The HERA Incubator will lay the foundations for a possible future fully-fledged bio-preparedness authority, the European Health Emergency Preparedness and Response Authority (HERA). An EU authority for bio-preparedness could remediate structural gaps in the EU's health preparedness and response capacities with regard to biomedical development, production and surge capacity development. It could also provide a horizon scanning function, focusing on emerging biomedical technologies that can be scaled-up for real-world application during times of crisis. The authority would engage with industry, science, academia and clinical research organisation networks, with the aim of

HERA Incubator:
No crisis definition***

- essential in times of urgency” (p. 13, No. 6.3**)
- “The Council activation of the emergency framework will also specify which of the [...] emergency measures, appropriate to the economic situation, should be implemented” (p. 9, No. 4)**
- Two phases: "preparedness phase" and "crisis phase". In the “crisis phase”, HERA will be able to draw on stronger powers for swift decision-making and implementation of emergency measures. (p. 2, No. 2**)

***Communication from the Commission to the European Parliament, the European Council and the Council HERA Incubator: Anticipating together the threat of COVID-19 variants COM/2021/78 final [EUR-Lex - 52021DC0078 - EN - EUR-Lex \(europa.eu\)](#)

				implementing successful public-private cooperation.			
4	Emergency Assistance on Cross-Border Cooperation in Healthcare	Communication	DG Health and Food Safety	Reaction to the call of several Member States for emergency assistance from the EU and other EU Member States. A coordinated approach in cross-border healthcare is envisioned.	No definition. However, the instrument is a reaction to the specific current crisis – cf. name of initiative “related to the COVID-19 crisis”; reference to “public health emergency”; “exceptional emergency situations” existing and justifying a more coordinated approach etc. (cf. No. 1, 9)*		*Communication from the Commission – Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis EUR-Lex - 52020XC0403(02) - EN - EUR-Lex (europa.eu)
5	COVAX Facility and Vaccine Sharing Mechanism	Global initiative	TRADE/ INTPA	18 September 2020 - Commission confirmed its participation in the COVAX Facility for equitable access to affordable COVID-19 vaccines. COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration between governments, scientists, businesses, civil society, philanthropists and global health organisations to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. EU supports the global recovery with a total of €500 million plus vaccine donations. The Commission has also set up an EU vaccine sharing mechanism to structure the provision of vaccines shared by Member States with partner countries.	--	--	--
6	Task Force for Industrial Scale-up of COVID-19	Ad hoc Task Force	GROW	The Commission set up the Task Force for Industrial Scale-up of COVID-19 vaccine production in February 2021, following an	--	--	--

	Vaccines			<p>announcement in the Commission’s communication on the European bio-defence preparedness plan against COVID-19 variants called ‘HERA Incubator’.</p> <p>The Task Force, operating under Commissioner Breton’s responsibility, ramps up production capacity for vaccines in Europe and acts as a one-stop shop for manufacturers in need of support. The Task Force’s work consists in particular of:</p> <ul style="list-style-type: none"> • Mapping European vaccine production capacities throughout the supply chain • Identifying, addressing and eliminating production bottlenecks, in terms of capacity and supply chain issues • Promoting partnerships through matchmaking events for vaccine and therapeutics production • Ensuring sufficient long-term manufacturing capacity in Europe via the ‘EU-Fab’ project, as a future asset of Europe’s Health Emergency Response Agency (HERA) 			
7	Coronavirus Response in Relation to Personal Protective Equipment	Commission Recommendation (13 March 2020) accompanied by guidance, followed by the introduction of temporary measures adjusting the PPE export	GROW	The Commission published guidance for manufacturers to help economic operators to assess whether they can convert their existing facilities to produce protective equipment. It details applicable EU legal frameworks and steps that manufacturers need to take to place their products on the EU market.	<p>No definition. However, the instrument is a reaction to the specific current crisis (pandemic):</p> <ul style="list-style-type: none"> • Reference to the current COVID-19 global outbreak/the context of the COVID-19 threat/adequate protection in the COVID-19 outbreak/current health crisis (recital 1, 8; recommendation 1, 8)* • Instrument follows the objective of protecting health and safety of the EU citizens (recital 2)* and, thus, is triggered where these are at risk: cf. protection “against harmful biological agents” & “risks that may cause ‘very serious consequences such as death or irreversible damage to health’” (recital 11)* 		*Commission recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat EUR-Lex - 32020H0403 - EN - EUR-Lex (europa.eu)

		authorisation scheme for 30 days		<p>On 13 March 2020, the Commission issued a recommendation to speed up the uptake of new products not based on harmonised standards, without compromising on our health and safety standards and without undue delays.</p> <p>The recommendations:</p> <ul style="list-style-type: none"> • Notified bodies should prioritise and swiftly make conformity assessments for all new requests by economic operators. • For protective equipment products not following harmonised standards, bodies should take WHO recommendations as reference for their technical assessment. • Market surveillance authorities may authorise products for the EU market without finalised conformity assessment procedures if the equipment ensures an adequate level of health and safety in line with EU law requirements. • In exceptional cases, purchases organised by EU countries for healthcare workers may skip necessary conformity assessment procedures for equipment, provided that the EU countries' authorities have ensured adequate safety levels. 		
8	Extra-EU Export Authorisation Mechanism of Covid-19 Vaccines and their Active Substances	Commission Regulation	SANTE/ TRADE	<p>The objective is to increase the transparency of vaccine exports from the EU and to ensure timely access to COVID-19 vaccines for EU citizens in accordance with contractual agreements. This mechanism aims at preventing exports from companies with whom the EU has concluded</p>	<p>Grounds for refusal of export authorisation:</p> <ul style="list-style-type: none"> • Article 1(7)*: Threat to the execution of APAs (Advance Purchased Agreements) concluded by the EU with vaccine manufacturers (in view of the volume of exports or any other relevant circumstances) – Threat to the security of continuous supply of the vaccines necessary for the 	*Commission Implementing Regulation (EU) 2021/442 of 11 March 2021 making the exportation of certain products subject to the production of an export

				Advance Purchased Agreements (APAs), where they threaten the execution of those APAs as well as to preserve the security of the EU's supply chains – while taking into account the principles of reciprocity and proportionality.	execution of the APAs within the EU (cf. Recital 4)* Temporary instrument: the COVID-19 vaccines export transparency and authorisation mechanism has been extended until 31 December 2021.	authorisation L_2021085EN.01019001.xml (europa.eu)
9	Joint Procurements for Medicinal Counter Measures	Legislative Proposal	SANTE	This option does already exist in a COM decision, but will be revamped for the SANTE cross-border health proposal. Has been used for example to jointly procure a therapeutics medicine as well as syringes.	See above for triggering mechanism (column European Health Union).*	*Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU EUR-Lex - 52020PC0727 - EN - EUR-Lex (europa.eu)
10	A New European Pandemic Information Gathering System & New European Chief Epidemiologist & European Health Data Space	Proposal announced in the Lessons Learnt Communication	SANTE/ ECDC	At European level, a new European pandemic information gathering system, building on the existing Early Warning and Response System and an upgrade of the European Surveillance System, should be set up to manage and exchange data in real time and integrated into the new global system. This should focus on Member States providing timely information, ranging from early signals of potential threats – whether pandemics, bioterrorism or anything in between – to concrete data on cases, exposures, risk factors, health outcomes and healthcare capacity. As part of this, connecting public health authorities would allow coordinated management of stockpiles and hospital beds, and rapid workforce redeployments. It would allow up-to-date screening of the situation to be shared, drawing on innovative sources of data like the wastewater	The focus is on providing “timely information” to Member States – this is done via “early signals of potential threats – whether pandemics, bioterrorism or anything in between ” (p. 5/6).*	*Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Drawing the early lessons from the COVID-19 pandemic (Lesson 1, p. 5/6) communication150621.pdf (europa.eu)

				<p>monitoring now being put in place. It will also allow swifter and more effective contact tracing, as well as enable patient records and data to follow patients across borders. This should also be integrated into the broader initiative to create a European Health Data Space. Seamlessly linking clinical and public health data, such as through the secure sharing of electronic health records, allows a real-time snapshot of the epidemiological situation and response capacity.*</p>		
11	<p>A Framework for the Activation of an EU Pandemic State of Emergency</p>	<p>Proposal announced in the Lessons Learnt Communication</p>	<p>“A striking feature of the pandemic was the increasing use of different emergency tools needed in response to the crisis. These include the use of the Emergency Support Instrument, the Advance Purchase Agreements used to purchase vaccines, or the use of the Union Civil Protection Mechanism for emergency response and repatriations. While these instruments were successfully deployed, the pandemic highlighted the importance to have fast, functioning and flexible temporary and exceptional measures ready to be activated, to allow the EU to react as quickly as it is needed. With speed being of the essence, the pandemic showed the need for a more systematic approach to these instruments. This requires a clear and decisive political decision on when to trigger crisis response, as well as a toolbox to be deployed for such situations.” This “could also ensure a more coordinated approach to information-sharing and decision-making on public health measures.”*</p>	<p>Lessons Learnt Communication discusses the automatic activation of the Emergency Support Instrument to allow surge funding, or other mechanisms to allow swift support for the research, development, manufacturing and procurement of essential countermeasures. It points to the need of a political decision on when to trigger a crisis response (Lesson 4, p. 7).*</p>	<p>*Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Drawing the early lessons from the COVID-19 pandemic (Lesson 4, p. 7) communication150621.pdf (europa.eu)</p> <p>Supplementary Regulation: Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak EUR-Lex - 32020R0521 - EN -</p>	

						EUR-Lex (europa.eu)
12	Short-term EU Health Preparedness for COVID-19 Outbreaks	Communication		“The EU must ensure that it is ready for possible resurgences of COVID-19 cases. This requires short-term and strongly coordinated action to strengthen key areas of preparedness and response. Early detection of cases and a rapid response to prevent further spread, combined with specific measures to protect the most vulnerable in [...] societ[y], are [...] [the] best shot to avoid having to reinstate large-scale restrictions such as lockdowns. Building on the ongoing work in the Member States, the Commission and EU Agencies, this Communication has set out the necessary actions to be taken.”*	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title for COVID-19 outbreaks).*	*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Short-term EU health preparedness for COVID-19 outbreaks EUR-Lex - 52020DC0318 - EN - EUR-Lex (europa.eu)

IMMEDIATE DISASTER RESPONSE AND CRITICAL INFRASTRUCTURE

1	Union Civil Protection Mechanism (UCPM)	Based on a number of legal acts, including a Decision 1313/2013 from 2013 and as amended by a Regulation from 2021/2021/836	ECHO	<p>The Mechanism aims to strengthen cooperation between the EU Member States and 6 Participating States on civil protection to improve prevention, preparedness and response to disasters (Article 1(1)*). When an emergency overwhelms the response capabilities of a country in Europe and beyond, it can request assistance through the Mechanism. The European Commission plays a key role in coordinating the disaster response worldwide, contributing to at least 75% of the transport and/or operational costs of deployments.</p> <p>The UCPM, among other things, provides a 24/7 Emergency Response Coordination Centre with 24/7 operational realtime monitoring of</p>	<p>Disaster: Article 4(1)*: "Disaster' means any situation which has or may have a severe impact on people, the environment, or property, including cultural heritage".</p> <p>Scope/Triggering of civil protection mechanisms by – Article 1(2)*: “The protection to be ensured by the Union Mechanism shall cover primarily people, but also the environment and property, including cultural heritage, against all kinds of natural and man-made disasters, including the consequences of acts of terrorism, technological, radiological or environmental</p>	Triggering of civil protection actions/mechanisms to assist in the response to immediate adverse consequences of a disaster inside or outside the EU (cf. Articles 5, 10* Prevention actions).	*Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, latest amendment by Regulation (EU) 2021/836 of the European Parliament and of the Council of 20 May 2021 EUR-Lex - 32013D1313 - EN - EUR-Lex (europa.eu) Amendment: Regulation (EU) 2021/836 of the European Parliament
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				disasters; notification requirement of Member States affected to other concerned Member States and the Commission; with Member States establishment of early warning systems and existing communication systems and networks of experts on natural and man-made disasters.	disasters, marine pollution, hydrogeological instability and acute health emergencies , occurring inside or outside the Union. In the case of the consequences of acts of terrorism or radiological disasters, the Union Mechanism may cover only preparedness and response actions.”		and of the Council of 20 May 2021 EUR-Lex - 32021R0836 - EN - EUR-Lex (europa.eu) Consolidated version: EUR-Lex - 02013D1313-20210101 - EN - EUR-Lex (europa.eu)
2	RescEU	See above	ECHO	RescEU has the objective of enhancing both the protection of citizens from disasters and the management of emerging risks. In addition, rescEU establishes a new European reserve of resources (the ‘rescEU reserve’) which includes a fleet of firefighting planes and helicopters, medical evacuation planes, as well as a stockpile of medical equipment and field hospitals that can respond to health emergencies, and chemical, biological, radiological, and nuclear incidents.	Falls under the umbrella of the EU Civil Protection Mechanism. ➔ Key triggering mechanism of “ disaster ” (Article 4(1)*). Article 12* : triggered “where overall existing capacities at national level and those pre-committed by Member States to the European Civil Protection Pool are not [...] able to ensure an effective response to the various kinds of disasters referred to in Article 1(2)”.* Article 12(3b)* : “In duly justified cases of urgency , the Commission may acquire, rent, lease or otherwise contract capacities determined by means of implementing acts adopted in accordance with the urgency procedure referred to in Article 33(3)” (urgency procedure in Article 31*). – Urgency is not defined.		*Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, latest amendment by Regulation (EU) 2021/836 of the European Parliament and of the Council of 20 May 2021 (see above: EU Civil Protection Mechanism)
3	Humanitarian Air Bridge	See above	ECHO	The European Union Humanitarian Air Bridge is an integrated set of services enabling the delivery of humanitarian and other aid to countries affected by COVID-19 and/or facing fragile humanitarian	The Humanitarian Air Bridge is an anticipatory or preventative approach that is meant to “help bolster the resilience of communities, including forcibly displaced groups, in regions vulnerable to climate-related and other hazards .” It builds on the submission of sufficiently reliable information via early warning systems including indicators or other criteria to trigger		*Communication from the Commission to the European Parliament and the Council on the EU’s humanitarian action: new challenges,

				<p>contexts. The air bridge carries medical equipment, and humanitarian cargo and staff. It provides humanitarian assistance for the most vulnerable populations, including where the pandemic imposes constraints on transport and logistics.</p> <p>The air bridge flights are fully funded by the European Union. They are operated in coordination with Member States and humanitarian organisations sending the material, and in cooperation with the receiving country. The Humanitarian Air Bridge is a temporary initiative operated on a needs-based approach.</p>	<p>action (cf. No. 3.3, p. 10).*</p> <p>The Communication further clarifies in a footnote that – given the anticipatory nature of the envisioned humanitarian responses – “anticipatory action involves pre-planning early actions based on which funding can be disbursed quickly before a natural or human-induced disaster takes place or any other trigger for action is reached. It is also relevant for other types of anticipated emergencies, not only those linked to climate change” (cf. No. 3.3, Fn. 43, p. 10).*</p>	<p>same principles hacommunication2021.pdf (europa.eu)</p>
4	European Civil Protection Pool (ECPP)	See above	ECHO	<p>Part of the EU’s approach to health disasters.</p> <p>The European Civil Protection Pool (ECPP) of voluntary pre-committed response capacities in the Member States, established for a large field of response capacities, needed in the response to natural and man-made disasters, The European Medical Corps is one part of the ECPP, established under the EU Civil Protection Mechanism. It enables quick medical assistance and public health expertise from all EU Member States and Participating States to a health emergency inside and outside the EU. The deployment is coordinated by the EU’s Emergency Response Coordination Centre, the operational hub of the EU Civil Protection Mechanism. The European Medical Corps gathers all medical response capacities committed by Member States to the European Civil Protection Pool. Following a request</p>	<p>(Health) disaster: no separate definition, but:</p> <ul style="list-style-type: none"> ➔ Key triggering mechanism of “disaster” (Article 4(1)*). ➔ European Civil Protection Pool (ECPP) article 11 (UCPM). 	<p>*Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, latest amendment by Regulation (EU) 2021/836 of the European Parliament and of the Council of 20 May 2021 (see above: EU Civil Protection Mechanism)</p>

			<p>for European assistance, medical capacities can be drawn from this Pool and from other Member States' response capacities.</p> <p>The European Medical Corps was set up in response to the acute shortage of trained medical teams during the Ebola crisis in West Africa in 2014. It continues to coordinate an effective European response in health emergencies under the EU Civil Protection Mechanism.</p> <p>Medical capacities available via the emergency response mechanisms are, i.a.: emergency medical teams (EMT), mobile biosafety laboratories, medical evacuation capacities.</p>			
5	EU Solidarity Corps	Regulation	<p>“Given the significant increase in global humanitarian needs and with a view to enhancing the promotion of solidarity and the visibility of humanitarian aid among Union citizens, there is a need to develop solidarity between Member States and with third countries affected by man-made or natural disasters” (cf. Recital 2)*</p> <p>“The European Solidarity Corps Programme (the ‘Programme’) provides a single entry point for solidarity activities throughout the Union and beyond” (cf. Recital 16)*</p> <p>The European Solidarity Corps helps young people take part in projects that benefit communities, either abroad or in their own country. Funding for projects is provided in the form of grants to organisations.</p>	--	--	<p>*Regulation (EU) 2021/888 of the European Parliament and of the Council of 20 May 2021 establishing the European Solidarity Corps Programme and repealing Regulations (EU) 2018/1475 and (EU) No 375/2014 Regulation (EU) 2021/ of the European Parliament and of the Council of 20 May 2021 establishing the European Solidarity Corps Programme and repealing Regulations (EU) 2018/1475 and (EU) No 375/2014 (europa.eu)</p>

6	The Seveso Directive Technological Disaster Risk Reduction	Directive	ENV	The Directive applies to more than 12 000 industrial establishments in the European Union where dangerous substances are used or stored in large quantities, mainly in the chemical and petrochemical industry, as well as in fuel wholesale and storage (incl. LPG and LNG) sectors.	<p>Major accident: Article 3(13)*: “major accident’ means an occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive, and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances”</p> <p>3 Cumulative Elements:</p> <ol style="list-style-type: none"> 1) Major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of an establishment + 2) Leading to serious danger to human health or the environment + 3) Involving one or more dangerous substances 	In particular, the “major accident” definition triggers information obligations as well as specific action obligations by the operators of establishments or installations (Article 16, 3(8), (9)*). It also triggers information obligations by the respective Member States (Article 18*). Moreover, the competent Member State authorities are required to take specific action (Article 17*).	*Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (europa.eu)
7	Proposal for a Directive to Enhance the Resilience of Critical Entities Providing Essential Services in the EU	Proposal for a Directive	Migration & Home Affairs	With this proposal, the Commission intends to create an all-hazards framework to support Member States in ensuring that critical entities are able to prevent, resist, absorb and recover from disruptive incidents , no matter if they are caused by natural hazards, accidents, terrorism, insider threats, or public health emergencies like the one the world faces today. The proposal covers ten sectors, namely energy, transport, banking, financial market	<p>Incident: Article 2(3)*: “Incident” means any event having the potential to disrupt, or that disrupts, the operations of the critical entity.”</p> <p>1 Element:</p> <ul style="list-style-type: none"> • Potential to disrupt the operations of a critical entity. 	The question of whether an incident would have a significant disruptive effect on the provision of the service of an entity is set out as a relevant criterion in classifying an entity as “critical” (Article 5(2)(c)*).	*Proposal for a Directive of the European Parliament and of the Council on the resilience of critical entities 15122020_proposal_directive_resilience_critical_entities_com-2020-829_en.pdf (europa.eu)

infrastructures, health, drinking water, waste water, digital infrastructure, public administration and space. The proposal sets up a physical resilience framework with minimum harmonisation rules, allowing for flexibility to reflect national specificities.

Noteworthy provisions include:

- Member States would be obligated to, among other things, have a strategy for ensuring the resilience of critical entities, carry out a national risk assessment and, on this basis, identify critical entities.
- Critical entities are those that provide services in the internal market that are essential for the maintenance of vital societal functions or economic activities in those 10 sectors
- Critical entities would be required to carry out risk assessments of their own, take appropriate technical and organisational measures (to prevent, resist, absorb and recover from disruptive incidents) in order to boost resilience, and report disruptive incidents to national authorities.
- Critical entities providing services to or in at least one-third of Member States would be subject to specific oversight, including advisory missions organised by the Commission.
- The Commission would offer different forms of support to Member States and critical entities, a Union-level risk overview, best practices, methodologies, cross-border

Significant disruptive effect
Article 6*: List of relevant criteria in the classification exercise, i.a. **number of users relying on service, dependency of other sectors on the service, market share** of the entity etc.

- Commission may adopt guidelines to facilitate the application of the relevant criteria for the classification of a “significant disruptive effect” (after consultation of a Critical Entities Resilience Group).

Article 13*: Incident notification requirement for entities that is triggered by “incidents that significantly disrupt or have the potential to **significantly disrupt their operations**”

				<p>training activities and exercises to test the resilience of critical entities.</p> <ul style="list-style-type: none"> Regular cross-border cooperation with regard to the implementation of the directive would be facilitated through an expert group, the Critical Entities Resilience Group. 			
8	Emergency Support Instrument	Financial instrument (set up by Council Regulation 2016/369 and activated by a separate Council Regulation)	BUDG	<p>The Emergency Support Instrument helps Member States respond to the coronavirus pandemic by addressing needs in a strategic and coordinated manner at European level.</p> <p>In particular, it provided support for: down payment for vaccines procured via APAs, treatments contracts and clinical trials, RAT testing and MS testing capacity, purchasing PPE, transport of essential goods, medical teams and patients, and other measures.</p>	<p>Ongoing or potential natural or man-made disaster: Article 1(1)*: Measures have to be “appropriate to the economic situation in the event of an ongoing or potential natural or man-made disaster. Such emergency support can only be provided where the exceptional scale and impact of the disaster is such that it gives rises to severe wide-ranging humanitarian consequences in one or more Member States and only in exceptional circumstances where no other instrument available to Member States and to the Union is sufficient.”</p> <p>3 Cumulative Elements: 1) An ongoing or potential natural or man-made disaster” + 2) Exceptional scale and impact of the disaster is such that it gives rises to severe wide-ranging humanitarian</p>	<p>Activation of the emergency support: Article 2(1)*: “The decision about the activation of the emergency support under this Regulation in case of an ongoing or potential disaster shall be taken by the Council on the basis of a proposal by the Commission, specifying where appropriate the duration of the activation.”</p> <p>Article 2(2)*: “The Council shall immediately examine the proposal of the Commission referred to in paragraph 1 and shall decide, in accordance with the urgency of the situation, on the activation of the emergency support.”</p>	<p>*Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak EUR-Lex - 02016R0369-20200201 - EN - EUR-Lex (europa.eu) Amendment: EUR-Lex - 32020R0521 - EN - EUR-Lex (europa.eu)</p> <p>**Proposal for a Decision of the European Parliament and of the Council amending Decision (EU) 2020/265 as regards adjustments to the amounts mobilised from the Flexibility Instrument for 2020 to</p>

					<p>consequences in one or more Member States</p> <p>+ 3) No other instrument available to Member States and to the Union is sufficient.</p> <p>Other initiative:</p> <p>Current health crisis: Article 1**": "The amounts [...] shall be used to finance measures to address the ongoing challenges of migration, refugee inflows and security threats as well as the current health crisis in the European Union resulting from the COVID-19 outbreak [...]"</p>	<p>+ Annex allowing for the financing of specific actions in case of pandemics with large-scale effects</p> <p>Article 1***: Emergency support to finance the necessary expenditures to address the COVID-19 pandemic until 31 January 2022 is activated by the adoption of the Regulation.</p>	<p>be used for migration, refugee inflows and security threats, for immediate measures in the framework of the COVID-19 outbreak and for reinforcement of the European Public Prosecutor's Office EUR-Lex - 52020PC0171 - EN - EUR-Lex (europa.eu)</p> <p>***Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak EUR-Lex - 32020R0521 - EN - EUR-Lex (europa.eu)</p>
9	Repair and Prepare for the Next Generation	Communi-cation		This Communication focuses on the “anatomy” of the economic crisis, the impact (e.g. recession) of the crisis and the way forward “to repair damage from the crisis and prepare a better future for the next generation.”*	No definition.*		*Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Europe’s moment: Repair and Prepare for the Next Generation EUR-Lex - 52020DC0456 - EN - EUR-Lex (europa.eu)

FREE MOVEMENT OF PERSONS, GOODS AND SERVICES

1	Border Management Measures to Protect Health and Ensure Availability of Goods	Guidelines		These guidelines set out principles for an integrated approach to an effective border management to protect health while preserving the integrity of the Single Market. Disruptions to the free movement of persons, and the delivery of goods and essential services across Europe are meant to be avoided.	No definition. However, the Guidelines are a reaction to the specific current health crisis (pandemic) – cf. reference in title to “COVID-19 crisis”. Guidelines also refer to the “green lanes” system.*	*COVID-19 Guidelines for border management measures to protect health and ensure the availability of goods and essential services EUR-Lex - 52020XC0316(03) - EN - EUR-Lex (europa.eu)
2	‘Green Lanes’ System and the Forthcoming Transport Mobility Contingency Plan	Communication and a planned Communication	MOVE	The Commission adopted in particular the ‘Green Lanes’ system, in response to the freight traffic halted at internal borders in March 2020 and upgraded it based on the experiences gained over time in October 2020. The aim was to ensure that EU-wide supply chains continued to operate in all circumstances. In line with the Green Lanes principles, Member States were requested to designate all the relevant internal border-crossing points on the trans-European transport network (TEN-T) as ‘green lane’ border crossings, open to all freight vehicles irrespective of the goods they carry. Crossing the border, including any checks and health screening, should not take more than 15 minutes and restrictions such as mandatory quarantine or testing of transport workers should be waived, without prejudice to the need for national authorities to take proportionate and specifically adapted measures to minimise the risk of contagion.	Green Lanes: No definition.*	*Communication from the Commission on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services EUR-Lex - 52020XC0324(01) - EN - EUR-Lex (europa.eu) (cf. also Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Sustainable and Smart Mobility Strategy – putting European transport on track for

				<p>The Green Lanes system should now be consolidated in a framework which can be activated in response to any new crisis. The Commission intends to put forward a Contingency plan to this effect by the end of 2021. As regards the transport and mobility aspects, this initiative will draw lessons from the current pandemic and address the needs of the European freight and passenger transport in the event of a pandemic. It will focus on ensuring free movement of transport workers and freight transport and providing clarity to the passenger transport. It will aim at better preparing the EU transport system for pandemic-like events and preserving the integrity of the Single Market. The plan is structured around 10 action points. Under each action point there are specific actions that are being proposed.</p>	<p>Transport & Mobility Contingency plan: The draft includes a passage on possible “triggering events” for the contingency measures: “the triggering event includes any accident or other events capable of causing lasting and severe disruption to the EU transport system. Such disruption could come from a wide range of events such natural disasters, pandemic outbreaks, terrorist attacks, Kessler effect, cyber-attacks, including ransomware, military conflicts, bridge or tunnel collapse or power outages.” (p. 8, para. 3.2**)</p> <p>1 Element:</p> <ul style="list-style-type: none"> • Any accident or other events capable of causing lasting and severe disruption to the EU transport system (usually originating from one of the listed events) <p>Factors with the ability to severely disrupt the EU transport and mobility system include:</p> <ul style="list-style-type: none"> • “Climate change and other environmental challenges, [...] digital hyperconnectivity and technological transformations.”, targeted disruptions of “telecommunication infrastructure, including 3G/4G/5G infrastructure (e.g. repeaters, repeater bridges or cell towers) or other components of the telecommunications network (e.g. relays or cables)”, “floods” etc. (p. 6, para. 3.1).** 	<p>the future EUR-Lex - 52020DC0789 - EN - EUR-Lex (europa.eu)</p> <p>**Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Learning from the COVID-19 crisis – A contingency plan for transport (not public yet)</p>
3	COVID-19 Clearing House for Medical Equipment (CCH)	Ad hoc group	SG	<p>COVID-19 Clearing House for medical equipment (CCH) was established by the SG to ensure availability of goods.</p> <p>A first ad hoc action was the setting up on 1 April 2020 of the COVID-19 Clearing House for medical equipment (CCH), which facilitated the matching of demand and supply at European level of essential medical equipment to fight the COVID-19</p>	No definition of a state of crisis.	--

				pandemic.		
4	Council Recommendation on Coordinated Approach to the Restriction of Free Movement	Council Recommendation	JUST HOME	<p>On 13 October 2020, the Council adopted a recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, which was updated on 1 February 2021 and on 14 June 2021. This recommendation establishes common criteria and a common framework for possible measures for travellers.</p> <p>The Council Recommendation suggests as a best practice not to impose either quarantine or testing requirements on transport workers/service providers and cross-border commuters.</p>	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title "in response to the COVID-19 pandemic").*	*Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic; updated by Council Recommendation (EU) 2021/119 of 1 February 2021 EUR-Lex - 32020H1475 - EN - EUR-Lex (europa.eu) Amendment: EUR-Lex - 32021H0119 - EN - EUR-Lex (europa.eu)
5	Free Movement of Workers, Posted Workers, Service Providers	Communications	EMPL	<p>The guidelines issued on 30 March 2020 identify a range of workers and service providers that exercise critical occupations, and for which continued free movement in the EU is deemed essential. The list provided in these guidelines is not exhaustive. The Commission urged Member States to establish specific burden free and fast procedures to ensure a smooth passage for such workers, including proportionate health screening.</p> <p>Beyond these specific categories of workers, the guidelines also clarify that Member States should allow frontier workers in general to continue crossing borders if work in the sector concerned is still allowed in the host Member State. Member States should treat cross-border workers and national workers in the</p>	<p>See above No. 3 column.*</p> <p>&</p> <p>No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title “during COVID-19 outbreak”).**</p> <p>&</p>	*Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic; updated by Council Recommendation (EU) 2021/119 of 1 February 2021 EUR-Lex - 32020H1475 - EN - EUR-Lex (europa.eu) Amendment: EUR-Lex - 32021H0119 - EN - EUR-Lex (europa.eu) **Communication from

				<p>same manner.</p> <p>As regards seasonal workers, particularly in the agricultural sector, Member States were asked to exchange information on their different needs at technical level and to establish specific procedures to ensure a smooth passage for such workers, in order to respond to labour shortages as a result of the crisis.</p> <p>On 16 July 2020, the European Commission issued guidelines on seasonal workers in the EU in the context of the COVID-19 outbreak. These guidelines complement the Commission Guidelines concerning the exercise of the free movement of workers during the COVID-19 outbreak published on 30 March.</p>	<p>No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title “in the context of the COVID-19 outbreak”).***</p>	<p>the Commission – Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak 2020-2051-Communication-free-movement_EN.pdf 2020-2051-Communication-free-movement_EN.pdf</p> <p>***Communication from the Commission – Guidelines on seasonal workers in the EU in the context of the COVID-19 outbreak guidelines on seasonal workers in the eu in the context of the covid-19 outbreak en.pdf europa.eu</p>
6	<p>Schengen Strategy and Foreseen Revision of Schengen Border Code as Regards Border Closures</p>	<p>Communication; planned proposal for a regulation and changes in Practical Handbook for Border Guards</p>	HOME	<p>The Commission intends to put forward a new proposal for an amendment of the Schengen Borders Code by the end of this year. The new proposal will need to address the lessons learned from the COVID-19 crisis and build on discussions related to the 2017 proposal, in particular as regards the preservation of Member States’ possibility to reintroduce internal border controls while reasserting the principle that this should only be as a measure of last resort, to be used in case of threats. To deal with any future Schengen-wide challenges, a revised Schengen Borders Code would address situations where a serious threat, including a threat to public health, such as that created by the COVID-19 pandemic, would arise. In such instances, it is important to</p>	<p>Revised Schengen Border Code:* Article 25: “General framework for the temporary reintroduction or prolongation of border control at internal borders</p> <ol style="list-style-type: none"> Where, in the area without internal border controls, there is a serious threat to public policy or internal security in a Member State, that Member State may exceptionally reintroduce border controls at all or specific parts of its internal borders. <p>A serious threat to public policy or internal security may be considered to arise from, in particular:</p> <ol style="list-style-type: none"> activities relating to terrorism or organised crime; large scale public health emergencies; a situation characterised by large scale unauthorised movements of third-country nationals between the Member States, putting at risk the overall functioning of the area without internal border control; large scale or high profile international events such as sporting, trade or political events. 	<p>*Amendment Schengen Border Code: Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/399 on a Union Code on the rules governing the movement of persons across borders EUR-Lex - 52021PC0891 - EN - EUR-Lex eur-lex.europa.eu</p> <p>& Communication from the Commission to the European Parliament and the Council - A strategy towards a fully functioning and</p>

ensure coordination and close cooperation at Union level with the necessary safeguards so that reintroducing border checks at internal borders remains a measure of last resort. In this way, the Commission and the Member States would be able to have an overview of the circumstances giving rise to the need for reintroduced border controls. The revised Code would also address the need for coordination of measures restricting travel into the EU, drawing notably from the experiences in response to the serious threat to public health posed by the pandemic where there have been divergences in the implementation of Council Recommendation (EU) 2020/912 by Member States, and allowing for a flexible framework to respond to crises.

To be better prepared for future crises and for the case that border control at internal borders should again become unavoidable, despite the measures being put in place, the Commission will codify the pertinent mitigating measures from the guidelines and recommendations developed in relation to COVID-19 in the Practical Handbook for Border Guards, which should become a first point of reference for border guards in a crisis situation. It would also ensure the free movement of professionals and provide safeguards for cross-border posting of workers at the time of crisis (including transport and health workers).

At the beginning of 2021, the Commission published an inception

Previous Schengen Border Code:

Threat to public health:

Article 2(21):** “Threat to public health’ means any disease with epidemic potential as defined by the International Health Regulations of the World Health Organization and other infectious diseases or contagious parasitic diseases if they are the subject of protection provisions applying to nationals of the Member States.”

- Under the Schengen Borders Code and national law adopted in order to ensure coordinated action to fight COVID-19, it is possible to refuse entry to non-resident third-country nationals where they present relevant symptoms or have been particularly exposed to risk of infection and are considered to be a threat to public health.*
- Threats to public policy, internal security, public health or the international relations of any of the Member States allow for a rejection of third-country nationals at the borders (Article 6, 8(2), subpara. 3, (3)(vi), Recital 6**).

resilient Schengen area
[02062021_strategy_to_wards_fully_functionin_g_and_resilient_schengen_area_com-2021-277_en\(9\).pdf](#)
([emnbelgium.be](#))

**Previous Version:
Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code)
[EUR-Lex - 32016R0399 - EN - EUR-Lex \(europa.eu\)](#)

				impact assessment (IIA), proposing amendments to the Schengen Borders Code with regard to border checks across EU internal borders, and ensuring better coordination of the measures applied by Member States during crises such as the current pandemic.		
7	Guidance on Free Movement of Health Professionals and Minimum Harmonisation of Training in Relation to COVID-19 Emergency Measures	Communication	GROW	<p>The guidance aims to help Member States address the shortages of healthcare workers caused by the pandemic. It does this by clarifying certain provisions of the Professional Qualifications Directive 2005/36/EC, in particular regarding:</p> <ul style="list-style-type: none"> • Recognition of qualifications and permission to work for health professionals in cross-border situations and speeding up the recognition process for recognising professional qualifications; • Early graduation for sectoral health professions or temporary adaptations of curricula; • Recognition of health professionals with qualifications from outside the EU or EFTA. 	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title “in relation to COVID-19 emergency”).*	*Communication from the Commission – Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures – recommendations regarding Directive 2005/36/EC guidance-movement-health-professionals-harmonisation-training-covid19_en.pdf (europa.eu)
8	Temporary Restriction on Non-essential Travel to the EU	Communications		“Travel restrictions should focus on drastically reducing incoming people flows at the external borders of the Union, thereby also slowing transmission to other countries on travellers’ return, and discouraging outgoing travel of EU citizens and other persons residing in the EU+ area.” (p. 1*)	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. "public health crisis", “coronavirus crisis”*)).	*Communication from the Commission to the European Parliament, the European Council and the Council – COVID-19: Temporary Restriction on Non-Essential Travel to the EU https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0115

							<p>(& Communication from the Commission to the European Parliament, the European Council and the Council – COVID-19 Guidance on persons exempted from the temporary restriction on non-essential travel to the EU as regards the implementation of Council Recommendation 2020/912 of 30 June 2020</p> <p>EUR-Lex - 52020DC0686 - EN - EUR-Lex (europa.eu))</p>
							<p>No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. reference to “public health reasons”, “public health emergency” and “COVID-19 emergency period” (No. 1a, 3**)).</p>
							<p>**Supplemented by practical guidance in the Communication COVID-19 Guidance on the implementation of the temporary restriction on non-essential travel to the EU, on the facilitation of transit arrangements for the repatriation of EU citizens, and on the effects on visa policy</p> <p>EUR-Lex - 52020XC0330(02) - EN - EUR-Lex (europa.eu)</p>
9	Re-open EU	Web portal	GROW/ JRC	A centralised portal providing information to EU citizens on key policies. Re-open EU provides	--	--	<p>*Re-open EU (europa.eu)</p>

				information on the various measures in place, including on quarantine and testing requirements for travellers, the EU Digital COVID certificate to help travellers exercise their right to free movement, and mobile coronavirus contact tracing and warning apps. The information is updated frequently and available in 24 languages.		
10	EU Digital COVID Certificate	Regulation	JUST/ CNECT	<p>The EU Digital COVID Certificate (formerly called Digital Green Certificate) facilitates safe free movement during the COVID-19 pandemic within the EU. It serves as proof that a person was vaccinated against COVID-19, received a negative test result or recovered from COVID-19. The certificate can be used across all EU Member States as well as in Iceland, Liechtenstein and Norway. Contacts are also ongoing to enable its use with Switzerland. The Commission is working to make sure that the certificates can be compatible with systems in other countries outside the EU.</p> <p>The EU Digital COVID Certificate system covers three different types of COVID-19 certificates: a vaccination certificate, a test certificate, and a certificate of recovery. The EU Certificate can be issued and used in all EU Member States to facilitate free movement during the COVID-19 pandemic. All EU citizens and their family members, as well as non-EU nationals legally staying or residing in the Member States and who have the right to travel to other Member States, would be eligible to receive such certificates free of charge. The EU certificate only includes a</p>	<p>System in place for current pandemic crisis – not envisioned to be triggered by specific future state of crisis.</p> <p>Recital 59*: “Specific power of Commission to adopt delegated acts – “In order to take into account the scientific progress in containing the COVID-19 pandemic, or to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to amend this Regulation by modifying or removing the data fields to be included in the EU Digital COVID Certificate regarding the identity of the holder, information about the COVID-19 vaccine, the test for SARS-CoV-2 infection, past SARS-CoV-2 infection and the certificate metadata, by adding data fields regarding information about the COVID-19 vaccine, the test for SARS-CoV-2 infection, past SARS-CoV-2 infection and certificate metadata and by amending the number of days after which a certificate of recovery is to be issued.”</p> <p>– Special rules under urgency procedure. (Cf. Articles 5(2), (4), 6(2), (4), 7(1), (2), (4), (6), (7), 13).*</p>	<p>*Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic EUR-Lex - 32021R0953 - EN - EUR-Lex (europa.eu)</p>

				<p>minimum set of information necessary to confirm and verify the holder's vaccination, testing or recovery status. Being vaccinated will not be a pre-condition to travel. All EU citizens have a fundamental right to free movement in the EU and this applies regardless of whether they are vaccinated or not.</p> <p>The regulation also provides for the legal ground to process the personal data necessary to issue such certificates and to process the information necessary to verify and confirm the authenticity and validity of such certificates in full compliance with Regulation (EU) 2016/679 (cf. Article 1, subpara. 2*).</p>		
11	EU Passenger Locator Form	Commission Implementing Decision		<p>Digital solution: Passenger Locator Forms help Member States undertake risk assessment of arrivals and enable contact tracing. The Council has agreed to work towards a common digital European Passenger Locator Form which would help both the swift processing of the information and improve data exchange between Member States.</p>	No definition. However, the instrument is a reaction to the specific current crisis (pandemic).*	<p>*Commission Implementing Decision (EU) 2021/858 of 27 May 2021 amending Implementing Decision (EU) 2017/253 as regards alerts triggered by serious cross-border threats to health and for the contact tracing of passengers identified through Passenger Locator Forms EUR-Lex - 32021D0858 - EN - EUR-Lex (europa.eu)</p> <p>& cf. Recommendation 20, of Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free</p>

						movement in response to the COVID-19 pandemic EUR-Lex - 32020H1475 - EN - EUR-Lex (europa.eu) (see above)
12	National Contact Tracing Apps	National actions & Recommendation & Implementing Decision		20 national apps are interoperable and work across borders; strong data protection rules.	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) for the duration of it (cf. reference to “current crisis”, “COVID-19 crisis”, “public health crisis caused by the current COVID-19 pandemic” (Recital 1,2,3,12,21,23,30,31, Recommendation 1, 1(2), 5, 10(1),(2), Recommendation 22 “for as long as the COVID-10 crisis persists”*)). (Cf. also reference to “public health crisis caused by the COVID-19 pandemic”, the COVID-19 crisis, (recital 3, 4**)).	*Commission Recommendation (EU) 2020/518 of 8 April 2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data EUR-Lex - 32020H0518 - EN - EUR-Lex (europa.eu) **Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 as regards the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic EUR-Lex - 32020D1023 - EN - EUR-Lex (europa.eu)
13	Treatment of Third Country Nationals at the External	Regulation		Some of the restrictions adopted by the Member States in order to limit the spread of severe acute respiratory		

<p>Borders</p> <p>1) Issuance, Verification and Acceptance of Interoperable Certificates on Vaccination, Testing and Recovery to Third-country Nationals</p>			<p>syndrome coronavirus 2 ('SARS-CoV-2'), which causes coronavirus disease 2019 ('COVID 19'), have had an impact on the exercise of the right of third country nationals to travel to the EU (border closures/restrictions on entry or other specific requirements applicable to cross-border travellers).</p> <p>1) The "Digital Green Certificate" framework to be established should lay out the format and content of certificates on COVID-19 vaccination, testing and recovery. The Commission also proposes that it should ensure that these certificates can be issued in an interoperable format and be reliably verified when presented by the holder in other Member States, thereby facilitating travel within the European Union.</p> <p>The proposed Regulation (EU) 2021/XXX takes into account ongoing efforts at the international level, such as under the auspices of the World Health Organization ('WHO') and other specialised agencies of the United Nations, to establish specifications and guidance for using digital technologies for documenting vaccination status. Third countries should be encouraged to recognise the "Digital Green Certificate" when waiving restrictions on non-essential travel. In particular, this could include interoperability between technological systems</p>	<p>No definition.*</p>	<p>*Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate) EUR-Lex - 52021PC0140 - EN - EUR-Lex (europa.eu)</p>
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2) Introduction of a Screening of Third Country Nationals at the External Borders

established at global level and the systems established for the purpose of this Regulation to facilitate travel within the European Union.

2) “The New Pact on Migration and Asylum, presented together with this proposal represents a fresh start on migration based on a comprehensive approach to migration management. It advocates integrated policy-making bringing together policies in the areas of asylum, migration, return, external border protection, fight against migrants’ smuggling and relations with key third countries reflecting a whole of government approach.”**

“This proposal puts in place a pre-entry screening that should be applicable to all third country nationals who are present at the external border without fulfilling the entry conditions or after disembarkation, following a search and rescue operation. The proposal introduces uniform rules concerning the procedures to be followed at the pre-entry stage of assessing the individual needs of third country nationals and uniform rules on the length of the process of collecting relevant information for identification of the procedures to be followed with regard to such persons.” It also “creates an EU framework by putting in place uniform rules for the screening of irregular migrants

No definition of migration crisis etc.**

**Proposal for a Regulation of the European Parliament and of the Council introducing a screening of third country nationals at the external borders and amending Regulations (EC) No 767/2008, (EU) 2017/2226, (EU) 2018/1240 and (EU) 2019/817
[EUR-Lex - 52020PC0612 - EN - EUR-Lex \(europa.eu\)](#)

				apprehended within the territory and who eluded border controls on entering the Schengen area. This aims to contribute to protecting the Schengen area and ensure efficient management of irregular migration.”**		
14	Contingency Plan for Ensuring Food Supply and Food Security	Communi-cation	AGRI/MARE/SANTE	<p>The plan includes the creation of a European Food Security Crisis preparedness and response Mechanism as well as a set of guidelines on how to respond in the event of a crisis.</p> <p>The initiative contains proposals: a dedicated group of experts, composed of Member States’ representative with participation of stakeholder organisations; development of broad guidelines and recommendations for times of crisis.</p>	<p>There is no “food crisis” definition. However, the Communication includes a passage setting out the circumstances warranting the convocation of a specific crisis forum, consisting of experts composed of Member State representatives. The forum is triggered only if three cumulative requirements are fulfilled. These requirements seem to describe a “food crisis” situation.</p> <p>3 Cumulative Elements (p. 11, No. 5.2.A)*:</p> <p>1) “In case of exceptional, unpredictable and large-scale events or risks – whether endogenous or exogenous to the food supply chain – that have the potential to threaten the EU food supply or food security”</p> <p>+</p> <p>2) “Unfolding in more than one Member State”</p> <p>+</p> <p>3) “Requiring EU-level coordination”.</p> <p>Clarification that (p. 11, No. 5.2.A)*:</p> <ul style="list-style-type: none"> • Significant threat to the overall EU food supply or security, i.e. availability of and the access to safe food, is required. • Insufficient: mere market tensions/disturbances (e.g. recent results of recent EU weather extremes). <p>Mechanisms of this instrument will likely be triggered by risks severely affecting the functioning of the food supply chain, such as (cf. extracts of the Communication, pp. 7/8, No. 4)*:</p> <ul style="list-style-type: none"> • “climate and environmental risks”, e.g. “resource scarcity and biodiversity loss”, “plant and animal health issues” • “public health, technology, geopolitical shifts” – cf. extract: “risks related to geopolitical shifts encompass foreign direct investment in critical infrastructures in the EU, bio-terrorism or competition to access some essential 	<p>*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Contingency plan for ensuring food supply and food security in times of crisis com2021-689-pe-2021-7931_en.pdf (europa.eu)</p>

				<p>inputs and commodities”</p> <ul style="list-style-type: none"> • “industrial or other accidents”, e.g. nuclear accidents, with “the potential to irradiate large tracts of agricultural land” • “Cyber-attacks” affecting the IT system of large companies. <p>The Farm to Fork Strategy already announces the contingency plan. It mentions two terms of crisis: (1) an “agricultural crisis (reserve)” that should be “used upfront in the case of crisis in agricultural markets”; and a (2) “food crisis” that should trigger response mechanisms coordinated by the Commission and involving Member States. “It [referring to the food crisis] will be comprised of various sectors (agriculture, fisheries, food safety, workforce, health and transport issues) depending on the nature of the crisis.” Moreover, “risk assessment and management measures” will be activated during “crisis”.**</p>	<p>**Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system EUR-Lex - 52020DC0381 - EN - EUR-Lex (europa.eu)</p>	
C o m m o n M a r k e t O r g a n i s a t i o n R	Common Market Organisation Regulation (EU) No 1308/2013	Regulation	AGRI	<p>Relevant provisions included in the Common Market Organisation Regulation (EU) No 1308/2013:</p> <p>Part V, Ch. 1 – Exceptional measures</p> <p>Art. 219 - Measures against market disturbance</p> <p>Art. 220 - Measures concerning animal diseases and plant pests and the loss of consumer confidence due to public, animal or plant health risks</p> <p>Art. 221 - Measures to resolve specific problems</p> <p>Section 4 – Agreements and decisions during periods of severe imbalance in markets</p> <p>Art. 222 - Application of Article</p>	<p>Art 219. 1. In order to react efficiently and effectively against threats of market disturbance caused by significant price rises or falls on internal or external markets or other events and circumstances significantly disturbing or threatening to disturb the market, where that situation, or its effects on the market, is likely to continue or deteriorate, the Commission shall be empowered to adopt delegated acts in accordance with Article 227 to take the measures necessary to address that market situation, while respecting any obligations resulting from international agreements concluded in accordance with the TFEU and provided that any other measures available under this Regulation appear to be insufficient.</p>	<p>Common Market Organisation Regulation (EU) No 1308/2013 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R1308</p>

			<p>101(1) TFEU (Competition rules)] Art. 223 – Communication requirements</p> <p>Art. 223(3) is the legal basis for Commission Implementing Regulation (EU) 2017/1185 laying down rules for the application of Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards notifications to the Commission of information and documents.</p> <p>Relevant provisions included in Regulation (EU) 2021/2115 on the CAP Strategic Plans: Art. 148 - Measures to resolve specific problems</p>		
	<p>Regulation (EU) 2021/2115 on establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans)</p>	<p>Regulation</p>	<p>AGRI</p> <p>Measures to resolve specific problems</p>	<p>Article 148</p> <p>Measures to resolve specific problems</p> <p>1. In order to resolve specific problems, the Commission shall adopt implementing acts which are both necessary and justifiable in an emergency. Such implementing acts may derogate from provisions of this Regulation to the extent and for such a period as is strictly necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 153(2).</p> <p>2. On duly justified imperative grounds of urgency, and in order to resolve such specific problems as referred to in paragraph 1 while ensuring the continuity of the CAP Strategic Plan in the case of extraordinary circumstances, the Commission shall adopt immediately applicable</p>	<p>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2115</p>

					<p>implementing acts in accordance with the procedure referred to in Article 153(3).</p> <p>3. Measures adopted under paragraph 1 or 2 shall remain in force for a period not exceeding twelve months. If after this period the specific problems referred to in those paragraphs persist, the Commission may, in order to establish a permanent solution, submit an appropriate legislative proposal.</p> <p>4. The Commission shall inform the European Parliament and the Council of any measure adopted under paragraph 1 or 2 within two working days of its adoption.</p>	
	Market observatories		AGRI	Information on different agricultural markets to cope better with market volatility and read market signals		https://ec.europa.eu/info/food-farming-fisheries/farming/facts-and-figures/markets/overviews/market-observatories_en
	Agricultural civil dialogue groups		AGRI	The European Commission holds regular dialogues on the common agricultural policy and its implementation.		https://ec.europa.eu/info/food-farming-fisheries/key-policies/committees-and-advisory-councils/civil-dialogue-groups/
DIGITAL INITIATIVES						
1	Fighting Disinformation – Communications, Action Plan and Code of Practice	In particular: Joint Communication accompanied by actions		Close contact with social media platforms regarding measures to promote authoritative content and limit disinformation.*	No particular triggering mechanism is established. Instead, these instruments initiate a more fundamental process of involving platforms through co-regulation and voluntary commitments in restructuring their public forums. The objective is to create a “safe cyberspace” whilst protecting the fundamental right to freedom of expression (Article 10 European Convention on Human Rights (ECHR), Article 11 EU	*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of

	<p>Responding to the problem of “infodemics”. As defined by the WHO “infodemics are an excessive amount of information about a problem, which makes it difficult to identify a solution. They can spread misinformation, disinformation and rumours during a health emergency. Infodemics can hamper an effective public health response and create confusion and distrust among people.”</p> <p>This initiative, thus, aims to tackle this problem, which could “create confusion and distrust and undermine an effective public health response.”**</p>	<p>Charter of Fundamental Rights). The measures aim to equip the big tech companies and their forums of exchange more reliably against the threat of the spread of mis-/disinformation (“Fake News”) and the almost automatic amplification and magnification of a (false) message across cyberspace. Tools to combat i.a. infodemics focus on transparency mechanisms and involve fact-checking processes, changes in the platforms’ architecture/code etc.</p>	<p>the Regions – Tackling online disinformation: a European Approach (April 2018) EUR-Lex - 52018DC0236 - EN - EUR-Lex (europa.eu)</p> <p>& Action Plan Against Disinformation (December 2018) eu-communication-disinformation-euco-05122018_en.pdf (europa.eu)</p> <p>& **Joint Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Tackling COVID-19 disinformation – Getting the facts right (June 2020) communication-tackling-covid-19-disinformation-getting-facts-right_en.pdf (europa.eu)</p> <p>& EU Code of Practice on Disinformation (October 2018) Code of Practice on Disinformation Shaping Europe’s digital future (europa.eu)</p>
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						<p>***& Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – European Commission Guidance on Strengthening the Code of Practice on Disinformation (May 2021) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=COM:2021:262:FIN</p> <p>****Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Drawing the early lessons from the COVID-19 pandemic communication150621.pdf (europa.eu)</p>
2	Data Act	Act	CNECT/G1	<p>The fight against mis-/disinformation has also been emphasised by the Lessons Learnt communication: “A more coordinated and sophisticated approach to misinformation and disinformation should be developed.” (Lesson 10, p. 13)****</p> <p>The Covid-19 crisis has shown the essential role of data use for crisis management and for informed decision-making by governments. With its European strategy for data, published on 19 February 2020, the Commission has formulated a vision for the data economy. It will work</p>	<p>The proposal of the Data Act is not public yet.</p> <p>Article 2 Definitions:* (11) “‘public emergency’ refers to exceptional situations negatively affecting a major part of a Member State(s) population or their fundamental rights, with a risk of serious and lasting repercussions on living conditions and the economic stability of the</p>	<p>*Proposal for a Regulation of the European Parliament and of the Council on ensuring fairness in the allocation of value across the data economy (Data Act)</p>

towards the creation of a Single Market for data, where data flows between countries and sectors, where data is available for use in full respect of European values and rules, and where there are fair, practical and clear rules for access and use of the data. The Data Strategy also underlined that the EU should ensure an open, but assertive approach towards international data flows, based on European values. The strategy announces the adoption of a horizontal legislative initiative, which would complement the proposal for a Regulation on European Data Governance*, already adopted by the Commission. This initiative will aim to increase access to and further use of data, so that more public and private actors can benefit from techniques such as Big Data and machine learning.

This Act is also meant to promote and facilitate data-sharing between government and businesses as well as between businesses (B2B) if this data serves the public interest.**

Member State(s). Public emergencies include major natural disasters, public health emergencies as well as human-induced major disasters, such as those caused by terrorism”

Information/Data requests:

Chapter V, Articles 14 – 22*: Making data available to public sector bodies and union institutions, agencies or bodies based on exceptional need

Article 14* Obligation to provide data based on exceptional need

1. Upon request, a data holder shall make data available to a public sector body or to a Union institution, agency or body demonstrating an exceptional need to use the data requested.
2. This Chapter shall not apply to small and micro enterprises within the meaning of Commission Recommendation 2003/361/EC.

Article 15* Exceptional need to use data held by enterprises

An exceptional need to use data within the meaning of this Chapter shall be deemed to exist where:

- (a) the data requested is necessary to respond to a public emergency, or
- (b) where the lack of available data prevents the public sector body or Union institution, agency or body from fulfilling its legal obligations; and
 - (1) the public sector body or Union institution, agency or body have been unable to obtain such data by alternative means, including by purchasing the data on the market or by relying on existing obligations to provide the data and found them not fit for purpose, and where the adoption of new legislative measures cannot ensure the timely availability of data; or
 - (2) where obtaining the data in line with the

**Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act)
[EUR-Lex - 52020PC0767 - EN - EUR-Lex \(europa.eu\)](#)

**Inception Impact Assessment Data Act
[Data Act & amended rules on the legal protection of databases \(europa.eu\)](#)

***Public Consultation on the Data Act:
[Summary Report Public Consultation on the Data Act: Summary Report | Shaping Europe’s digital future \(europa.eu\)](#)

					<p>procedure laid down in this Chapter would substantively reduce the administrative burden for enterprises.</p> <p>Article 18* Compliance with requests for data</p> <ol style="list-style-type: none"> 1. A data holder receiving a request for access to data under this Chapter shall make the data available to the requesting public sector body or a Union, agency or body without undue delay. 2. Without prejudice to specific needs regarding the availability of data defined in sectoral legislation, no later than 5 working days following the receipt of a request for the data necessary to respond to a public emergency and no later than 15 days in other cases of exceptional need, the data holder may decline or seek modification of the request on one of the following grounds: <ol style="list-style-type: none"> (a) the data is unavailable; or (b) the request fails to respect the conditions laid down in Article 17(1). 3. In case of the request for data necessary for responding to a public emergency, the data holder may also decline or seek modification of the request if it already provided the requested data in response to previously submitted request for the same purpose by another public sector body or Union institution agency or body and the data holder has not been notified of the destruction of the data pursuant to Article 19(1)(b). 4. ... 	
3	Cyber-security	Directive		<p>This proposal is part of a package of measures to improve further the resilience and incident response capacities of public and private entities, competent authorities and the Union as a whole in the field of cybersecurity and critical</p>	<p>Incident & Cyber Threat: Article 4(5)*: “‘incident’ means any event compromising the availability, authenticity, integrity or confidentiality of stored, transmitted or processed data or of the related services offered by, or accessible via, network and information systems”</p>	<p>*Proposal for a Directive of the European Parliament and of the Council on measures for a high common level of cybersecurity across the</p>

infrastructure protection. Cybersecurity is a priority in the Commission's response to the COVID-19 crisis. The package includes a new Strategy on Cybersecurity with the aim of strengthening the Union's strategic autonomy to improve its resilience and collective response and to build an open and global internet.

The Directive obliges every Member State to adopt a cybersecurity strategy (Article 5), envisions a European vulnerability registry, national cybersecurity crisis frameworks, a cooperation group for the exchange of information among Member States and establishes the European cyber crises liaison organisation network. Moreover, the Directive includes provisions on cybersecurity management and reporting (Articles 17 – 23).

Article 4(7)*: “‘cyber threat’ means a cyber threat within the meaning Article 2(8) of Regulation (EU) 2019/881” in

Article 2(8) Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act): “‘cyber threat’ means any **potential circumstance, event or action** that could **damage, disrupt or otherwise adversely impact network and information systems, the users** of such systems and other persons”

Measures are triggered with regard to “incidents” or “cyber threats” (cf. reference in:

- Article 7* (National cybersecurity crisis management frameworks): “large-scale incidents and crises”
- Article 9* (Computer security incident response teams (CSIRTs)): “incident handling”
- Article 10* (Requirements and tasks of CSIRTs): (2)(a) “monitoring cyber threats, vulnerabilities and incidents at national level”, (2)(b) “providing early warning alerts [...] to essential and important entities as well as to other relevant interested parties on cyber threats, vulnerabilities and incidents;” (2)(c) “responding to incidents”; etc.,
- Article 11* (Cooperation at national level): (2) “Member States shall ensure that either their competent authorities or their CSIRTs receive notifications on incidents, and significant cyber threats and near misses submitted pursuant to this Directive”; (3) “[...] inform its single point of contact of notifications on incidents, significant cyber threats [...]”
- Article 13* (CSIRTs network): (3) “The CSIRTs network shall have the following tasks: [...]” (b) “exchanging relevant information on incidents, near misses, cyber threats, risks and vulnerabilities”, (g) “discussing and identifying further forms of operational cooperation, including in relation to: (i) categories of cyber threats and incidents”
- Article 20(2)* (Reporting obligations): “Member States shall ensure that essential and important entities notify, without undue delay, the competent authorities or the CSIRT of any significant cyber threat [...]”
- Etc.)

Union, repealing Directive (EU) 2016/1148
[EUR-Lex - 52020PC0823 - EN - EUR-Lex \(europa.eu\)](#)

**Regulation (EU) 2021/887 of the European Parliament and of the Council of 20 May 2021 establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres
[Regulation \(EU\) 2021/ of the European Parliament and of the Council of 20 May 2021 establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres \(europa.eu\)](#)

Cf. also Article 2(4)** – same definition: “‘cyber threat’ means any **potential circumstance, event or action** that could **damage, disrupt or otherwise adversely impact network and information systems**, the **users** of such systems and other persons”.

PRODUCTION CAPACITIES

1	Chips Act	Act	<p>“Semiconductors are at the core of our world’s digitisation, but global supply is currently struggling to meet the explosion of demand driven by smartphones, Internet of Things and connected cars.”</p> <p>“Semiconductors are at the centre of strong geostrategic interests, and at the core of the global technological race.”</p> <p>"Member States are currently designing national strategies to develop on their soil industrial and production capacities in order to reduce their dependencies."</p> <p>"With the European Chips Act, national efforts can be integrated in a coherent European vision and strategy. It will also provide a framework to avoid a race to national public subsidies fragmenting the single market, set conditions to protect European interests and place Europe firmly in the global geopolitical landscape."</p> <p>The dimensions envisioned include:</p>	<p>Article 2*</p> <p>1. Definitions:</p> <p>(17) “‘crisis-relevant product’ means semiconductors, intermediate products and raw materials required to produce semiconductors or intermediate products, that are affected by the semiconductor crisis or of strategic importance to remedy the semiconductor crisis or economic effects thereof;”</p> <p>Article 18* Activation of the crisis stage</p> <p>1. A semiconductor crisis shall be considered to occur when there are serious disruptions in the supply of semiconductors leading to significant shortages, which:</p> <p>(a) entail significant delays or significant negative effects on one or more important economic sectors in the Union, or</p> <p>(b) prevent the supply, repair and maintenance of essential products used by critical sectors.</p> <p>2. Where an assessment of the Commission provides concrete, serious, and reliable evidence of a semiconductor crisis, the Commission may activate the crisis stage by means of implementing acts in accordance with Article 33(2). The duration of the activation shall be specified in the implementing act. Where, in view of the scope and gravity of the semiconductor crisis, duly justified imperative grounds of urgency so require, the procedure provided for in Article 33(3) shall apply to implementing acts adopted pursuant to this Article.</p> <p>3. Before the expiry of the duration for which the crisis stage was activated, the Commission shall, after consulting the</p>	<p>Communication from the Commission: A Chips Act for Europe</p> <p>*Proposal for a Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act)</p> <p>Complemented by:</p> <p>Proposal for a Council Regulation amending Regulation (EU) 2021/2085 establishing the Joint Undertakings under Horizon Europe, as regards the Chips Joint Undertaking</p> <p>Commission Recommendation on a common Union toolbox to address semiconductor shortages and an EU</p>
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Pillar 1: “Chips for Europe Initiative”
“to support large-scale technological capacity building and innovation throughout the Union to enable the development and deployment of cutting-edge and next generation semiconductor and quantum technologies”

Pillar 2: “Security of supply”
“a framework to ensure security of supply by attracting investments and enhanced production capacities in semiconductor manufacturing as well as advanced packaging, test, and assembly”

Pillar 3: “Monitoring and crisis response”

"a coordination mechanism between the Member States and the Commission for strengthening collaboration with and across Member States, monitoring the supply of semiconductors, estimate demand, anticipate shortages, trigger the activation of a crisis stage and act through a dedicated toolbox of measures "

In short: This Act proposes a comprehensive approach to strengthen the EU's semiconductor sector, based on three pillars: (1) strengthening R&D&I and supporting innovative digital infrastructure, (2) fostering investments in chips production capacities, as well as (3) developing an instrument for coordinated monitoring and response to disruptions of the semiconductor supply chain. Notably, pillar 3 introduces regular monitoring of the semiconductor value chain and an emergency toolbox to respond to disruptions and ensure supply to

European Semiconductor Board, assess whether the activation of the crisis stage should be prolonged. Where the assessment concludes that a prolongation is appropriate, the Commission may prolong the activation by means of implementing acts. The duration of the prolongation shall be specified in the implementing acts adopted in accordance with Article 33(2). The EN 48 EN Commission may repeatedly decide to prolong the activation of the crisis stage where this is appropriate.

4. During the crisis stage, the Commission shall, upon request from a Member State or on its own initiative, convene extraordinary meetings of the European Semiconductor Board as necessary. Member States shall work closely with the Commission and coordinate any national measures taken with regard to the semiconductor supply chain within the European Semiconductor Board.
5. Upon expiry of the duration for which the crisis stage is activated, the measures taken in accordance with Articles 20, 21 and 22 shall cease to apply. The Commission shall review the Union risk assessment pursuant to Article 16(2) no later than six months after the expiry of the duration of the crisis stage

Article 19* Emergency toolbox

1. Where the crisis stage is activated and where appropriate in order to address the semiconductor crisis in the Union, the Commission shall take the measure provided for in Article 20 under the conditions laid down therein. In addition, the Commission may take the measures provided for in Article 21 or Article 22, or both, under the conditions laid down therein.
2. ...

Article 20* Information gathering

1. The Commission shall, **after consulting the European Semiconductor Board, request representative organisations of undertakings** or, if necessary, **individual undertakings operating along the semiconductor supply chain to inform** the Commission about their **production capabilities**, production capacities, current primary disruptions and provide other existing data necessary to assess the nature of the semiconductor crisis or to identify and assess potential mitigation or emergency measures at national or Union level.

mechanism for monitoring the semiconductor ecosystem

[European Chips Act: Communication, Regulation, Joint Undertaking and Recommendation | Shaping Europe's digital future \(europa.eu\)](#)

				critical sectors, coordinated through the European Semiconductor Board.	2. The request for information shall state its legal basis, be proportionate in terms of the granularity and volume of the data and frequency of access to the data requested, have regard for the legitimate aims of the undertaking and the cost and effort required to make the data available, and set out the time limit within which the information is to be provided. It shall also indicate the penalties provided for in Article 28.	
					3. ...	

SUPPLY CHAINS

1	Security of Energy Supply	Regulation	ENERGY	<p>This crisis instrument has been established prior to the Corona pandemic. It builds on the idea of emergency plans.</p> <p>The EU energy policy pursues the objective of ensuring and securing the energy supply at all times to all EU citizens. It is also the backbone of the Energy Union strategy with a forward looking climate policy. Since the gas crises in the winters of 2006 and 2009, significant progress has been made in mitigating the risk of possible future gas supply crises.</p> <p>Remark: the current energy crisis in the European Union might point to the need of revising the existing Regulation (no such legislative initiatives public yet).</p>	<p>3 Crisis Levels: Article 11(1):*</p> <ul style="list-style-type: none"> • (a) “early warning level (‘early warning’): where there is concrete, serious and reliable information that an event which is likely to result in significant deterioration of the gas supply situation may occur and is likely to lead to the alert or the emergency level being triggered; the early warning level may be activated by an early warning mechanism” • (b) “alert level (‘alert’): where a disruption of gas supply or exceptionally high gas demand which results in significant deterioration of the gas supply situation occurs but the market is still able to manage that disruption or demand without the need to resort to non-market-based measures;” • (c) “emergency level 	<p>Activation: Triggering of responses/ action/ obligations by declaration of a crisis or of an emergency (Article 11(2), (3) subpara. 1, (4))*</p> <ul style="list-style-type: none"> • By the competent MS authority for one of the three crisis levels (Article 11(2), (4))* • By the Commission for regional or Union emergency (Article 12(1))* <p>Deactivation:</p> <ul style="list-style-type: none"> • Declaration of end of crisis level at Member State level: by Member State (Article 11(3),(9))*, or by Commission if it concludes that the declaration of an emergency is not or no longer justified (Articles 11(3) subpara. 2, (8), 13(15), 	<p>*Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010 EUR-Lex - 32017R1938 - EN - EUR-Lex (europa.eu)</p>
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					<p>(‘emergency’): where there is exceptionally high gas demand, significant disruption of gas supply or other significant deterioration of the gas supply situation and all relevant market-based measures have been implemented but the gas supply is insufficient to meet the remaining gas demand so that non-market-based measures have to be additionally introduced with a view, in particular, to safeguarding gas supplies to protected customers in accordance with Article 6.”</p>	<p>Recital 55)*</p> <ul style="list-style-type: none"> • Declaration of end of regional or Union emergency by Commission: when it decides that the underlying basis for the emergency no longer justifies the declaration of an emergency (Articles 12(1), subpara. 2)* 	
2	Critical Raw Materials Resilience	Communi- cation	<p>“Critical raw materials are essential to the functioning and integrity of a wide range of industrial ecosystems.“</p> <p>“Building on the EU’s Raw Materials Initiative, this Communication presents:</p> <ul style="list-style-type: none"> • The EU 2020 list of critical raw materials • The challenges for a secure and sustainable supply of critical raw materials and actions to increase EU resilience and open strategic autonomy.” <p>The Communication concludes that “one of the lessons of the COVID-19 crisis is the need to reduce dependency and strengthen diversity and security of supply. Enhancing open strategic autonomy will be a long-term benefit to the EU. “*“</p>	No definition.*		<p>*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Critical Raw Materials Resilience: Charting a Path towards greater Security and Sustainability https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0474</p>	

EU SPACE

1	<p>Copernicus Programme</p> <p>& Galileo Programme</p>	Regulations	<p>“EU Space monitors and helps fight against the consequences of the pandemic. Data from EU satellites [that is] available for over 20 years offer a comprehensive, efficient and cost-effective way to quantify the industrial and environmental impacts of Coronavirus.”</p> <p>(cf. about Space programme: Actions against COVID-19 (europa.eu))</p> <p>“With its 30+satellites, the EU Space Programme, notably through its Earth Observation component, Copernicus, and its satellite navigation system, Galileo, offers free and open data/information that can help monitor and potentially mitigate against the impact of the coronavirus outbreak.“ (cf. EU Space and the Coronavirus Copernicus)</p> <p>Copernicus:</p> <ul style="list-style-type: none"> • “Helps decision-makers assess the impact on traffic at borders between EU Member States as the Coronavirus pandemic causes serious disruptions in the flow of goods and medical equipment. • Mitigates disruptions in the EU Common Agricultural activity by making available satellite data and cloud-based processing solutions, while speeding up the satellite-based area monitoring 	<p>Copernicus:</p> <ul style="list-style-type: none"> • “Response to Natural and man-made disasters: Copernicus provides information and rapid mapping of the affected areas for emergency response to natural and man-made disasters, humanitarian disasters as well as prevention, preparedness, response and recovery activities.” Cf. about Space programme: Actions against COVID-19 (europa.eu) • Article 5(1)(e)*: listing “the emergency management service, which is to provide information for emergency response in relation to different types of disasters, including meteorological hazards, geophysical hazards, 	<p>*Regulation (EU) No 377/2014 of the European Parliament and of the Council of 3 April 2014 establishing the Copernicus Programme and repealing Regulation (EU) No 911/2010 EUR-Lex - 32014R0377 - EN - EUR-Lex (europa.eu)</p>
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			<p>process for payments related to the Common Agriculture Policy.</p> <ul style="list-style-type: none"> • Maps temporary health facilities as well as public gathering spaces to get a clear understanding of activities during the Coronavirus emergency.”* <p>Galileo:</p> <ul style="list-style-type: none"> • “Provides precise geolocation services to map contagion areas. • Monitors in real-time the circulation of goods between the EU Member States and facilitates freight traffic at borders allowing border authorities to visualise the overall border situation. • Develops a dedicated app “<i>Galileo for outbreak monitoring and post-emergency management</i>”, which will monitor the spread of the virus. It will create interference between local authorities and citizens showing high-risk infection points, statistics on infection risks based on symptoms, level of quarantine enforcement as well as an assessment of infection risk and dynamic updates.”* <p>(Cf. about Space programme: Actions against COVID-19 (europa.eu))</p>	<p>deliberate and accidental man-made disasters and other humanitarian disasters, as well as the prevention, preparedness, response and recovery activities”.</p> <p>Galileo: No crisis definition.**</p>	<p>**Regulation (EC) No 683/2008 of the European Parliament and of the Council of 9 July 2008 on the further implementation of the European satellite navigation programmes (EGNOS and Galileo) EUR-Lex - 32008R0683 - EN - EUR-Lex (europa.eu)</p>
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SINGLE MARKET COMPLIANCE

1	Single Market Enforcement	Communication		“In this forum, the European Commission and EU country	--	--	*Communication from the Commission to the
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Task Force for Compliance with Single Market Rules (SMET)

authorities discuss the most pressing single market barriers needing to be addressed to ensure the proper functioning of the single market, including by better coordinating national responses to the COVID-19 crisis.”

“The creation of SMET was announced in the Commission’s Single Market Enforcement Action Plan on 10 March in the context of the industrial strategy. The Task Force was envisaged as a platform for Member States and the Commission to work together to ensure better compliance with Single Market rules. This first meeting kick-started the work of the new Task Force in light of the urgency of issues hampering the correct functioning of the Single Market, mainly intra-EU export restrictions of vital protective, medical and medicinal supplies, border controls and the need to increase production of essential equipment. This also aims at implementing the clear guidance of Europe’s leaders given at the European Council of 26 March to remove all internal bans or restrictions to the free movement of goods. The task force will be convened on a regular basis to discuss issues concerning enforcement issues in the Single Market.”

(Source: [Removing restrictions to the Single Market – European Commission \(europa.eu\)](#))

European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Long term action plan for better implementation and enforcement of single market rules
[EUR-Lex – 52020DC0094 – EN – EUR-Lex \(europa.eu\)](#)

Adopted in March 2020 as part of the European industrial strategy
[Strategy \(europa.eu\)](#)

1.	Defence and Security Work Contracts	Directive		The objective of this Directive is to contribute to the gradual establishment of a European defence equipment market, which is deemed essential to strengthen the European Defence Technological and Industrial Base and to develop the military capabilities required to implement the European Security and Defence Policy.	Article 1 Definitions: 10. “‘Crisis’ means any situation in a Member State or third country in which a harmful event has occurred which clearly exceeds the dimensions of harmful events in everyday life and which substantially endangers or restricts the life and health of people , or has a substantial impact on property values , or requires measures in order to supply the population with necessities; a crisis shall also be deemed to have arisen if the occurrence of such a harmful event is deemed to be impending ; armed conflicts and wars shall be regarded as crises for the purposes of this Directive;”		*Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC
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FREE MOVEMENT OF CAPITAL

1.	Crisis Management and Resilience Acquis in the Financial Services Area	Regulations and Directives		... & Inhaltsverzeichnis und Overview updaten!	Article 2* Definitions 1. “For the purposes of this Directive the following definitions apply: (1) .. (30) ‘ systemic crisis ’ means a disruption in the financial system with the potential to have serious negative consequences for the internal market and the real economy . All types of financial intermediaries, markets and infrastructure may be potentially systemically important to some degree; (101) ‘ crisis prevention measure ’ means the exercise of powers to direct removal of deficiencies or impediments to recoverability under Article 6(6), the exercise of powers to address or remove impediments		*The Bank recovery and resolution Directive (BRRD): Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives
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to resolvability under Article 17 or 18, the application of an early intervention measure under Article 27, the appointment of a temporary administrator under Article 29 or the exercise of the write down or conversion powers under Article 59;

(102) ‘**crisis management measure**’ means a resolution action or the appointment of a special manager under Article 35 or a person under Article 51(2) or under Article 72(1);” ...

Article 66* Power to enforce crisis management measures or crisis prevention measures by other Member States

Article 81* Notification requirements (also of crisis prevention measures)

Article 85* Ex-ante judicial approval and rights to challenge decisions

1. “Member States may require that a decision to take a crisis prevention measure or a crisis management measure is subject to ex-ante judicial approval, provided that in respect of a decision to take a crisis management measure, according to national law, the procedure relating to the application for approval and the court’s consideration are expeditious.”

2. ...

Etc.

Article 2 Definitions**

(1) ...

(48) “‘**crisis prevention measure**’ means the exercise of powers to require a CCP to take measures to remedy deficiencies in its recovery plan under Article 10(8) and (9), the exercise of powers to address or remove impediments to resolvability under Article 16, or the application of an early intervention measure under Article 18;”

Article 18 Early intervention measures**

1. Where a CCP infringes, or is likely to infringe in the near future, the capital and prudential requirements of Regulation (EU) No 648/2012, or poses a risk to financial

2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council Text [EUR-Lex - 32014L0059 - EN - EUR-Lex \(europa.eu\)](#)

**The Regulation on the recovery and resolution of central counterparties (CCP-RRR): Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties and amending Regulations

stability in the Union or in one or more of its Member States, or where the competent authority has determined that there are other indications of an emerging crisis situation that could affect the operations of the CCP, in particular, its ability to provide clearing services, the competent authority may:

- (a) require the CCP to update the recovery plan in accordance with Article 9(6) of this Regulation, where the circumstances that required early intervention are different from the assumptions set out in the initial recovery plan;
- (b) require the CCP to implement one or more of the arrangements or measures set out in the recovery plan within a specific timeframe. Where the plan is updated pursuant to point (a), those arrangements or measures shall include any updated arrangements or measures;
- (c) require the CCP to identify the causes of the infringement or likely infringement as mentioned in paragraph 1 and draw up an action programme, including suitable measures and timeframes;
- (d) require the CCP to convene a meeting of its shareholders or, if the CCP fails to comply with that requirement, convene the meeting itself. In both cases the competent authority shall set the agenda, including the decisions to be considered for adoption by the shareholders;
- (e) require one or more members of the board or senior management to be removed or replaced where any of those persons is found unfit to perform their duties pursuant to Article 27 of Regulation (EU) No 648/2012;
- (f) require changes to the business strategy of the CCP;
- (g) require changes to the legal or operational structures of the CCP;
- (h) provide the resolution authority with all the information necessary to update the CCP's resolution plan in order to prepare for the possible resolution of the CCP and the valuation of its assets and liabilities in accordance with Article 24 of this Regulation, including any information acquired through on-site inspections;

(EU) No 1095/2010, (EU) No 648/2012, (EU) No 600/2014, (EU) No 806/2014 and (EU) 2015/2365 and Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132
[EUR-Lex - 32021R0023 - EN - EUR-Lex \(europa.eu\)](#)

- (i) require, where necessary and in accordance with paragraph 4, the implementation of the CCP's recovery measures;
- (j) ...

Article 27 General provisions on resolution tools**

1. ...
2. In the event of a **systemic crisis**, a Member State may as a last resort provide **extraordinary public financial support by applying government stabilisation tools** in accordance with Articles 45, 46 and 47 on the condition of prior and final approval under the Union State aid framework and where credible arrangements for the timely and comprehensive recovery of the funds in accordance with paragraph 10 of this Article are provided for.

Article 45 Government financial stabilisation tools**

1. In the very **extraordinary situation of a systemic crisis**, Member States may apply the government stabilisation tools in accordance with Articles 46 and 47 for the purpose of resolving a CCP only where the following conditions are met:
 - (a) ...

Article 52 Power to enforce crisis prevention measures or resolution actions by other Member States**

Article 74 Ex-ante judicial approval and rights of appeal**

1. A decision to take a crisis prevention measure or resolution action may be subject to ex-ante judicial approval where provided in national law, where the procedure relating to that approval and the court's consideration are expeditious.
2. ...

Article 79 Cooperation with third-country authorities**

1. ...
4. Cooperation arrangements concluded between resolution authorities and competent authorities of Member States and third countries pursuant to paragraph 2 may include provisions on the following matters:
 - (a) ...

- (f) procedures and arrangements for the exchange of information and cooperation under points (a) to (e) of this paragraph, including, where appropriate, through the establishment and operation of crisis management groups.

Article 31* Capital instruments subscribed by public authorities in emergency situations**

- 5. In **emergency situations**, competent authorities may **permit institutions to include in Common Equity Tier 1 capital instruments** that comply at least with the conditions laid down in points (b) to (e) of Article 28(1) where all the following
- 6. ...

***The Capital Requirements Regulation (CRR): Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012
[EUR-Lex - 32013R0575 - EN - EUR-Lex \(europa.eu\)](#)

Article 112** Coordination of supervisory activities by the consolidating supervisor**

- 1. In addition to the obligations imposed by this Directive and by Regulation (EU) No 575/2013, the consolidating supervisor shall carry out the following tasks:
 - (a) ...
 - (c) planning and coordination of supervisory activities in cooperation with the competent authorities involved, and if necessary with ESCB central banks, in preparation for and during emergency situations, including adverse developments in institutions or in financial markets using, where possible, existing channels of communication for facilitating crisis management.

****The Capital Requirements Directive (CRD): Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC
[EUR-Lex -](#)

		<p>Article 10***** Response and recovery</p> <ol style="list-style-type: none"> 1. ... 2. Financial entities shall implement the ICT Business Continuity Policy referred to in paragraph 1 through dedicated, appropriate and documented arrangements, plans, procedures and mechanisms aimed at: <ol style="list-style-type: none"> (a) ... (f) setting out communication and crisis management actions which ensure that updated information is transmitted to all relevant internal staff and external stakeholders in accordance with Article 13, and reported to competent authorities in accordance with Article 17. 3. ... 5. As part of their comprehensive ICT risk management, financial entities shall: <ol style="list-style-type: none"> (a) test the ICT Business Continuity Policy and the ICT Disaster Recovery Plan at least yearly and after substantive changes to the ICT systems; (b) test the crisis communication plans established in accordance with Article 13. ... 6. Financial entities other than microenterprises shall have a crisis management function, which, in case of activation of their ICT Business Continuity Policy or ICT Disaster Recovery Plan, shall set out clear procedures to manage internal and external crisis communications in accordance with Article 13. 7. ... <p>Article 43***** Financial cross-sector exercises, communication and cooperation</p> <ol style="list-style-type: none"> 1. The ESAs, through the Joint Committee and in collaboration with competent authorities, the ECB and the ESRB, may establish mechanisms to enable the sharing of effective practices across financial sectors to enhance situational awareness and identify common cyber vulnerabilities and risks across-sectors. 	<p>32013L0036 - EN - EUR-Lex (europa.eu)</p> <p>***** The Digital Operational Resilience Act (DORA): Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on digital operational resilience for the financial sector and amending Regulations (EC) No 1060/2009, (EU) No 648/2012, (EU) No 600/2014 and (EU) No 909/2014 EUR-Lex - 52020PC0595 - EN - EUR-Lex (europa.eu)</p> <p>Other :</p> <p>The European Market Infrastructure Regulation: Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories EUR-Lex - 32012R0648 - EN - EUR-Lex (europa.eu)</p> <p>The Single resolution mechanism regulation (SRMR): Regulation (EU) No 806/2014 of</p>
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They may develop **crisis-management and contingency exercises** involving cyber-attack scenarios with a view to develop communication channels and gradually enable an effective EU-level coordinated response in the event of a major cross-border ICT-related incident or related threat having a systemic impact on the Union's financial sector as a whole.

These exercises may as appropriate also test the financial sector' dependencies on other economic sectors.

2. ...

Etc.

the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010

[EUR-Lex - 32014R0806 - EN - EUR-Lex \(europa.eu\)](#)

The Markets in Financial Instruments Regulation (MiFIR): Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 Text

[EUR-Lex - 32014R0600 - EN - EUR-Lex \(europa.eu\)](#)

The Markets in Financial Instruments (MiFID II): Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments

