

COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 89 | 14 October 2022

This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- Council of the European Union approves the Netherlands' recovery and resilience plan
- European Commission approves €292.5 million Italian measure to support construction of plant in semiconductor value chain
- European Commission announces Member State consultation on proposal to prolong and amend Ukraine Temporary Crisis Framework
- European Commission approves further schemes under Ukraine Temporary Crisis Framework

Trade / Export Controls

• European Commission publishes 2nd Annual Report on Implementation and Enforcement of EU Trade Agreements

Medicines and Medical Devices

- EU and US meet to reaffirm commitment to Cooperation Arrangement on preparedness and response to public health threats
- EU and WHO issue Joint Statement on COVID-19 and seasonal influenza vaccinations
- European Parliament endorses agreement with Council on reinforced role for European Centre for Disease Prevention and Control (ECDC)
- HERA announces Dynamic Purchasing System to better address Member States and European Commission needs in joint procurement of PPE

Cybersecurity, Privacy & Data Protection

- Council of the European Union approves the Digital Services Act
- EDPB's Coordinated Supervision Committee publishes 2020-2022 Report of Activities
- · Council of the European Union approves conclusions on ICT supply chain security
- European Commission adopts equivalence decision for Brazilian COVID digital certificates

COMPETITION & STATE AID

State Aid

European Commission	On 5 October 2022, the Commission announced the approval, under EU State aid rules, of a €292.5 million Italian measure made available through
	for the disbursement of approx. EUR 7 billion in NextGenerationEU grants. The <u>Recovery and Resilience Scoreboard</u> provides an overview of how implementation of the RRF and national plans is progressing (see <u>here</u>).
	With respect to <u>Hungary</u> , to recall, the <u>Commission</u> launched a "conditionality mechanism of the rule of law procedure" against Hungary in April 2022. On 18 September 2022 (see <u>here</u>), it proposed budget protection measures to the Council under the EU's conditionality regulation. The Commission has proposed: (i) a suspension of 65% of the commitments for three operational programs under cohesion policy, and (ii) a prohibition to enter into legal commitments with the public interest trusts for programs implemented in direct and indirect management. Additional risks for the Hungarian economy would be the result of a failure to approve Hungary's national recovery plan
	The <u>Commission's approval remains pending for 1 Member State plan</u> (Hungary (€7.2 billion) (see <u>here</u>).
	Following the Council's approval of the Netherlands' recovery plan, the Commission will authorize disbursements to the Netherlands based on the satisfactory fulfilment of the milestones and targets outlined in its plan, reflecting progress on the implementation of the investments and reforms (see below for recent RRF disbursement for Italy).
	The Commission's appraisal of Member State plans will also, in particular, determine whether the plans dedicate at least 37% of expenditure to investments and reforms that pursue climate objectives and 20% to the digital transition.
	In evaluating Member State plans under the RRF Regulation, notably, the RRF guidelines make clear that the investment projects included in Member State recovery plans must comply with State aid rules (<i>Jones Day Commentary, EU Member State COVID-19 Recovery Plans Must Comply with State Aid Rules, March 2021, see <u>here</u>).</i>
	To recall, Member State recovery plans set out the reforms and public investment projects foreseen for implementation with the support of the RRF, the key component of NextGenerationEU, the EU's historic recovery fund.
recovery and resilience plan (see <u>here</u>)	The Netherlands was the final Member State to submit a recovery plan, as earlier indicated in the Commission's first Report on implementation of the Recovery and Resilience Facility (RRF) in March 2022 (<i>see <u>Jones Day</u></i> <u>COVID-19 Update No. 78 of 4 March 2022</u>).
Council of the European Union approves the Netherlands'	On 4 October 2022, the Council adopted its Implementing Decision for the Netherlands' €4.7 billion recovery plan, following the Commission's positive assessment of the plan on 8 September 2022.

approves €292.5 million Italian measure to support construction of plant in semiconductor value chain (see <u>here</u>)	 the Recovery and Resilience Facility (RRF, see above for further details) to support STMicroelectronics in building a plant in the semiconductor value chain in Catania, Sicily. The €292.5 million direct grant will support STMicroelectronics' €730 million investment to construct a Silicon Carbide (SiC) wafer plant. SiC is a material used to manufacture wafers serving as a base for specific microchips used in high-performance power devices, e.g., electric vehicles, fast-charging stations, and renewable energies. According to the Commission, the Italian measure will reinforce Europe's security of supply, resilience, and digital sovereignty in semiconductor technologies, in line with the European Chips Act Communication's objectives (see Jones Day COVID-19 Update No. 76 of 9 February 2022; and Jones Day Commentary, <u>EU Chips Act: The EU's Push for Semiconductor Autonomy</u>, March 2022). To recall, the Commission has previously contended that the COVID-19 crisis exposed vulnerabilities in certain sectors in Europe due to high dependency on an allegedly narrow range of non-EU suppliers, especially for raw materials. The Commission believes that this is particularly the case for EU industries confronted by semiconductor shortages and the emergence of fake semiconductor chips on the market that compromise the security of electronic devices and systems Under the Italian measure, STMicroelectronics shall (i) satisfy EU priority rated orders in case of a supply shortage, (ii) invest in developing next generation microchips, and (iii) continue contributing to reinforcing the European semiconductor ecosystem.
European Commission announces Member State consultation on proposal to prolong and amend Ukraine Temporary Crisis Framework (see here)	 On 6 October 2022, Executive Vice-President and Competition Commissioner Margrethe Vestager announced the Commission's launch of a Member State consultation on a draft proposal to prolong and amend the Ukraine State aid Temporary Crisis Framework, in view of the "heavy toll" of Russia's war against Ukraine and the consequent "severe energy crisis that is affecting households and businesses all over Europe." To recall, in adopting this Crisis Framework on 23 March 2022, the Commission noted that Russia's war against Ukraine had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The Crisis Framework was first amended on 20 July 2022, in particular, to broaden its scope to include additional types of aid measures, which may be granted until 30 June 2023. The Commission is now consulting Member States on potential amendments to the Crisis Framework, such as: <u>Extending</u> the Temporary Crisis Framework; <u>Proportionately increasing maximum aid ceilings</u> in the provisions on limited amounts of aid, which allow Member States to provide direct grants or other forms of aid to companies in any sector affected by the crisis; In view of high market volatility, using a <u>targeted adjustment to further facilitate access to liquidity support</u> to energy companies in

	view of covering the financial collaterals for their trading activities; and
	• <u>Simplifying the criteria enabling Member States to support</u> <u>businesses impacted by high energy prices</u> , including energy- intensive users, ensuring that support remains targeted and proportionate while maintaining incentives for reducing energy demand.
	Commissioner Vestager noted that the draft proposal already reflected Member State responses to a survey launched mid-September 2022 and that the Commission would continue its close cooperation with Member States in the revision process.
European Commission approves further schemes under Ukraine Temporary Crisis Framework (see here)	The Commission continues to approve additional measures under the State aid Temporary Crisis Framework for State Aid measures in the context of Russia's invasion of Ukraine.
	The Crisis Framework, adopted by the Commission on 23 March 2022, sets out the criteria for Member States to support businesses in the context of Russia's invasion of Ukraine and its serious disruption to the EU economy (see <u>Jones Day COVID-19 Update No. 80 of 25 March 2022</u>).
	To recall, in adopting this Crisis Framework, the Commission noted that the conflict had significantly impacted the energy market, and steep rises in energy prices had affected various economic sectors, including some of those particularly affected by the COVID-19 pandemic, such as transport and tourism. The conflict has also disrupted supply chains for both EU imports from Ukraine (in particular, cereals and vegetable oils) and EU exports to Ukraine.
	The Crisis Framework was first amended on 20 July 2022, in particular, to broaden its scope to include additional types of aid measures, which may be granted until 30 June 2023 (see <u>Jones Day COVID-19 Update No. 86 of 8</u> <u>September 2022</u>).
	Among the latest schemes under the Crisis Framework (until 14 Oct 2022):
	 €25 million Italian scheme to support haulage operators using liquefied natural gas as fuel in context of the Russia's war against Ukraine
	 – €10 million Slovak scheme to support food producers in context of Russia's war against Ukraine
	 €80 million Slovenian scheme to support its economy in context of Russia's war against Ukraine
	 — €1 million Maltese aid measure to support fast ferry passenger transport between the Maltese islands of Malta and Gozo in context of Russia's war against Ukraine
	 €10 billion Finnish scheme to support electricity producers in the context of Russia's war against Ukraine
	 – €5 billion Finnish umbrella scheme to support municipal electricity

producers and suppliers in the context of Russia's war against Ukraine

- €800 million Greek scheme to support non-household electricity consumers in context of Russia's war against Ukraine

Notably, the Crisis Framework complements the various possibilities for Member States to design measures in line with existing EU State aid rules. For instance, State aid measures under the Crisis Framework may be cumulated with aid granted under the COVID-19 Temporary Framework, provided that their respective cumulation rules are respected.

The Crisis Framework, applicable since 1 February 2022, will be in place until 31 December 2022. During its period of application, the Commission will keep the Framework under review in light of developments regarding the energy markets, other input markets, and the general economic situation. Prior to the Crisis Framework's end date, and in view of maintaining legal certainty, the Commission will assess whether it should be prolonged.

TRADE / EXPORT CONTROLS

European Commission publishes 2nd Annual Report on Implementation and Enforcement of EU Trade Agreements (see here) On 11 October 2022, the European Commission released its 2nd Annual Report on the Implementation and Enforcement of EU Trade Agreements, covering the period 2021 and Q1 2022.

In presenting the Report, the Commission highlighted that EU exports to preferential partners surpassed €1 trillion for the first time in 2021, confirming that EU trade deals lead to increased exports, more stable economic relations, and secure access to resources.

In 2021, the EU had 42 preferential trade agreements in place with 74 partners. These agreements continued to serve a key role over the reporting period, as businesses in the EU and worldwide emerged from the COVID pandemic. The Report also emphasized that the impact of these agreements depends on their proper implementation and enforcement, alongside international trade rules.

The Report notes, in particular, that <u>COVID-induced disruptions to trade flows</u> negatively impacted businesses seeking to navigate foreign markets. The Report indicated a continuing trend among certain partners to "look inwards", imposing discriminatory trade restrictions to favor local production and domestic industry. This created difficulties for logistics and supply chains confronted by price increases in transportation, commodities and energy. These circumstances were further aggravated by the COVID omicron variant's resurgence in late 2021 and its reappearance in China in 2022, as well as by the unstable geo-political situation with Russia's war against Ukraine.

Notwithstanding these difficult conditions, the Report emphasizes that the EU continued work in 2021 to identify and remove trade barriers. The Commission, in close cooperation with the European Parliament, Member States and businesses, worked to engage directly with third countries on these issues.

The Report states that in 2021, 39 trade barriers were resolved, i.e. six more than in 2020: 16 were fully removed, while 23 were partially resolved. In

particular, SPS (sanitary and phytosanitary) barriers accounted for the largest category with 15 solved barriers, as in 2020. Eliminating these SPS barriers again had a direct positive effect, including on EU exporters in many sectors, notably in the food sector.

The accompanying Staff Working Document provides further details on the Report, including in relation to the 38 major EU trade agreements and for the first time, a country sheet on the EU-UK Trade and Cooperation Agreement (EU-UK TCA) (see <u>here</u>).

MEDICINES AND MEDICAL DEVICES

EU and US meet to reaffirm commitment to Cooperation Arrangement on preparedness and response to public health threats (see <u>here</u>)	On 13 October 2022, Stella Kyriakides (European Commissioner for Health and Food Safety) and Xavier Becerra (Secretary of US Department of Health and Human Services (HHS)) met in Washington DC to confirm the shared EU and US commitment to strengthen cooperation in the health sector. The discussions centered on health preparedness and response, cancer, and global cooperation.
	This meeting followed the signing on 9 June 2022 of a Cooperation Arrangement on preparedness and response to public health threats between the Commission and the US HHS. To recall, the Cooperation Arrangement is a deliverable of the US-EU Agenda for Beating the Global Pandemic, announced on 22 September 2021, and also complements the US–Commission Joint Statement announced the same day on the launch of the Joint COVID-19 Manufacturing and Supply Chain Taskforce (see Jones Day COVID-19 Update No. 86 of 8 September 2022).
	Commissioner Kyriakides and US Secretary Becerra noted that strong research and manufacturing ties between the EU and the US have contributed to the successful deployment of COVID-19 vaccines worldwide. They agreed on the importance of continuing to collaborate on research and development of new and more robust vaccines, and to work with vaccine developers and their partners to facilitate their development.
	The leaders also stressed that strengthening pandemic prevention, preparedness and response is a shared responsibility requiring strong international commitment and coordination, e.g., through the newly established Financial Intermediary Fund (FIF) for global health security and pandemic preparedness with sustainable capitalization, to be achieved in particular with EU Member States, the G20, lower-middle income countries, the World Bank, and the World Health Organization.
EU and WHO issue Joint Statement on COVID-19 and seasonal influenza vaccinations (see <u>here</u>)	On 12 October 2022, a Joint Statement on working together towards COVID-19 and seasonal influenza vaccinations for this winter was issued by Stella Kyriakides (Commissioner for Health and Food Safety), Dr. Andrea Ammon (Director of the European Centre for Disease Prevention and Control (ECDC)), and Dr. Hans Henri P. Kluge (WHO Regional Director for Europe).
	The Joint Statement emphasized that the COVID-19 pandemic persists, with rising numbers of infections, and a resurgence of influenza can be expected with the arrival of autumn and winter. This potential co-circulation of COVID-19 and seasonal influenza will put vulnerable people at

	heightened risk of severe illness and death. In this context, the EU must continue preparedness measures, and vaccination remains one of the most effective tools against both the COVID-19 and influenza viruses. However, millions of people across Europe remain unvaccinated against COVID-19. The Joint Statement urged Member States to prioritize protecting the most vulnerable groups by co-administering influenza and COVID-19 vaccines whenever feasible, and urged all eligible persons to receive both COVID-19 and influenza vaccinations.
European Parliament endorses agreement with Council on reinforced role for European Centre for Disease Prevention and Control (ECDC) (see <u>here</u>)	 On 4 October 2022, the European Parliament endorsed the agreement reached with the Council of the European Union on 29 November 2021 on the Proposal for amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC) (see <u>here</u> and <u>Jones Day COVID-19 Update No. 70 of 6 December 2021</u>). The ECDC is tasked with supporting the EU in combating infectious diseases through epidemic intelligence, scientific advice, and training activities, among other areas. Reinforcing the ECDC's role is one of the components of the EU's response to the COVID-19 pandemic and the pursuit of constructing a European Health Union to continue to effectively address COVID-19 and improve Europe's ability to respond to cross-border health threats and emergencies (see also <u>Jones Day COVID-19 Update No. 27 of 18</u> November 2020). The ECDC's broader role includes, for instance: Coordinating the standardization of data collection procedures, data validation, analysis and dissemination of data at EU level; Developing risk assessments and maintain databases for epidemiological surveillance and work towards harmonized approaches to data collection and modelling in order to produce comparable EU-wide data; and Monitoring the uptake of vaccination against major communicable diseases across the EU, taking into account the specificities of national and regional vaccination schedules.
HERA announces Dynamic Purchasing System to better address Member States and European Commission needs	On 4 October 2022, the European Health Emergency Preparedness and Response Authority (HERA) announced that it launched a pilot Dynamic Purchasing System (DPS) in June 2022 (see <u>here</u>) to better respond to the needs of Member States and the Commission in the joint procurement of Personal Protective Equipment (PPE). The pilot DPS, based on a fully electronic procedure, aims to facilitate
Commission needs in joint procurement of PPE (see <u>here</u>)	future joint procurement of medical countermeasures to respond to cross- border health threats. PPE suppliers seeking to offer products may pre-qualify and register in the pilot DPS. This will enable HERA to act more swiftly in identifying suitable
	potential candidates for procuring PPE in the event of a health crisis. The pre-qualification phase of PPE suppliers will remain open for 4 years

(until May 2026).

On the basis of the outcome of this pilot DPS, the Commission may consider extending the DPS to other medical countermeasures beyond PPE.

CYBERSECURITY, PRIVACY & DATA PROTECTION

Council of the European Union approves the Digital Services Act (see <u>here</u>) On 4 October 2022, the Council of the European Union gave its final approval to the Digital Services Act (Regulation on a Single Market For Digital Services (Digital Services Act (DSA)) and amending Directive 2000/31/EC) (see also *Jones Day COVID-19 Update No. 85 of 1 June 2022*).

The DSA is one of the measures taken as part of the EU Recovery Plan to lead the EU out of the COVID-19 pandemic (see <u>Jones Day COVID-19</u> <u>Update No. 10 of 29 May 2020</u>). The Explanatory Memo to the proposed DSA also noted that the public consultation revealed: "A majority of respondents, all categories included, indicated that they have encountered both harmful and illegal content, goods or services online, and specifically noted an alarming spike during the Covid-19 pandemic."

The DSA introduces rules and obligations on digital services that act as intermediaries in their role of connecting consumers with goods, services and content (i.e., social networks, online marketplaces, internet service providers).

Among other things, the DSA:

- Sets out requirements for online marketplaces in view of combating the online sale of illegal products and services;
- Introduces measures to counter illegal content online and obligations for platforms to react swiftly, while preserving fundamental rights;
- Protects minors online by prohibiting platforms from using targeted advertising based on the use of minors' personal data;
- Limits the presentation of advertising and on use of sensitive personal data for targeted advertising, including in relation to gender, race and religion; and
- Places transparency reporting obligations on online platforms.

In addition, the DSA imposes stricter rules on very large online platforms and search engines (i.e., online platforms which reach a number of average monthly users in the EU equal to or higher than 45 million), which must:

- Assess and mitigate the systemic risks they generate (e.g., risks concerning illegal content dissemination, detrimental effects on fundamental rights, electoral processes and gender-based violence or mental health);
- Offer users a system for recommending content that is not based on profiling; and
- Provide detailed information on online advertisement, such as the information necessary to allow users to understand when and on whose behalf the advertisement is presented.

	After signing by the President of the European Parliament and the President of the Council, the DSA will apply fifteen months after its entry into force.
EDPB's Coordinated Supervision Committee publishes 2020- 2022 Report of Activities (see here)	 On 5 October 2022, the Coordinated Supervision Committee (CSC), established within the framework of the European Data Protection Board (EDPB), published its 2020-2022 Report of Activities, adopted on 6 July 2022. The Report summarizes the CSC's work accomplished during the first two years of its existence. The CSC was established in 2019 to enhance cooperation amongst Data Protection Authorities (DPAs) of each EU Member State and the European Data Protection Supervisor and to ensure a more effective supervision of EU large-scale information technology systems (connecting EU Member States' authorities and EU bodies (EUIs), EU bodies, offices and agencies). The Report notes that a large part of the CSC is still under construction. Within its mission, the CSC can, for example, assist DPAs in carrying out audits and inspections; examine difficulties of interpretation or application of the EU legal act establishing the EUIs or the EU office, body or agency subject to coordinated supervision; and examine problems related to the exercise of the rights of individuals. On setting up the CSC, the Report notes that the COVID-19 pandemic led EU institutions to adapt to new ways of working, including holding meetings remotely in order to be able to continue their activities. The CSC, which must meet at least twice a year, also resorted to remote meetings and will need to do so again in the future. In line with its biannual work programme, the CSC carried out the following main activities from 2020 to 2022: (1) Promote and facilitate the exercise of data subject rights; (2) Examine difficulties of interpretation or application of EU and national law; (3) Exchange information and conduct joint audits or coordinated inspections; and (4) Prepare for the start of the EPPO's (European Public Prosecutor's Office) activities and other EU bodies and information systems that will fall under the Committee's scope. The CSC will be gradually expand
Council of the European Union approves conclusions on ICT supply chain	On 17 October 2022, the Council of the European Union approved the Council conclusions on information and communication technologies (ICT) supply chain security, which present an urgent call for action to bolster ICT supply chain security and constitute a first step towards addressing threats of unwanted strategic dependencies in ICT supply chains.

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security (see <u>here</u>)	 As noted in the Council conclusions, the COVID-19 pandemic caused disruptions in supply chains, notably in relation to pharmaceuticals and semiconductors, which exposed the EU's strategic external dependencies in relation to ICT products and services. Additionally, the conclusions cite the threat related to dependence on Russian ICT vendors at the time of Russia's military aggression against Ukraine and the EU's strategic dependencies on Russian forsil fuels. To address such challenges, the Council conclusions feature specific actions for strengthening ICT supply chain security aspects of existing instruments and detail how existing and upcoming cyber-specific legislation can contribute to ICT supply chain security. In particular: On strengthening existing instruments as concerns ICT supply chain security aspects, the Council conclusions propose targeted actions aimed at, for instance, including cyber-related selection criteria in the public procurement processes and invite the Commission to issue methodological guidelines to encourage contracting authorities to put appropriate focus on the cybersecurity practices of tenderers and their subcontractors; On the relevance of forthcoming legislation, such as the proposed NIS2 Directive or the Cyber Resilience Act (see Jones Day COVID-19 Update No. 87 of 23 September 2022), the Council conclusions highlight their role in enhancing ICT supply chain security. In this respect, it calls for the creation of an ICT Supply Chain Toolbox consisting of generic measures for reducing critical ICT supply chain risks and facilitating the implementation of coordinated risk assessments of critical supply chains under the NIS2 Directive (see Jones Day COVID-19 Update No. 84 of 17 May 2022); On other supporting mechanisms, the Council conclusions suggest measures aimed at: boosting financial support incentives towards strengthening ICT supply chain security; and enhancing cooperation within the EU and internationally, including building t
European Commission adopts equivalence decision for Brazilian COVID digital certificates (see <u>here</u>)	 On 14 October 2022, the European Commission adopted an equivalence decision certifying that COVID-19 certificates issued by Brazil are equivalent to the EU Digital COVID Certificate (see also <i>Jones Day COVID-19 Update No. 86 of 8 September 2022</i>) for the latest preceding Commission Equivalence Decisions. Holders of certificates issued by Brazil will be able to use them under the same conditions as holders of an EU Digital COVID Certificate do. As a result of this decision, 70 countries are now connected to the EU's system (see overview of all decisions <u>here</u>). The Commission's Decision entered into force on 15 October 2022.

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