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Delegations will find attached document SWD(2022) 289 final (2/2).

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EUROPEAN
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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

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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	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. ***Why IPCR is not sufficient for SM crisis impacts (governance, coordination and response)*** - It does not allow for technical level discussion, analysis and fact-finding, needs to be requested to intervene by any Member State concerned	**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". **2 Cumulative Elements:** **1)** **Wide-ranging impact** or political significance + **2)** Requirement of **timely** policy **coordination & response** at **Union level**	**Two Modes:** **(Article 2(1)(2),(b)):*** • **Information sharing mode** (pre-stage) to establish the situation & prepare for possible full activation • **Full activation mode** to prepare response measures **Activation:** **(Article 4):*** • **Article4(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 information sharing mode may also be taken by agreement of the GSC, the Commission services and the EEAS, in consultation with the Presidency"	*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)

						Switching between modes: • **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) **Deactivation:** **(Article 5):*** • 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

					Commission with regard to defective medicinal products: • 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.)	to all members of the network within 24 hours (upon verification) – border rejection notifications are transmitted without undue delay (cf. Articles 3, 5)*	16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feedText (europa.eu) 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)
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.	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	**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"*.	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

					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.
HEALTH, VACCINATION AND RELATED PRODUCTION CAPACITY							
1	**EU Vaccines Strategy and Joint Vaccine Procurement**	Communi-cation	SANTE	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: • 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	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)*. • 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*).		*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)

				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	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: • 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;	**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.**	**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**." **2 Cumulative Elements for recognition:** **1) Serious cross-border threat to health** + **2) Endangerment of public health at Union level** • 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**	*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)

				scientific advice on medicines; coordinating studies and clinical trials to monitor the effectiveness and safety of vaccines)		**its spread** among Member States – more expeditious procedure: immediately applicable implementing acts to recognise a public health emergency • "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*) **Termination:** **Article 23(2)*:** termination as soon as one of the applicable conditions is no longer met.	**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:** • 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_propcouncreg_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)

						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)
				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***		

				implementing successful public-private cooperation.			
4	**Emergency Assistance on Cross-Border Cooperation in Healthcare**	Communi-cation	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			announcement in the Commission's communication on the European bio-defence preparedness plan against COVID-19 variants called 'HERA Incubator'. 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: • 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.	No definition. However, the instrument is a reaction to the specific current crisis (pandemic): • 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		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. The recommendations: • 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	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	Grounds for **refusal of export authorisation:** • **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 Epidemio-logist** **& European Health Data Space**	Proposal announced in the Lessons Learnt Communi-cation	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)

				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.*		
11	**A Framework for the Activation of an EU Pandemic State of Emergency**	Proposal announced in the Lessons Learnt Communi-cation		"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."*	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).*	*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) 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 -

							EUR-Lex (europa.eu)
12	**Short-term EU Health Preparedness for COVID-19 Outbreaks**	Communi-cation		"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 20212021/836	ECHO	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. The UCPM, among other things, provides a 24/7 Emercency Response Coordination Centre with 24/7 operational realtime monitoring of	**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**". 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**	**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

				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 emergencie**s, 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,

				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. 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.	action (cf. No. 3.3, p. 10).* 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).*	same principles hacommunication2021.pdf (europa.eu)
4	**European Civil Protection Pool (ECPP)**	See above	ECHO	Part of the EU's approach to health disasters. The Europen Civil Protection Pool (ECPP) of voluntary pre-committed response capacities in the Member Scovers, 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 theECPP , 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	**(Health) disaster:** no separate definition, but: ➔ Key triggering mechanism of "**disaster**" (Article 4(1)*). ➔ European Civil Protection Pool(ECPP) article 11 (UCPM).	*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)

				for European assistance, medical capacities can be drawn from this Pool and from other Member States' response capacities. 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. Medical capacities available via the emergency response mechanisms are, i.a.: emergency medical teams (EMT), mobile biosafety laboratories, medical evacuation capacities.			
5	**EU Solidarity Corps**	Regulation		"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)* "The European Solidarity Corps Programme (the 'Programme') provides a single entry point for solidarity activities throughout the Union and beyond" (cf. Recital 16)* 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.	– –	– –	*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)

6	**The Seveso DirectiveTechnological 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.	**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**" **3 Cumulative Elements:** 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/ECText (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	**Incident:** **Article 2(3)*: "'Incident'"** means any event having the **potential to disrupt,** or that **disrupts**, the **operations of the critical entity**." **1 Element:** • **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**"	

				training activities and exercises to test the resilience of critical entities. • 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	The Emergency Support Instrument helps Member States respond to the coronavirus pandemic by addressing needs in a strategic and coordinated manner at European level. 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.	**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**." **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**	**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." **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."	*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) **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

					consequences in **one or more Member States** + 3) **No other instrument available** to Member States and to the Union is sufficient. **Other initiative:** **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 […]"	+ **Annex** allowing for the financing of specific actions in case of pandemics with large-scale effects 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.**	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) ***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)
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**	Communi-cation and a planned Communi-cation	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

						the future EUR-Lex - 52020DC0789 - EN - EUR-Lex (europa.eu))
				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.	**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**) **1 Element:** • **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) Factors with the ability to severely disrupt the EU transport and mobility system include: • "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).**	**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)
3	**COVID-19 Clearing House for Medical Equipment (CCH)**	Ad hoc group	SG	COVID-19 Clearing House for medical equipment (CCH) was established by the SG to ensure availability of goods. 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	No definition of a state of crisis.	– –

				pandemic.		
4	**Council Recommendation on Coordinated Approach to the Restriction of Free Movement**	Council Recommen-dation	JUST HOME	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. 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.	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**	Communi-cations	EMPL	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. 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	See above No. 3 column.* & No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title “during COVID-19 outbreak”).** &	*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

				same manner. 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. 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.	No definition. However, the instrument is a reaction to the specific current crisis (pandemic) (cf. title "in the context of the COVID-19 outbreak").***	the Commission – Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak 2020-2051-Communication-free-movement_EN.pdf (lgseeds.es) ***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)
6	**Schengen Strategy and Foreseen Revision of Schengen Border Code as Regards Border Closures**	Communi-cation; planned proposal for a regulation and changes in Practical Handbook for Border Guards	HOME	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	**Revised Schengen Border Code:*** **Article 25:** "General framework for the temporary reintroduction or prolongation of border control at internal borders 1. 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. A serious threat to public policy or internal security may be considered to arise from, in particular: (a) activities relating to **terrorism or organised crime**; (b) **large scale public health emergencies**; (c) 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; (d) **large scale or high profile international events** such as sporting, trade or political events.	*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 (europa.eu) & Communication from the Commission to the European Parliament and the Council - A strategy towards a fully functioning and

				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_towards_fully_functioning_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	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: • 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

					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**)).		(& 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 EUR-Lex - 52020DC0686 - EN - EUR-Lex (europa.eu)) **Supplemented by practical guidance in the Communication from the Commission 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 EUR-Lex - 52020XC0330(02) - EN - EUR-Lex (europa.eu)
9	**Re-open EU**	Web portal	GROW/ JRC	A centralised portal providing information to EU citizens on key policies. Re-open EU provides	– –	– –	*Re-open EU (europa.eu)

				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	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. 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	System in place for current pandemic crisis – not envisioned to be triggered by specific future state of crisis. **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." – Special rules under **urgency** procedure. (Cf. Articles 5(2), (4), 6(2), (4), 7(1), (2), (4), (6), (7), 13).*		*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)

				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. 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*).		
11	**EU Passenger Locator Form**	Commission Implemen-ting Decision		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.	No definition. However, the instrument is a reaction to the specific current crisis (pandemic).*	*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) & cf. Recommendation 20, of 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 EUR-Lex - 32020H1475 - EN - EUR-Lex (europa.eu) (see above)
12	**National Contact Tracing Apps**	National actions & Recommen-dation & 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		

	Borders			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).		
	1) Issuance, Verification and Acceptance of Inter-operable Certificates on Vaccination, Testing and Recovery to Third-country Nationals			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. 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	No definition.*	*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)

				established at global level and the systems established for the purpose of this Regulation to facilitate travel within the European Union.		
	2) Intro-duction of a Screening of Third Country Nationals at the External Borders			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	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. 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.	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. **3 Cumulative Elements** (p. 11, No. 5.2.A)*: 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**" + 2) "Unfolding in **more than one Member State"** + 3) "**Requiring EU-level coordination**". **Clarification** that (p. 11, No. 5.2.A)*: • **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). 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)*: • "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	*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)

				Moreover, the Commission has issued another Communication – the Farm to Fork Strategy – to make food systems more resilient and ensure lasting food security.	inputs and commodities" • "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. 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**".**	**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)
Common Market Organisation R	**Common Market Organisation Regulation (EU) No 1308/2013**	Regulation	AGRI	Relevant provisions included in the Common Market Organisation Regulation (EU) No 1308/2013: Part V, Ch. 1 – Exceptional measures Art. 219 - Measures against market disturbance Art. 220 - Measures concerning animal diseases and plant pests and the loss of consumer confidence due to public, animal or plant health risks Art. 221 - Measures to resolve specific problems Section 4 – Agreements and decisions during periods of severe imbalance in markets Art. 222 - Application of Article	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.	Common Market Organisation Regulation (EU) No 1308/2013 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R1308

egulation (EU) No 1308/2013				101(1) TFEU (Competition rules)] Art. 223 – Communication requirements 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. Relevant provisions included in Regulation (EU) 2021/2115 on the CAP Strategic Plans: Art. 148 - Measures to resolve specific problems		
	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)	Regulation	AGRI	Measures to resolve specific problems	Article 148 Measures to resolve specific problems 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). 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	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2115

					implementing acts in accordance with the procedure referred to in Article 153(3). 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. 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.	
	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 Communi-cation 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

				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." This initiative, thus, aims to tackle this problem, which could "create confusion and distrust and undermine an effective public health response."**	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.	the Regions – Tackling online disinformation: a European Approach (April 2018) EUR-Lex - 52018DC0236 - EN - EUR-Lex (europa.eu) & Action Plan Against Disinformation (December 2018) eu-communication-disinformation-euco-05122018_en.pdf (europa.eu) & **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) & EU Code of Practice on Disinformation (October 2018) Code of Practice on Disinformation | Shaping Europe's digital future (europa.eu)

				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)****		***& 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 ****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)
2	**Data Act**	Act	CNECT/ G1	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	The proposal of the Data Act is not public yet. **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**	*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)

				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	**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)

					adoption of new legislative measures cannot ensure the timely availability of data; or (2) where obtaining the data in line with the procedure laid down in this Chapter would substantively reduce the administrative burden for enterprises. **Article 18* Compliance with requests for data** 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: (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		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 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).	**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**" **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	*Proposal for a Directive of the European Parliament and of the Council on measures for a high common level of cybersecurity across the 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

					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.) 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”.	National Coordination Centres (europa.eu)
PRODUCTION CAPACITIES						
1	**Chips Act**	Act		“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.” “Semiconductors are at the centre of strong geostrategic interests, and at the core of the global technological race.” "Member States are currently designing national strategies to develop on their soil industrial and production capacities in order to reduce their dependencies." "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	**Article 2*** **1. Definitions:** **(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;” **Article 18* Activation of the crisis stage** 1. A semiconductor crisis shall be considered to occur when there are **serious disruptions in the supply of semiconductors** leading to **significant shortages**, which: (a) entail **significant delays** or **significant negative effects** on **one or more important economic sectors in the Union**, or (b) **prevent the supply, repair and maintenance of essential products** used by **critical sectors**. 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**	Communication from the Commission: A Chips Act for Europe *Proposal for a Regulation establishing a framework of measures for strengthening Europe's semiconductor ecosystem (Chips Act) Complemented by: Proposal for a Council Regulation amending Regulation (EU) 2021/2085 establishing the Joint Undertakings under Horizon Europe, as regards the Chips Joint Undertaking

				single market, set conditions to protect European interests and place Europe firmly in the global geopolitical landscape." The dimensions envisioned include: 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	**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. 3. Before the expiry of the duration for which the crisis stage was activated, the Commission shall, **after consulting the 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**	Commission Recommendation on a common Union toolbox to address semiconductor shortages and an EU mechanism for monitoring the semiconductor ecosystem European Chips Act: Communication, Regulation, Joint Undertaking and Recommendation | Shaping Europe’s digital future (europa.eu)

				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 critical sectors, coordinated through the European Semiconductor Board.	**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. 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	This crisis instrument has been established prior to the Corona pandemic. It builds on the idea of emergency plans. 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. 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).	**3 Crisis Levels:** **Article 11(1):*** • (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**	**Activation:** Triggering of responses/ action/ obligations by **declaration of a crisis or of an emergency (Article 11(2), (3) subpara. 1, (4))*** • **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))*** **Deactivation**: • **Declaration of end of crisis level at Member State level**: by Member State **(Article 11(3),(9))***, or by	*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)

					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 ('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."	Commission if it concludes that the declaration of an emergency is not or no longer justified **(Articles 11(3) subpara. 2, (8), 13(15), Recital 55)*** • **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		"Critical raw materials are essential to the functioning and integrity of a wide range of industrial ecosystems." "Building on the EU's Raw Materials Initiative, this Communication presents: • 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." The Communication concludes that	No definition.*		*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/?

				"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. "*		uri=CELEX:52020DC0474
				EU SPACE		
1	**Copernicus Programme** **& Galileo Programme**	Regulations		"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." (cf. about Space programme: Actions against COVID-19 (europa.eu)) "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) **Copernicus:** • "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	**Copernicus**: • "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."	*Regulation (EU) No 377/2014 of the European Parliament and of the Council of 3 April 2014 establishing

				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 process for payments related to the Common Agriculture Policy. • Maps temporary health facilities as well as public gathering spaces to get a clear understanding of activities during the Coronavirus emergency."* **Galileo:** • "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 *"Galileo for outbreak monitoring and post-emergency management"*, 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."* (Cf. about Space programme: Actions against COVID-19 (europa.eu))	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, deliberate and accidental man-made disasters and other humanitarian disasters**, as well as the prevention, preparedness, response and recovery activities". **Galileo**: No crisis definition.**	the Copernicus Programme and repealing Regulation (EU) No 911/2010 EUR-Lex - 32014R0377 - EN - EUR-Lex (europa.eu) **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)

				SINGLE MARKET COMPLIANCE			
1	**Single Market Enforcement Task Force for Compliance with Single Market Rules (SMET)**	Communi-cation		"In this forum, the European Commission and EU country 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	– –	– –	*Communication from the Commission to the 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)

				Single Market – European Commission (europa.eu))			
DEFENCE AND SECURITY							
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
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,		*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

					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 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	recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 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

					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 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;	16 December 2020 on a framework for the recovery and resolution of central counterparties and amending Regulations (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)

					(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; (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	****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,

					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. **Article 10***** Response and recovery** 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: (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: (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.	amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC EUR-Lex - 32013L0036 - EN - EUR-Lex (europa.eu) ***** 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) Other : 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 -

					7. …	EUR-Lex (europa.eu)
					Article 43*** Financial cross-sector exercises, communication and cooperation** 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. 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 Single resolution mechanism regulation (SRMR): Regulation (EU) No 806/2014 of 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 and amending Directive 2002/92/EC and Directive 2011/61/EU Text EUR-Lex - 32014L0065 - EN - EUR-Lex (europa.eu)